

TRANS1 INC

FORM 10-Q (Quarterly Report)

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Address	301 GOVERNMENT CENTER DRIVE WILMINGTON, NC 28403
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Industry	Medical Equipment & Supplies
Sector	Healthcare

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2011

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-33744

TRANS1 INC.

(Exact name of Registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

33-0909022
(I.R.S. Employer
Identification No.)

301 GOVERNMENT CENTER DRIVE, WILMINGTON, NC 28403
(Address of principal executive office) (Zip code)

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The number of shares of the registrant's common stock outstanding as of August 5, 2011 was 20,946,885 shares.

TRANS1 INC.
FORM 10-Q FOR THE QUARTER ENDED JUNE 30, 2011
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PART I. FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	2011	2010	2011	2010
Revenue	\$ 5,337	\$ 7,244	\$ 10,467	\$ 13,957
Cost of revenue	1,173	1,364	2,469	2,793
Gross profit	<u>4,164</u>	<u>5,880</u>	<u>7,998</u>	<u>11,164</u>
Operating expenses:				
Research and development	1,212	1,027	2,794	2,282
Sales and marketing	5,671	6,447	12,054	14,144
General and administrative	1,610	2,067	3,223	4,706
Total operating expenses	<u>8,493</u>	<u>9,541</u>	<u>18,071</u>	<u>21,132</u>
Operating loss	(4,329)	(3,661)	(10,073)	(9,968)
Other income (expense), net	20	15	38	(34)
Net loss	<u>\$ (4,309)</u>	<u>\$ (3,646)</u>	<u>\$ (10,035)</u>	<u>\$ (10,002)</u>
Net loss per common share — basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.18)</u>	<u>\$ (0.48)</u>	<u>\$ (0.48)</u>
Weighted average common shares outstanding — basic and diluted	<u>20,915</u>	<u>20,685</u>	<u>20,901</u>	<u>20,670</u>

The accompanying notes are an integral part of these financial statements.

TranS1 Inc.
Consolidated Balance Sheets
(in thousands, except share amounts)
(Unaudited)

	<u>June 30,</u> <u>2011</u>	<u>December 31,</u> <u>2010</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,963	\$ 24,461
Short-term investments	26,123	18,075
Accounts receivable, net	3,771	3,654
Inventory	4,468	3,878
Prepaid expenses and other assets	359	389
Total current assets	<u>40,684</u>	<u>50,457</u>
Property and equipment, net	1,589	1,562
Total assets	<u>\$ 42,273</u>	<u>\$ 52,019</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,110	\$ 2,214
Accrued expenses	1,348	2,077
Total current liabilities	<u>3,458</u>	<u>4,291</u>
Noncurrent liabilities	32	—
Stockholders' equity:		
Common stock, \$0.0001 par value; 75,000,000 shares authorized 20,940,210 and 20,877,171 shares issued and outstanding at June 30, 2011 and December 31, 2010, respectively	2	2
Additional paid-in capital	139,477	138,401
Accumulated other comprehensive loss	(15)	(29)
Accumulated deficit	<u>(100,681)</u>	<u>(90,646)</u>
Total stockholders' equity	<u>38,783</u>	<u>47,728</u>
Total liabilities and stockholders' equity	<u>\$ 42,273</u>	<u>\$ 52,019</u>

The accompanying notes are an integral part of these financial statements.

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

	<u>Six Months Ended June 30,</u>	
	<u>2011</u>	<u>2010</u>
Cash flows from operating activities:		
Net loss	\$(10,035)	\$(10,002)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	309	426
Stock-based compensation	937	1,062
Allowance for excess and obsolete inventory	348	285
Provision for bad debts	40	38
Loss on sale of fixed assets	1	70
Changes in operating assets and liabilities:		
Increase in accounts receivable	(157)	(693)
(Increase) decrease in inventory	(938)	613
Decrease in prepaid expenses	30	57
Decrease in accounts payable	(104)	(735)
Increase (decrease) in accrued expenses	(697)	677
Net cash used in operating activities	<u>(10,266)</u>	<u>(8,202)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(337)	(356)
Purchases of investments	(16,102)	(7,969)
Sales and maturities of investments	8,054	14,960
Net cash provided by (used in) investing activities	<u>(8,385)</u>	<u>6,635</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	139	41
Net cash provided by financing activities	<u>139</u>	<u>41</u>
Effect of exchange rate changes on cash and cash equivalents	14	(11)
Net decrease in cash and cash equivalents	(18,498)	(1,537)
Cash and cash equivalents, beginning of period	24,461	29,298
Cash and cash equivalents, end of period	<u>\$ 5,963</u>	<u>\$ 27,761</u>

