TRANS1 INC

FORM 8-K
(Current report filing)

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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 30, 2008

TRANS1 INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-33744**	**33-0909022**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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))

Item 2.02 Results of Operations and Financial Condition.

On October 30, 2008, TranS1 Inc. (the "Company") issued a press release to report its financial results for the quarter ended September 30, 2008. The release is furnished herewith as Exhibit 99.1 and incorporated herein by this reference.

Also on October 30, 2008, following the issuance of the press release referred to above, the Company conducted a conference call to discuss its financial results for the quarter ended September 30, 2008. 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.

Exhibit Number	*Description*
99.1	Press release, dated October 30, 2008.
99.2	Conference call transcript, dated October 30, 2008.

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.

November 3, 2008

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

EXHIBIT INDEX

Exhibit Number	*Description*
99.1	Press release, dated October 30, 2008.
99.2	Conference call transcript, dated October 30, 2008.

Exhibit 99.1

TranS1 Inc. Reports Operating Results for the Third Quarter of 2008

Highlights:

Third quarter revenues increased 39% to $6.0 million

671 TranS1 procedures performed in the quarter

Gross margin was 83.2% for the quarter

GAAP loss per share was $0.23 for the quarter

Non-GAAP loss per share was $0.20 for the quarter

Limited Market Release of the AxiaLIF 2L, Two Level Percutaneous Lumbar Fusion System Completed

WILMINGTON, NC — (PRIME NEWSWIRE)—October 30, 2008—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 affecting the lower lumbar region of the spine, today announced its financial results for the third quarter ended September 30, 2008.

Revenues were $6.0 million in the third quarter of 2008, representing a 39% increase over revenues of $4.3 million in the third quarter of 2007. Gross margin was 83.2% in the third quarter, an increase from 82.6% in the third quarter of 2007.

Operating expenses were $10.4 million in the third quarter of 2008 compared to $5.9 million in the third quarter of 2007. The increase in operating expenses is primarily attributable to an increase in sales and marketing costs as a result of the continued expansion of the direct sales force, increased commissions as a result of increased sales and increased surgeon training costs. Additionally, general and administrative costs increased primarily due to the addition of personnel and increased legal and professional fees.

Net loss was $4.8 million and $2.2 million for the quarters ended September 30, 2008 and 2007, respectively. GAAP net loss per common share was $0.23 in the third quarter of 2008 compared to a net loss per share of $0.87 in the third quarter of 2007.

For the quarter ended September 30, 2008, on a non-GAAP basis, adjusting for non-cash stock compensation expense, net loss was $0.20 per common share based upon 20,474,000 weighted average common shares outstanding. For the quarter ended September 30, 2007, on a non-GAAP basis, adjusting for non-cash stock compensation expense, the issuance of 6.3 million shares of common stock from the company’s initial public offering in October 2007 and the conversion of preferred stock into common stock in connection with the public offering, net loss was $0.08 per common share based upon 19,667,000 weighted average common shares outstanding.

Cash, cash-equivalents and investments were $83.2 million as of September 30, 2008.

“I am pleased with the early impact the AxiaLIF two-level product has had on our domestic business,” said Rick Randall, President and Chief Executive Officer of TranS1. “I look forward to future growth driven by the transition from the successful limited release to the national launch of the two-level device combined with the continued maturation of our domestic sales force.”

Conference Call

TranS1 will host a conference call today at 4:30 pm EDT to discuss its third quarter financial results. To listen to the conference call on your telephone, please dial 877-548-7906 for domestic callers and 719-325-4917 for international callers approximately ten minutes prior to the start time. The call will be concurrently webcast. To access the live audio broadcast or the subsequent archived recording, visit the TranS1 Web site at www.trans1.com under the investor relations section.

Non-GAAP Measures

Management uses certain non-GAAP financial measures such as non-GAAP net loss and net loss per share, which exclude stock based compensation and include the assumed conversion of preferred stock to common stock. This non-GAAP presentation is given in part to enhance the understanding of the company’s historical financial performance and comparability between periods. The company believes that the non-GAAP presentation to exclude stock-based compensation and the assumed conversion of preferred stock to common stock is relevant and useful information that will be widely used by investors and analysts. Accordingly, the company is disclosing this information to permit additional analysis of the company’s performance. These non-GAAP measures are not in accordance with, or an alternative for, GAAP, and may be different from non-GAAP measures used by other companies. Investors should consider these non-GAAP measures in addition to, and not as a substitute for, financial performance measures in accordance with GAAP. A reconciliation of the GAAP financial measures to the comparable non-GAAP financial measure is included below.

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 affecting the lower lumbar region of the spine. TranS1 currently markets two single-level fusion products, the AxiaLIF® and the AxiaLIF 360º™, 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, 2007.

CONTACT:
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TranS1 Inc.
Michael Luetkemeyer, 910-332-1700
Chief Financial Officer

or

Westwicke Partners
Mark Klausner, 443-213-0501
mark.klausner@westwickepartners.com

Source: TranS1 Inc.

TranS1 Inc.
Statements of Operations
(in thousands, except per share amounts)
(Unaudited)

	Three Months Ended Sept. 30,		Nine Months Ended Sept. 30,	
	2008	2007	2008	2007
Revenue	$ 6,021	$ 4,327	$ 17,950	$ 11,514
Cost of revenue	1,011	754	3,186	2,213
Gross profit	5,010	3,573	14,764	9,301
Operating expenses:				
Research and development	1,163	1,320	3,940	3,599
Sales and marketing	7,782	3,780	20,680	10,616
General and administrative	1,418	812	4,864	1,895
Total operating expenses	10,363	5,912	29,484	16,110
Operating loss	(5,353)	(2,339)	(14,720)	(6,809)
Interest income	589	125	2,218	468
Net loss	$ (4,764)	$ (2,214)	$(12,502)	$ (6,341)
Net loss per common share - basic and diluted	$ (0.23)	$ (0.87)	$ (0.62)	$ (2.54)
Weighted average common shares outstanding - basic and diluted	20,474	2,549	20,206	2,495
Stock-based compensation is included in operating expenses in the following categories:				
Cost of revenue	$ 18	$ 14	$ 45	$ 40
Research and development	99	179	394	378
Sales and marketing	445	400	1,319	1,117
General and administrative	181	121	839	239
	$ 743	$ 714	$ 2,597	$ 1,774

Reconciliation of Second Quarter Results
(in thousands, except per share amounts)
(Unaudited)

	2008	2007
GAAP net loss	$ (4,764)	$ (2,214)
Stock based compensation	743	714
Non-GAAP net loss	$ (4,021)	$ (1,500)
Shares used in computing GAAP loss per share	20,474	2,549
Assumed issuance of common shares from initial public offering	—	6,325
Assumed conversion of preferred stock to common stock	—	10,793
Shares used in computing non-GAAP loss per share	20,474	19,667
Non-GAAP loss per share	$ (0.20)	$ (0.08)

Reconciliation of Year-To-Date Results
(in thousands, except per share amounts)
(Unaudited)

	2008	2007
GAAP net loss	$(12,502)	$ (6,341)
Stock based compensation	2,597	1,774
Non-GAAP net loss	$ (9,905)	$ (4,567)
Shares used in computing GAAP loss per share	20,206	2,495
Assumed issuance of common shares from initial public offering	—	6,325
Assumed conversion of preferred stock to common stock	—	10,793
Shares used in computing non-GAAP loss per share	20,206	19,613
Non-GAAP loss per share	$ (0.49)	$ (0.23)

TranS1 Inc.
Balance Sheets
(in thousands)
(Unaudited)

	September 30, 2008	December 31, 2007
Assets		
Current assets:		
Cash and cash equivalents	$ 42,930	$ 64,676
Short-term investments	25,949	29,245
Accounts receivable, net	3,752	3,225
Inventory	5,453	4,025
Prepaid expenses and other assets	401	597
Total current assets	78,485	101,768
Property and equipment, net	1,508	1,088
Long-term investments	14,331	—
Total assets	$ 94,324	$ 102,856
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,403	$ 1,631
Accrued expenses	2,198	1,786
Total current liabilities	4,601	3,417
Stockholders' equity		
Common stock	2	2
Additional paid-in capital	133,111	130,325
Accumulated deficit	(43,390)	(30,888)
Total stockholders' equity	89,723	99,439
Total liabilities and stockholders' equity	$ 94,324	$ 102,856

TranS1 Inc.
Statements of Cash Flows
(in thousands)
(Unaudited)