The accompanying notes are an integral part of these financial statements.

TranS1 Inc.

Notes to Consolidated Financial Statements
(Unaudited)

1. Description of Business

TranS1 Inc., a Delaware corporation (the “Company”), was incorporated in May 2000 and is headquartered in Wilmington, North Carolina. The Company is a medical device company focused on designing, developing and marketing products that implement its minimally invasive surgical approach to treat degenerative conditions of the spine affecting the lower lumbar region. The Company operates in one business segment. The Company currently markets the AxiaLIF[®] family of products for single and multilevel lumbar fusion, the Vectre[™] and Avatar[™] lumbar posterior fixation systems, and Bi-Ostetic[™] bone void filler, a biologics product. All of the Company’s AxiaLIF products are delivered using its pre-sacral approach. The Company also markets products that may be used with its surgical approach, including bowel retractors, a bone graft harvesting system and additional discectomy tools. The AxiaLIF 1L product was commercially released in January 2005. The AxiaLIF 2L[™] product was commercially released in Europe in the fourth quarter of 2006 and in the United States in the second quarter of 2008. The AxiaLIF 2L product was discontinued in 2010 after the Company launched its AxiaLIF 2L+[™] product in July 2010. The Company commercially launched its next generation Vectre facet screw system in April 2010. In the first quarter of 2010, the Company entered into agreements to distribute Avatar, a pedicle screw system, and Bi-Ostetic bone void filler, a biologics product. In March 2011, the Company received 510(k) clearance for its next generation AxiaLIF 1L+ product and made it commercially available in a limited market release. The Company sells its products directly to hospitals and surgical centers in the United States and certain European countries, and to independent distributors elsewhere.

The Company owns eight trademark registrations in the United States and eight trademark registrations in the European Union. The Company also owns two pending trademark applications in the United States and two pending trademark applications in Canada.

The Company is subject to a number of risks similar to other similarly-sized companies in the medical device industry. These risks include, without limitation, acceptance and continued use of the Company’s products by surgeons, the lack of clinical data about the efficacy of these products, uncertainty of reimbursement from third-party payors, cost pressures in the healthcare industry, competitive pressures from substitute products and larger companies, the historical lack of profitability, the dependence on key employees, regulatory approval and market acceptance for new products, the reliance on a limited number of suppliers to provide these products, changes in economic conditions, the ability to effectively manage a sales force to meet the Company’s objectives and the ability to conduct successful clinical studies.

2. Basis of presentation

The Company has prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange

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Commission. The consolidated financial statements are unaudited and should be read in conjunction with the audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2010. The accompanying unaudited interim consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) which are, in the opinion of the Company's management, necessary for a fair statement of the Company's consolidated financial position, results of operations and cash flows for the periods presented. These principles require management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The principal estimates relate to accounts receivable reserves, inventory reserves, stock-based compensation, accrued expenses and income tax valuations. Actual results could differ from those estimates. The year-end balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. All intercompany accounts and transactions have been eliminated in consolidation.

Impact of Recently Issued Accounting Standards

In May 2011, the Financial Accounting Standard Board ("FASB") issued new authoritative guidance to provide a consistent definition of fair value and ensure that fair value measurements and disclosure requirements are similar between GAAP and International Financial Reporting Standards. This guidance changes certain fair value measurement principles and enhances the disclosure requirements for fair value measurements. This guidance is effective for interim and annual periods beginning after December 15, 2011 and is applied prospectively. The Company does not expect that the adoption of this guidance will have a material impact on its financial statements.