	Nine Months Ended Sept. 30,	
	2008	**2007**
Cash flows from operating activities:		
Net loss	$(12,502)	$ (6,341)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	583	410
Stock-based compensation	2,598	1,774
Allowance for excess and obsolete inventory	376	168
Provision for bad debts	84	32
Changes in operating assets and liabilities:		
(Increase) decrease in accounts receivable	(611)	(2,231)
(Increase) decrease in inventory	(1,804)	(1,791)
(Increase) decrease in prepaid expenses	196	(154)
Increase (decrease) in accounts payable	772	1,001
Increase (decrease) in accrued expenses	412	1,062
Net cash used in operating activities	(9,896)	(6,070)
Cash flows from investing activities:		
Purchase of property and equipment	(1,003)	(414)
Purchases of short-term investments	(36,495)	(2,783)
Sales and maturities of short-term investments	39,791	10,644
Purchases of long-term investments	(14,331)	—
Net cash provided by (used in) investing activities	(12,038)	7,447
Cash flows from financing activities:		
Proceeds from issuance of common stock	188	107
Deferred financing costs	—	(1,214)
Net cash provided by financing activities	188	(1,107)
Net increase (decrease) in cash and cash equivalents	(21,746)	270
Cash and cash equivalents, beginning of period	64,676	5,034
Cash and cash equivalents, end of period	$ 42,930	$ 5,304

Exhibit 99.2

Operator: Ladies and gentlemen, welcome to the TranS1 Incorporated Third Quarter 2008 Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Mr. Mark Klausner of Westwicke Partners. Please go ahead, sir.

Mark R. Klausner, Managing Partner, Westwicke Partners

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, 2007.

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

Rick Randall, President and Chief Executive Officer

Thanks, Mark. Good afternoon and thank you for joining us today to discuss TranS1's third quarter. On today's call, I will discuss some of the key highlights of the quarter, and Mike will provide you with the details of our financial results and our updated guidance. I then would like to share with you some perspective on some of the key operating trends in our business, after which we will take your questions.

Worldwide, 671 TranS1 procedures were performed and we generated $6 million in revenue during the third quarter. Both of these numbers reflect significant increases and continued adoption from the comparable period a year ago. We made good progress operationally in the third quarter. We have recently completed the limited market release of our AxiaLIF two-level product and began the full market launch. We kicked off training of our sales force and distribution partners in September, began training users in early October, and followed through with the big push at NASS [North American Spine Society] in mid-October.

Since the limited release in May, there have been approximately 120 two-level procedures completed. In early October, we sponsored the first Association of Presacral Spine Surgeons event, where we had approximately 100 of our surgeon users in attendance. The event created national attention and allowed our surgeon users to hear how their peers have incorporated AxiaLIF into their practice.

During the quarter, our sales force continued to gain experience and we ended the quarter with north of 50 direct sales reps in the field. Some of the newer reps gained invaluable experience at both the APSS and NASS conferences. We trained 77 physicians in the United States during the quarter and have continued to make progress in developing effective training programs to convert spine surgeons to users of our products. Additionally, we now have trained 63 of our existing surgeons on the two-level procedure.

We continued clinical trials of our next-generation PNR [Percutaneous Nucleus Replacement] product in Europe and have implanted devices in five patients to date. We continue to make progress in developing the supporting evidence to proactively work with commercial payers to prospectively cover our physician reimbursement, and we made product improvements to enhance the safety and efficacy of our technique.

I'd now like to turn the call over to Mike to review our financial results.

Michael Luetkemeyer, Chief Financial Officer

Thanks Rick. In the third quarter of 2008, we generated revenue of $6.0 million, in line with our previously issued guidance for the quarter. This represents a 39% increase over the $4.3 million of revenue generated in the third quarter of 2007 and is comparable to the revenue generated in the second quarter of 2008. For the third quarter of 2008, we generated 94% of our revenue or $5.7 million in United States. In the comparable period in 2007, we generated 90% or $3.9 million of our revenue in the United States.

During the third quarter of 2008, 555 procedures were performed in the United States utilizing TranS1 products. This represents a 36% increase over the 409 procedures performed in the third quarter of 2007 and an increase of 14 procedures or 3% over the 541 procedures performed in the second quarter of 2008.

Our average selling prices in the United States for the third quarter of 2008, excluding standalone sales of our percutaneous facet screw system, was $9,800. This represents an increase of $500 over the comparable period of last year and $300 over the second quarter of 2008. The increase in average selling price has primarily been driven by the limited market release of our AxiaLIF two-level product in the third quarter of 2008, along with the continued traction of our AxiaLIF 360 products. For the third quarter of 2008, 201 of the 555 AxiaLIF procedures performed in the United States or about 36% were AxiaLIF 360 procedures, and 64 AxiaLIF two-level procedures were performed.

For the third quarter of 2008, we generated revenue of $203,000 from the standalone sales of our percutaneous facet screw system, compared with $88,000 for the third quarter of 2007. Gross margin was 83.2% for the third quarter of 2008. This represents an increase from 82.6% in the third quarter of 2007. The increase in gross margin was primarily the result of increased efficiencies associated with higher production and sales volumes, the increasing traction of our AxiaLIF two-level procedure in the third quarter of 2008, and the decreased mix year-over-year of the lower margin sales outside the United States.

Turning to expenses, total operating expenses for the third quarter of 2008 were $10.4 million, an increase of $4.5 million from $5.9 million for the third quarter of 2007. The increase in operating expenses was primarily the result of higher sales and marketing costs of $4.0 million due to the continued expansion of our direct sales force and increased commissions as a result of increased sales. And additionally, general and administrative costs increased by $600,000, primarily due to the addition of personnel, increased professional fees, and higher insurance and franchise taxes.

Other and interest income, which primarily consists of interest income, was $589,000 in the third quarter of 2008. This compares to $125,000 in the third quarter of 2007 and the increase was the result of interest income generated from the proceeds of our October 2007 IPO.

Our GAAP net loss for the third quarter was $4.8 million or $0.23 per share. On a non-GAAP basis, adjusting for non-cash stock compensation charges of $743,000 in the quarter, our net loss was $4.0 million or $0.20 per share. This compares favorably to our previously issued guidance for the third quarter on a GAAP basis of a loss of $0.24 to $0.26 per share and on a non-GAAP basis of a loss of $0.21 to $0.23 per share.

At the end of the quarter, we had $68.9 million in cash, cash equivalents and short-term investments, and $14.3 million in investments with an initial maturity greater than one year and no debt. Our operating cash burn for the third quarter, defined as cash used in operating activities and investment in fixed assets, was $4.6 million.

With regard to guidance, we anticipate revenue for the fourth quarter to be in the range of $6.1 to $6.5 million, and based on estimated shares outstanding for the quarter of approximately 20.5 million, the GAAP loss per share to be in the range of $0.26 to $0.28 and the non-GAAP loss per share to be in the range of $0.22 to $0.24.

For the total year 2008, we now anticipate revenue to be in the range of $24.0 to $24.5 million, and based on estimated shares outstanding for the year of approximately 20.5 million, the GAAP loss per share to be in the range of $0.87 to $0.89 and the non-GAAP loss per share to be in the range of $0.70 to $0.72. Rick, back to you.

Rick Randall, President and Chief Executive Officer

Thanks, Mike. Before we open the call up for questions, I'd like to spend a few minutes providing some details on the key operating trends from the quarter. I'm pleased to announce that we commenced the full market launch of our AxiaLIF two-level product in October as planned. We've seen good clinical results from the approximately 120 procedures completed to-date. We have gained critical insight from these procedures that will help us best position the product as we continue with the full market release.

We completed our three-phase rollout of the two-level product over a four-week period beginning mid-September. First, we began by training our full sales force over a four-day weekend. We then hosted a meeting for current AxiaLIF users in early October in Las Vegas to present the clinical data and then train them on the two-level device.

Finally, at NASS, we made a big push to educate and train surgeons on the new product. I will share some additional perspective on the NASS conference in a few minutes. We had a very positive experience with our sponsorship of the first Association of Presacral Spine Surgeons or APSS held in Las Vegas. This event created national attention and approximately 100 of our surgeons were in attendance. APSS created a support group for surgeons using new MIS technology, fostering opportunities for peer-to-peer interaction to share their experiences and best practices.

As we discussed in the past, the key to adoption of this new technology is the ability of a seasoned sales rep to guide the surgeon through this new treatment paradigm. We will continue to invest in events like APSS that create peer-to-peer selling interaction, lessening the burden on our young sales force. To this end, we are planning to host several regional events that build on the success of APSS throughout the year to highlight our procedures to both existing and prospective surgeons.

Before we move on to discuss the development of our sales force, I want to address the topic we've heard raised in the market place regarding radiolucencies observed in several two-level cases. As many of you know, when surgeons evaluate their patients post surgery, they look for radiographic evidence that a fusion is occurring. In some cases, the surgeon will observe some space between the implant and the bone or radiolucency. The most serious concern around radiolucency is that it could be a sign that the implant is loose and thus could impact the fusion.