In June 2011, FASB issued guidance on the presentation of other comprehensive income. This guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity and requires the presentation of other comprehensive income in a single continuous statement, or in two separate, but consecutive, statements. This guidance is effective for fiscal years and interim periods beginning after December 15, 2011, and is not expected to have a material effect on the Company's financial statements.

3. Income Taxes

No provisions for federal or state income taxes have been recorded as the Company has incurred net operating losses since inception.

4. Net Loss Per Common Share

Basic net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding. Diluted net loss available to common stockholders per common share is computed by dividing net loss by the weighted average number of common shares and dilutive potential common share equivalents then outstanding. The Company's potential dilutive common shares, which consist of shares issuable upon the exercise of stock options, have not been included in the computation of diluted net loss per share for all periods as the result would be anti-dilutive.

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The following table sets forth the potential shares of common stock that are not included in the calculation of diluted net loss per share as the result would be anti-dilutive as of the end of each period presented:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
Weighted average stock options outstanding	<u>2,845,286</u>	<u>2,080,393</u>	<u>2,660,286</u>	<u>1,774,184</u>

5. Cash, Cash Equivalents and Investments

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents include money market treasury funds. Short-term investments consist of U.S. agency backed debt instruments.

At June 30, 2011, the Company held certain assets that are required to be measured at fair value on a recurring basis. These assets include available for sale securities classified as cash equivalents and short-term investments. Accounting Standards Codification 820-10 requires the valuation of investments using a three-tiered approach, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

Available for sale securities classified as Level 1 assets were:

	June 30, 2011	December 31, 2010
	(In thousands)	
Cash and cash equivalents	\$ 5,442	\$ 24,070
Short-term investments	26,123	18,075
Total available for sale securities	<u>\$31,565</u>	<u>\$ 42,145</u>

The Company had no Level 2 or Level 3 assets or liabilities at June 30, 2011 or December 31, 2010.

6. Accounts Receivable, Net

The following table presents the components of accounts receivable:

	June 30, 2011	December 31, 2010
	(In thousands)	
Gross accounts receivable	\$ 4,146	\$ 4,001
Allowance for uncollectible accounts	(375)	(347)
Total accounts receivable, net	<u>\$ 3,771</u>	<u>\$ 3,654</u>

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7. Inventories

The following table presents the components of inventories:

	June 30, 2011	December 31, 2010
	(In thousands)	
Finished goods	\$ 2,153	\$ 1,727
Work-in-process	2,138	2,005
Raw materials	177	146
Total inventories	<u>\$ 4,468</u>	<u>\$ 3,878</u>

8. Accrued Expenses

The following table presents the components of accrued expenses:

	June 30, 2011	December 31, 2010
	(In thousands)	
Commissions	\$ 416	\$ 589
Vacation	301	175
Legal and professional fees	168	300
Bonus	140	770
Travel and entertainment	110	53
Salaries and benefits	89	52
Franchise Tax	88	116
Other	36	22
Total accrued expenses	<u>\$ 1,348</u>	<u>\$ 2,077</u>

9. Comprehensive Loss

The following table presents the components of other comprehensive loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2011	2010	2011	2010
	(In thousands)		(In thousands)	
Net loss	\$ (4,309)	\$ (3,646)	\$(10,035)	\$(10,002)
Other comprehensive income (loss):				
Translation adjustments	<u>6</u>	<u>(3)</u>	<u>14</u>	<u>(11)</u>
Total comprehensive loss	<u>\$ (4,303)</u>	<u>\$ (3,649)</u>	<u>\$(10,021)</u>	<u>\$(10,013)</u>