When a surgeon investigator in our two-level clinical trial presented his clinical results, he demonstrated a 90% fusion rate, but expressed concern over radiolucencies that he found in several of his 19 two-level cases. Upon hearing this, we assembled an independent panel to review all 19 of this surgeon's two-level cases. The independent panel found a radiolucency of 1-mm or less in size around the distal tip of our implants in four cases and the panel noted that these radiolucencies resolved themselves as the fusion bone mass developed over time. Importantly, the panel also noted that in each case where a radiolucency was observed, the surgeon had not elected to provide posterior fixation at each treated level. We have submitted the panel's findings to the FDA and the panel report was also presented to our surgeon users at the APSS.

Going forward, we recommend to our surgeons that our surgeons use posterior fixation at each level in a two-level fusion. Given the positive feedback from the APSS presentation and the fact that three of the four patients with radiolucencies went on to fuse at both levels, we do not feel that this market noise will impact the continued adoption of the two-level procedure.

Turning to the sales force, at the end of the third quarter, our direct sales force was just north of 50 direct reps. We recently analyzed the productivity ramp of every rep since commercialization who was a direct

rep for at least one year. The data demonstrated that sales productivity per rep increases along a pretty consistent curve. Specifically, we found that at six months of experience an average rep generates approximately $20,000 in monthly revenue or two cases. At 12 months of experience, an average rep generates approximately $40,000 in monthly revenue or four cases. Rep productivity tends to accelerate after twelve months and by their twentieth month on the job, an average rep generates approximately $80,000 in monthly revenue or eight cases. This equates to about a $1 million annual run rate for that rep.

The importance of this productivity curve is that it gives us confidence that if we manage turnover and support our reps while our sales force matures, their productivity and our market adoption will continue to increase. To put this in perspective, if you look at our reps today, approximately 40 of our reps have been in the field less than 12 months.

Regarding new surgeon training, we trained 77 physicians in the United States during the quarter and continue to make progress in developing effective training programs to convert spine surgeons to users of our products. Additionally, we've now trained 63 of our existing surgeons on the two-level procedure. We are targeting approximately 70 to 80 new surgeons for training in the fourth quarter of the year, and thus we'll have trained approximately 300 new surgeons in 2008.

It is important to note that we are also dedicating a significant portion of our training capacity over the balance of this year to support our two-level launch. In addition to new surgeon training, we expect to train in the range of an additional 50 to 60 of our existing surgeons on the two-level procedure by the end of 2008.

Our clinical trials of our next-generation PNR product are progressing in Europe and we've implanted five devices in five patients to date. As with most of Europe, the chief investigator was on vacation during the summer months, however, activity is gearing up again as we enter the fourth quarter. To reiterate our goal in this phase of study, we intend to complete 10 cases prior to initiating a more definitive study. So far, we've seen no major issues or device changes that might be needed. We will continue to watch these patients and do follow-up imaging studies. We believe that we're on track to begin our broader study in Europe in early 2009 and are beginning to recruit surgeons for this study and think about study design. I look forward to updating you on progress as we move this product through trials.

On the reimbursement front, we remain diligent about helping our surgeons obtain appropriate reimbursement for our procedure. We have an 800-number and call-in resource center up and running to assist surgeons with any reimbursement issues that may arise. Further, we are on track to support our physicians utilizing a category III CPT code in January 2009 and do not anticipate that this will create any additional headwinds with regards to adoption.

We also are continuing to make progress in developing supporting evidence to proactively work with commercial payers to prospectively cover our physician reimbursement. During the quarter, we saw two peer-reviewed articles published that included clinical data. Additionally, there are more articles in the pipeline that have been accepted for publication that will further highlight TranS1's clinical effectiveness. These articles will be used to demonstrate to payers that our procedure delivers positive patient outcomes with fusion rates equivalent to those of current standard of care.

Finally, I wanted to highlight some of the product improvements we've made to enhance the safety and efficacy of our technique. We constantly evaluate and continue to upgrade the toolkit. First, we've introduced a more aggressive flat cutter that is a more effective discectomy tool to treat collapsed disks and also helps in preparing the endplates to promote better fusion. Also, we have improved the exchange cannula in order to even further reduce the potential of soft tissue injury in and around the bowel area.

Before I open the call up for questions, I'd like to share my impressions from the recently completed NASS meeting. At the conference, both the quality and quantity of booth activity was at an all time high. Building on the heightened interest, we trained 20 new surgeons at the conference. We also hosted our panel

presentation featuring two of our experienced surgeons who discussed how the adoption of the AxiaLIF has impacted their practices, their experience with a two-level procedure, and their views on the low rate of complications with our procedure.

I'd now like to open the call up for questions.

Operator: Thank you very much, sir. [Operator Instructions] And we will take our first question that will come from Matt Miksic with Piper Jaffray.

Q — Matt Miksic

Hi guys. Can you hear me okay?