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to our consolidated financial statements included in this report. In addition to historical financial information, this report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those projected in the forward-looking statements. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact contained in this report, including statements regarding future events, our future financial performance, our business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should” or “will” or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Such forward-looking statements are subject to risks, uncertainties and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by such forward-looking statements. Actual results could differ materially from those projected in forward-looking statements as a result of the following factors, among others: acceptance and continued use of our products by surgeons, the lack of clinical data about the efficacy of our products, uncertainty of reimbursement from third-party payors, our historical lack of profitability, cost pressures in the healthcare industry, competitive pressures from substitute products and larger companies, our dependence on key employees, regulatory approval and market acceptance for new products, our reliance on a limited number of suppliers to provide our products, our ability to effectively manage a sales force to meet our objectives and our ability to conduct successful clinical studies. Readers are urged to carefully review and consider the various disclosures made by us, which attempt to advise interested parties of the risks, uncertainties, and other factors that affect our business, operating results, financial condition and stock price, including without limitation the disclosures made under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this report and in the consolidated financial statements and notes thereto included elsewhere in this report, as well as the disclosures made under the captions “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, “Risk Factors”, “Consolidated Financial Statements” and “Notes to Consolidated Financial Statements” included in our Annual Report on Form 10-K for the year ended December 31, 2010, and in other filings we make with the Securities and Exchange Commission, or the SEC. Furthermore, such forward-looking statements speak only as of the date of this report. We expressly disclaim any intent or obligation to update any forward-looking statements after the date hereof to conform such statements to actual results or to changes in our opinions or expectations except as required by applicable law or the rules of the NASDAQ Stock Market. References in this report to “TranSI”, “we”, “our”, “us”, or the “Company” refer to TranSI Inc.

Overview

We are a medical device company focused on designing, developing and marketing products that implement our proprietary approach to treat degenerative conditions of the spine affecting the lower

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lumbar region. Using our pre-sacral approach, a surgeon can access discs in the lower lumbar region of the spine through a small incision adjacent to the tailbone and can perform an entire interbody fusion procedure through a small tube that provides direct access to the intervertebral space. We developed our pre-sacral approach to allow spine surgeons to access and treat intervertebral spaces without compromising important surrounding soft tissue. We believe this approach enables fusion procedures to be performed with low complication rates, low blood loss, short hospital stays, fast recovery times and reduced pain. We currently market our AxiaLIF® family of products for single and multilevel lumbar fusion, the Vectre™ and Avatar™ lumbar posterior fixation systems and Bi-Ostetic™ bone void filler, a biologics product. We also market products that may be used with our surgical approach, including bowel retractors, a bone graft harvesting system and additional discectomy tools.

From our incorporation in 2000 through 2004, we devoted substantially all of our resources to research and development and start-up activities, consisting primarily of product design and development, clinical trials, manufacturing, recruiting qualified personnel and raising capital. We received 510(k) clearance from the U.S. Food and Drug Administration, or FDA, for our AxiaLIF 1L product in the fourth quarter of 2004, and commercially introduced our AxiaLIF 1L product in the United States in the first quarter of 2005. We received a CE mark to market our AxiaLIF 1L product in the European market in the first quarter of 2005 and began commercialization in the first quarter of 2006. We received a CE mark for our AxiaLIF 2L product in the third quarter of 2006 and began commercialization in the European market in the fourth quarter of 2006. We received FDA 510(k) clearance for our AxiaLIF 2L product and began marketing this product in the United States in the second quarter of 2008. The AxiaLIF 2L product was discontinued in 2010 after we launched our AxiaLIF 2L+™ product in July 2010, for which we had received FDA 510(k) clearance in January 2010. We commercially launched our next generation Vectre facet screw system in April 2010. In the first quarter of 2010, we entered into agreements to distribute Avatar, a pedicle screw system, and Bi-Ostetic bone void filler, a biologics product. In March 2011, we received FDA 510(k) clearance for our next generation AxiaLIF 1L+ product and made it commercially available in a limited market release. We currently sell our products through a direct sales force, independent sales agents and international distributors.

We rely on third parties to manufacture all of our products and their components, except for our nitinol nucleus cutter blades, which we manufacture at our facility in Wilmington, North Carolina. Our outsourcing partners are manufacturers that meet FDA, International Organization for Standardization, or ISO, or other internal quality standards, where applicable. We believe these manufacturing relationships allow us to work with suppliers who have the best specific competencies while we minimize our capital investment, control costs and shorten cycle times, all of which we believe allows us to compete with larger-volume manufacturers of spine surgery products.