A — Rick Randall

We hear you fine, Matt.

Q — Matt Miksic

Great. Sorry for any background noise, but I'm on the road. But, I have a couple of questions. One on the P&L, Rick or Mike. R&D, the bottom-line your have number came in a little better than we were looking for. The R&D number was quite a bit higher than we were modeling. I am just wondering if there has been an uptick and why, or if we were just wrong?

A — Rick Randall

Yeah, no Matt. There has been nothing unusual that happened in R&D. It has been running at pace all year long. We haven't started any new sizable projects or haven't completed any sizable R&D projects. It's pretty stable.

Q — Matt Miksic

Okay. So should we model the Q3 number good sort of through for the rest of the year?

A — Rick Randall

Yeah, I mean, we are obviously in the process of recruiting a VP of R&D and so that would be the only major change I could think of in the fourth quarter, if we bring that person on board. But again, it would be minor in terms of dollars.

Q — Matt Miksic

Okay. And then the other — on the top line, it looks like the single-level was a little lighter than we expected and the two-level a little stronger. Could you help with launch in the quarter, is there some — is the two-level rollout or the two-level training or even for your existing users, it's soaking up any bandwidth here in the sales force? We are just trying to understand what might have caused at least a shortfall to our estimates. I know, you came in in-line with guidance on the top-line.

A — Rick Randall

Yeah, Matt, most of our surgeons who participated in the limited market release of our two-level product or almost all of them, were obviously current high-volume TranS1 users. So, we were getting all of those

cases for the most part at 5-1 and the two-level product just added to — or allowed us to double up on that same patient. So many of those single-level cases that you don't see converted to two-level cases. There were only a few surgeons or just a couple of surgeons who did not have another minimally-invasive arrow in their quiver, where we got that patient de novo, but most of those patients would have been treated with a single-level case had we not had the two-level product.

A — Michael Luetkemeyer

So, getting the incremental...

Q — Matt Miksic

Okay. So maybe I was doing some double — double counting in my end, but — I am sorry, Mike, you're going to say something.

A — Michael Luetkemeyer

Well, the point is that we are getting the incremental revenue for the two-level ASP, but we were already getting the single-level revenue, so it's another level, not another case, in a lot of the cases that Rick was explaining.

Q — Matt Miksic

Got you. And then last thing just some color on the sales force. Can you give us, and I may have missed it, but an idea of where you think you will end the year, and also the degree to which you're seeing some — it looks like the number has hung in there from the last time you reported, but has there been any stability in kind of the net turn within the sales force? Is there any additional turnover or are you pretty stable on an absolute basis as well?

A — Rick Randall

Yeah, Matt, we've been fairly stable. There will always be some turnover. We actually induced some turnover by promoting two of our clinical sales managers to a regional spot. One of the things we have learned as we've looked deeply into the numbers and we're learning as we go along in building this sales force is that in general the managers who are promoted from within, and these were people who in 2005 and 2006 and 2007 perhaps had to make a living selling the AxiaLIF product, they have proven to probably be better coaches of and managers of our newer reps than managers that we brought in from the outside with management experience. So, picking up on that theme, we have moved a couple of those folks, very experienced, talented people into the coaching role as regional managers, but for the most part we've been fairly stable. There has been some turnover, but we've been pretty stable.

Q — Matt Miksic

And one last question and then I'll jump off. Just stepping back and thinking about the process you are going through to educate and sell AxiaLIF is very much of a push in education sales, as I understand it. At what point do you get out there far and long enough and deep enough into the surgeon base in the U.S. for example, where you start to get some sort of positive word of mouth that starts pulling business and bringing people to you at a more rapid rate than we're seeing now? Is that — and maybe it's just a function of the number of meetings and the number of — maybe is it two quarters, is it four quarters? How far away are we from that kind to tipping point?

A — Rick Randall

Well, that's a great question. If you look at, for instance, our business in the State of Florida. In the State of Florida, when I go back to our early launch of the product in 2005, we happened to have a couple of early adopters, one in the Miami area and one in the Tampa area. And then, we because of the existence of those surgeons, we put a direct rep in Tampa and a direct rep in Miami. And over the last three years, we built that market and now we have four or five direct reps and a dedicated independent sales force to support that and I would say that that's our most advanced market. So clearly in that market, what we are now seeing is a combination of again experienced seasoned reps who are in operations on a daily basis and a congregation or a density of users where now they are surgeons who lose patients because of AxiaLIF or other minimally-invasive techniques. We are starting to see more of a tipping point in that market due to that phenomenon. I can go to another market like the Pacific Northwest, where we are two to three years behind and our reps are out there trying to build from de novo in those territories. So, as we build those markets and we are starting to see some of those markets come together in areas like New England and Ohio, clearly it gets a little bit easier to promote and convert surgeons to this type of operation.