Since inception, we have been unprofitable. As of June 30, 2011, we had an accumulated deficit of \$100.7 million.

We expect to continue to invest in creating a sales and marketing infrastructure for our AxiaLIF family of products in order to gain wider acceptance for them. We also expect to continue to invest in research and development and related clinical trials, and increase general and administrative expenses as we grow. As a result, we will need to generate significant revenue in order to achieve profitability.

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Financial Operations

	Three Months Ended June 30,			Six Months Ended June 30,		
	2011	2010	% change	2011	2010	% change
Revenue	\$ 5,337	\$ 7,244	-26.3%	\$ 10,467	\$ 13,957	-25.0%
Cost of revenue	1,173	1,364	-14.0%	2,469	2,793	-11.6%
Gross margin %	78.0%	81.2%	-3.9%	76.4%	80.0%	-4.5%
Total operating expenses	8,493	9,541	-11.0%	18,071	21,132	-14.5%
Net loss	(4,309)	(3,646)	-18.2%	(10,035)	(10,002)	-0.3%

Revenue

We generate revenue from the sales of our implants and disposable surgical instruments. We have two distinct sales methods. The first method is when implants and/or disposable surgical instruments are sold directly to hospitals or surgical centers for the purpose of conducting a scheduled surgery. Our sales representatives or independent sales agents hand deliver the products to the customer on or before the day of the surgery. The sales representative or independent agent is then responsible for reporting the delivery of the products and the date of the operation to the corporate office for proper revenue recognition. We recognize revenue upon the confirmation that the products have been used in a surgical procedure. The other sales method is for sales to hospitals for consumption during future surgeries or to distributors outside the United States. These transactions require the customer to send in a purchase order before shipment will be made and the customer only has the right of return for defective products. We expect that a substantial amount of our revenues will continue to be generated in the United States in future periods.

Cost of Revenue

Cost of revenue consists primarily of material and overhead costs related to our products. Cost of revenue also includes facilities-related costs, such as rent, utilities and depreciation.

Research and Development

Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical functions and the costs of clinical studies and product development projects. In future periods, we expect research and development expenses to grow as we continue to invest in basic research, clinical trials, product development and intellectual property.

Sales and Marketing

Sales and marketing expenses consist of personnel costs, sales commissions paid to our direct sales representatives and independent sales agents, and costs associated with physician training programs, promotional activities and participation in medical conferences. In future periods, we expect sales and marketing expenses to increase as we expand our sales and marketing efforts.

General and Administrative

General and administrative expenses consist of personnel costs related to the executive, finance, business development, and human resource functions, as well as professional service fees, legal fees,

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accounting fees, insurance costs and general corporate expenses. We expect general and administrative expenses to increase as we grow our business.

Other Income (Expense), Net

Other income (expense), net is primarily composed of interest earned on our cash, cash equivalents and available-for-sale securities and the loss on disposal of fixed assets.

Results of Operations

Comparison of the Three Months Ended June 30, 2010 and 2011

Revenue Revenue decreased from \$7.2 million in the three months ended June 30, 2010 to \$5.3 million in the three months ended June 30, 2011. The \$1.9 million decrease in revenue from 2010 to 2011 was primarily a result of a lower number of AxiaLIF cases performed in 2011, which was due primarily to physician reimbursement limitations and insurance denials for lumbar fusion surgery due to medical necessity. Domestically, sales of our AxiaLIF 1L products decreased from \$3.5 million in the three months ended June 30, 2010 to \$2.8 million in the three months ended June 30, 2011, and sales of our AxiaLIF 2L products decreased from \$2.1 million in the three months ended June 30, 2010 to \$1.4 million in the three months ended June 30, 2011. Sales of our pedicle screw system decreased from \$0.2 million in the three months ended June 30, 2010 to \$0.1 million in the three months ended June 30, 2011 and sales of our Bi-Ostetic bone void filler increased from \$0.2 million in the three months ended June 30, 2010 to \$0.3 million in the three months ended June 30, 2011. In the three months ended June 30, 2011, average revenue per AxiaLIF case continued to increase, helped by a price increase effective April 1, 2011, the release of new AxiaLIF products and penetration into existing cases by our other products. In the three months ended June 30, 2010 and 2011, we recorded 541 and 367 domestic AxiaLIF cases, respectively, including 148 AxiaLIF 2L cases in the three months ended June 30, 2010, and 90 AxiaLIF 2L+ cases in the three months ended June 30, 2011. Additionally, during the three months ended June 30, 2010 and 2011, we generated \$0.6 million and \$0.3 million, respectively, in revenues from sales of our facet and Vectre screw systems. Revenue generated outside the United States decreased from \$0.6 million in the three months ended June 30, 2010 to \$0.4 million in the three months ended June 30, 2011. There was \$51,000 in initial stocking shipments to new distributors outside the United States in the three months ended June 30, 2010 compared to \$47,000 in initial stocking shipments to new distributors in the three months ended June 30, 2011. In the three months ended June 30, 2010 and 2011, 92% of our revenues were generated in the United States.