Q — Matt Miksic

Okay. Well, I appreciate the color. I'll jump out of queue and let some other folks ask some questions.

Operator: And we'll move to our next question that will come from Doug Schenkel with Cowen & Company.

Q — Doug Schenkel

Hi, good afternoon.

A — Rick Randall

Hi Doug.

Q — Doug Schenkel

Recognizing that there are clear revenue and margin benefits to an increased mix of two-level. Given how early you are in the overall adoption curve and given that there is just a lot more known about the one-level and there is more experience in the market with the one-level, can you provide a little bit more color on why you would seemingly prioritize the two-level so much? It just seems like it should still be an easier sale for the one-L and that the two-L should be incremental. Can you help us understand this a little bit and specifically could you talk about whether there is anything you are seeing in the market that makes you a little bit more cautious about the outlook for the one-level relative to what you were seeing a couple of quarters ago?

A — Rick Randall

Yeah, sure Doug. I think we are still early with the one-level — the two-level experience, and I think what we're seeing now is that we built up a user base of surgeons who've been frankly waiting for the two-level for quite some time. I think for those of you who are at our event at NASS, you heard two surgeons basically tell you that. So, right now there is a lot of pent-up enthusiasm for the two-level device. And after events like APSS where surgeons, even surgeons early in their experience with AxiaLIF, not only got comfortable with multiple presentations focused on the long-term data around the single-level experience, they also got to see some of these early adopters talk about their early two-level experience. So I think we're getting some of that.

But in the markets with new surgeons, we are still focused heavily on getting new surgeons onto this operation and I think we are going to see them get more comfortable early on with the single-level

experience. And then, as they gain comfort with the single-level experience, then obviously migrate to two-level cases. And there is another component where there is surgeons that were now starting to come across with the full market release, who frankly until we had a two-level operation, the single — and they didn't have a good minimally-invasive operation to offer their patients. They weren't that interested in just treating the smaller percentage of their patients, just the 5-1. So, their interest in this new technology really lies in the fact that we can treat both L4-L5 and L5-S1 that broadens the total market available to them. It just basically doubles it. So, now 50 to 60% of their patients are now candidates for this operation, as opposed to 25%.

Q — Doug Schenkel

Okay. I mean, fair enough. It's just by my math; you guys are at least at the end of the period in the U.S. You trained just over, I think, 800 to 850 surgeons and the aggregate, and you talked about total eligible surgeons exceeding 7,000 in the U.S. So, while there is pent-up demand, presumably more so amongst surgeons you've already been trained in the 1-L, it would seemingly still there is a lot of greenfield for you to go after in terms of working on — just getting people to use even the one-level. So, it's just a little surprising to me that you guys would talk so much about prioritizing 2-L's in the near term when it seems like there is still a lot of work to do in terms of getting people to use the 1-L.

A — Rick Randall

Yes, we are prioritizing the new customers as well. It's just that obviously we have a great deal of enthusiasm because there are so many folks who have been waiting for the two-level operation and to even the surgeon who has not crossed the minimally-invasive chiasm, which I think is still about 85% of the surgeons out there have not become practiced in the art of minimally-invasive spine surgery. I think that the two-level operation now and the ease of use of this operation gives them another reason for coming over to the dark side of minimally invasive spine surgery.

Q — Doug Schenkel

Okay. And then one thing I don't think you guys talked about, but we are all focused on is macroeconomic environment. Any impact that you saw on the quarter and how does that factor into the change in full-year sales guidance?

A — Michael Luetkemeyer

Doug, it's Mike. I think we are so early in the adoption process frankly, that any weakness in the economy for, what I would call, surgeries that are absolutely necessary would be masked by the adoption and the growth that we are getting by introducing and getting traction in the new product. I mean, obviously at the margin, right, the unemployment rate has increased significantly year-over-year and to the extent that people who become unemployed are coming off COBRA and don't have insurance. That certainly would impact all surgeries and all medical care, not just ours. But I think it's at the margin, and I don't think we can have enough experience and enough data to be able to take that into account in the guidance that we are giving in the fourth quarter.

Q — Doug Schenkel

Okay. And you guys did provide updates on progress with the new sales force hires and talked about some of your efforts on the reimbursement front? Anyway that you could quantify the impact on Q3 performance of losing a couple of those sales people back in Q2 and the changes in reimbursement seen earlier this year?