Cost of Revenue Cost of revenue decreased from \$1.4 million in the three months ended June 30, 2010 to \$1.2 million in the three months ended June 30, 2011. Gross margin decreased from 81.2% in the three months ended June 30, 2010 to 78.0% in the three months ended June 30, 2011. The decrease in gross margin was primarily due to a higher percentage of sales being derived from distributed products in 2011 as compared to 2010, which have a lower gross margin than our AxiaLIF products and additional inventory reserves as we introduced changes to our current AxiaLIF products.

Research and Development Research and development expenses increased from \$1.0 million in the three months ended June 30, 2010 to \$1.2 million in the three months ended June 30, 2011. The \$0.2 million increase in expenses from 2010 to 2011 was primarily related to an increase in clinical trials expense.

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Sales and Marketing Sales and marketing expenses decreased from \$6.4 million in the three months ended June 30, 2010 to \$5.7 million in the three months ended June 30, 2011. The decrease in expenses from 2010 to 2011 of \$0.7 million was primarily due to lower personnel-related costs of \$0.8 million, including lower commissions of \$0.5 million, as we reduced our direct sales headcount to align with our geographically focused approach and decreased promotional expenses of \$0.2 million offset by an increase to surgeon training expenses of \$0.2 million.

General and Administrative General and administrative expenses decreased from \$2.1 million in the three months ended June 30, 2010 to \$1.6 million in the three months ended June 30, 2011. The decrease in expenses from 2010 to 2011 of \$0.5 million was primarily due to a decrease in personnel-related expenses, including management transition costs that occurred in the second quarter of 2010.

Other Income (Expense), Net Other income (expense), net, increased from \$15,000 in the three months ended June 30, 2010 to \$20,000 in the three months ended June 30, 2011.

Comparison of the Six Months Ended June 30, 2010 and 2011

Revenue Revenue decreased from \$14.0 million in the six months ended June 30, 2010 to \$10.5 million in the six months ended June 30, 2011. Consistent with the second quarter comparison, the \$3.5 million decrease in revenue from 2010 to 2011 was primarily a result of a lower number of AxiaLIF cases performed in 2011, which was due primarily to physician reimbursement limitations and insurance denials for lumbar fusion surgery due to medical necessity. Domestically, sales of our AxiaLIF 2L products decreased from \$4.0 million in the six months ended June 30, 2010 to \$2.9 million in the six months ended June 30, 2011 and sales of our AxiaLIF single level products decreased from \$7.0 million in the six months ended June 30, 2010 to \$5.2 million in the six months ended June 30, 2011. Sales of our pedicle screw system decreased from \$0.3 million for the six months ended June 30, 2010 to \$0.2 million in the six months ended June 30, 2011 and sales of our Bi-Ostetic bone void filler increased from \$0.3 million in the six months ended June 30, 2010 to \$0.5 million in the six months ended June 30, 2011. In the six months ended June 30, 2011, average revenue per AxiaLIF case continued to climb, helped by a price increase effective April 1, 2011, the release of new AxiaLIF, and penetration into existing cases by our other products. In the six months ended June 30, 2010 and 2011, we recorded 1,078 and 736 domestic AxiaLIF cases, respectively, including 289 AxiaLIF 2L cases in 2010 and 192 AxiaLIF 2L cases in 2011. Additionally, during the six months ended June 30, 2010 and 2011, we generated \$1.1 million and \$0.6 million, respectively, in revenues from sales of our facet and Vectre screw systems. Revenue generated outside the United States decreased from \$1.3 million in the six months ended June 30, 2010 to \$1.0 million in the six months ended June 30, 2011. In the six months ended June 30, 2010 and 2011, there were \$51,000 and \$47,000, respectively, in initial stocking shipments to new distributors outside the United States. In the six months ended June 30, 2010 and 2011, 91% of our revenues were generated in the United States.

Cost of Revenue Cost of revenue decreased from \$2.8 million in the six months ended June 30, 2010 to \$2.5 million in the six months ended June 30, 2011. Gross margin decreased from 80.0% in the six months ended June 30, 2010 to 76.4% in the six months ended June 30, 2011. The decrease in gross margin was primarily due to a higher percentage of sales being derived from distributed products in 2011 as compared to 2010, which have a lower gross margin than our AxiaLIF products and additional inventory reserves as we introduced changes to our current AxiaLIF products.

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Research and Development Research and development expenses increased from \$2.3 million in the six months ended June 30, 2010 to \$2.8 million in the six months ended June 30, 2011. The \$0.5 million increase in expenses from 2010 to 2011 was primarily related to an increase in clinical trial expense of \$0.5 million and an expense of \$0.3 million to acquire the exclusive license to a new technology under development offset by a decrease in project spending of \$0.2 million and a decrease in personnel related expenses of \$0.1 million.

Sales and Marketing Sales and marketing expenses decreased from \$14.1 million in the six months ended June 30, 2010 to \$12.1 million in the six months ended June 30, 2011. The decrease in expenses from 2010 to 2011 of \$2.0 million was primarily due to lower personnel-related costs of \$1.5 million, including lower commissions of \$0.8 million, as we reduced our direct sales headcount to align with our geographically focused approach and decreased promotional expenses of \$0.4 million.

General and Administrative General and administrative expenses decreased from \$4.7 million in the six months ended June 30, 2010 to \$3.2 million in the six months ended June 30, 2011. The decrease in expenses from 2010 to 2011 of \$1.5 million was primarily related to a decrease in personnel-related costs, including those related to the management transition that occurred in the first half of 2010. These transition costs included compensation, recruiting and severance related expenses.

Other Income (Expense) Other income (expense) decreased from a loss of \$34,000 in the six months ended June 30, 2010 to income of \$38,000 in the six months ended June 30, 2011. The change of \$72,000 from 2010 to 2011 was primarily related to a loss on disposal of fixed assets in the six months ended June 30, 2010 of \$70,000.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2000, we have incurred significant losses and, as of June 30, 2011, we had an accumulated deficit of \$100.7 million. We have not yet achieved profitability, and anticipate that we will continue to incur losses in the near term. We expect to continue to fund research and development, sales and marketing and general and administrative expenses at similar to current levels or higher and, as a result, we will need to generate significant revenues to achieve profitability. Prior to our October 2007 initial public offering, our operations were funded primarily with the gross proceeds from the sale of preferred stock of \$40.5 million. The net proceeds from our October 2007 initial public offering of \$86.7 million have funded our operations since then. In June 2011, we filed a “universal shelf” registration statement on Form S-3 (the “Registration Statement”) which became effective on August 1, 2011. Depending on our non-affiliated public equity float during the time period prior to consummating a financing transaction, the Registration Statement will allow us to raise up to \$50 million through the sale of debt securities, common stock, preferred stock, or warrants, or any combination thereof. The timing and terms of any such financing have not yet been determined.

As of June 30, 2011, we did not have any outstanding debt financing arrangements, we had working capital of \$37.2 million and our primary source of liquidity was \$32.1 million in cash, cash equivalents and short-term investments. We currently invest our cash and cash equivalents primarily in money market treasury funds and our short-term investments primarily in U.S. agency backed debt instruments.