A — Rick Randall

Yeah, the reimbursement changes that remains — the reimbursement kind of remains constant with us. That's whatever headwind we've described in the past, I think still exists. We from time-to-time still see cases that are scheduled, but don't happen to reimbursement, but frankly we've done a good job of providing more data and giving them back.

On the turnover side, yes, we articulated last quarter that some of the reps who left — that we lost some of those cases from the surgeons they were servicing, and we have replaced all of those reps, but that doesn't necessarily mean that as soon as that new rep steps onto the scene that those cases come back. In fact, we track those surgeons and I'm pleased to say that in September and now in October, we're starting to see some of those surgeons come back with the rep that they've regained confidence with the rep, the new rep, and some of the surgeons are coming back.

I look at one particular area, like Chicago as an example. We lost the rep there. He had two or three surgeons who were fairly consistent surgeons treating with the product, they dropped off. We replaced that rep, trained that rep over the summer months, he got back into the saddle in the summer, and now we've seen two of the three surgeons who are treating actually book and treat in late September and October. So, I think that's pretty consistent with some of the other holes that we had to fill from our Q2 experience.

Q — Doug Schenkel

Okay. Thanks a lot for taking my questions.

Operator: [Operator Instructions] And we'll move to our next question. That will come from Vincent Ricci with Wachovia.

Q — Vincent Ricci

Hey guys. I got a question for you on the radiolucencies. When you guys had the independent group look at that, did they have any feeling of whether there was a correlation between radiolucencies and pseudoarthrosis or not?

A — Rick Randall

No, that was — Vince, that was the point. There was no correlation between radiolucencies and pseudoarthrosis. As I mentioned, three of the four patients who — where we saw radiolucencies actually went on to fuse at both levels. And the fourth one just has — I mean, they are beyond a year, and one level has fused, the other level has not fused, but it's not a pseudoarthrosis. So, there's still the potential as we see with many patients, that as we go beyond the year or for two years as follow-up, that patient could go on to fuse, but there was no correlation. And as the bone mass stabilized, as the fusion mass stabilized in all of those patients, we started to see bone regrowth at the very tip of the distal rod. So, we're comfortable that there's no issue there, and I think when the surgeons — the 100 surgeons at the Nevada meeting saw those results, I think. Well, the proof is in the pudding, a lot of those surgeons came back and started using two-level for the first time.

Q — Vincent Ricci

Okay, great. And then just a quick question. What are you seeing in terms of any utilization at all in an outpatient setting?

A — Rick Randall

We still see — it's relatively small percentage of our surgeons. There are outpatient patients being treated every day across the country. I still characterize it as part — we don't track that as well as perhaps we

should, but I could still characterize it, it's about 10% of our cases are done on an outpatient basis, and it remains that most of those surgeons on their own negotiated the reimbursement with the various payers in those markets, so that remains the case. Obviously, as we cited some publications that have already been published or are about to be published have been accepted for publication as we get two or three of these publications out there with data, we will work with our surgeons who want to take this to the outpatient clinic and be more aggressive with the data with their payers.

Q — Vincent Ricci

Okay, great. Last question. With the macro environment, the way it's been, there has been some discussion about some other smaller players in some states running out of capital leading to maybe some kind of consolidation, just curious you guys came back from NASS. What are you seeing with kind of the competitive environment, both from the bigger guys and the r guys?

A — Rick Randall

Well, that's a good point and clearly there are companies out there that are privately-held and raising money in a very difficult environment. And I do believe there will be consolidation and there are some technologies that frankly we could use and we would like to put in the bag that are often used in the same procedures our rep is participating in today. So, we're looking at the availability of some of these technologies, and hopefully over time we'll be able to take advantage of this situation and add some of this products into our bag.

Q — Vincent Ricci

Good. Thanks for taking my questions.

A — Rick Randall

Thank you, Vince.

Operator: And at this time, we have no additional questions in the queue. I'd like to turn it back over to our speakers for any additional or closing remarks.

Rick Randall, President and Chief Executive Officer

Yes. Let me close by thanking all of you for taking the time to join us on our call today. With the full launch of our two-level product underway, I remain enthusiastic about our products, our clinical results, and market opportunity. We sincerely appreciate your interest in TranS1 and look forward to updating you on our continued progress.

Operator: Once again, ladies and gentlemen, that does conclude today's conference. We'd like to thank you for your participation. Have a wonderful day.