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Cash, cash equivalents and short-term investments decreased from \$42.5 million at December 31, 2010 to \$32.1 million at June 30, 2011. The decrease of \$10.4 million was primarily the result of net cash used in operating activities of \$10.3 million and purchases of property and equipment of \$0.3 million offset by net cash provided from issuance of our common stock upon the exercise of stock options of \$139,000.

Cash Flows

Net Cash Used in Operating Activities Net cash used in operating activities was \$10.3 million in the six months ended June 30, 2011. This amount was attributable primarily to the net loss after adjustment for non-cash items, such as depreciation, stock-based compensation expense, inventory and bad debt reserves, combined with changes in working capital requirements to support the market acceptance of our products

Net Cash Used by Investing Activities Net cash used by investing activities was \$8.4 million in the six months ended June 30, 2011. This amount reflected net purchases or sales and maturities of short-term investments of approximately \$8.0 million, and purchases of property and equipment of \$0.3 million, primarily for reusable instrument kits used in the field and information technology needs.

Net Cash Provided by Financing Activities Net cash provided by financing activities in the six months ended June 30, 2011 was \$139,000, which represented proceeds from the issuance of shares of common stock under our employee stock purchase program and upon the exercise of stock options.

Operating Capital and Capital Expenditure Requirements

We believe that our existing cash and cash equivalents, together with cash received from sales of our products, will be sufficient to meet our cash needs for at least the next two years. We intend to spend substantial sums on sales and marketing initiatives to support the ongoing commercialization of our products and on research and development activities, including product development, regulatory and compliance, clinical studies in support of our currently marketed products and future product offerings, and the enhancement and protection of our intellectual property. We may need to obtain additional financing to pursue our business strategy, to respond to new competitive pressures or to take advantage of opportunities that may arise. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Any additional financing may not be available in amounts or on terms acceptable to us, if at all. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts. The Registration Statement will allow us to raise up to \$50 million through the sale of debt securities, common stock, preferred stock or warrants, or any combination thereof. The timing of such financing, if ever, has not yet been determined.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of financial statements requires management to make estimates and judgments that affect the reported amounts of assets and liabilities, revenue and expenses, and disclosures of contingent assets and liabilities at the date of the financial statements. On

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an on-going basis, we evaluate our estimates, including those related to revenue recognition, accounts receivable reserves, inventory reserves, accrued expenses, income tax valuations and stock-based compensation. We base our estimates on historical experience and various other assumptions that we believe to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results could differ from those estimates under different assumptions or conditions.

For a description of our critical accounting policies and estimates, please refer to the “Critical Accounting Policies and Estimates” section of the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section contained in our Annual Report on Form 10-K for the year ended December 31, 2010. There have been no material changes in any of our accounting policies since December 31, 2010.

New Accounting Standards

In May 2011, the FASB issued new authoritative guidance to provide a consistent definition of fair value and ensure that fair value measurements and disclosure requirements are similar between GAAP and International Financial Reporting Standards. This guidance changes certain fair value measurement principles and enhances the disclosure requirements for fair value measurements. This guidance is effective for interim and annual periods beginning after December 15, 2011 and is applied prospectively. We do not expect that the adoption of this guidance will have a material impact on our financial statements.

In June 2011, FASB issued guidance on the presentation of comprehensive income. This guidance eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders’ equity and requires the presentation of other comprehensive income in a single continuous statement, or in two separate, but consecutive, statements. This guidance is effective for fiscal years and interim periods beginning after December 15, 2011. We do not expect that the adoption of this guidance will have a material effect on our financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2011. We maintain disclosure controls and procedures that are designed to provide a reasonable assurance level that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating

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the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2011, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Effective July 1, 2010, we became a “Smaller Reporting Company” under Rule 12b-2 of the Exchange Act. Previously we were an “Accelerated Filer”. This classification is based on the aggregate market value of our voting stock held by non-affiliates as of June 30 of any given year.

PART II. OTHER INFORMATION

Item 6. Exhibits

A list of the exhibits required to be filed as part of this report is set forth in the “Exhibit Index,” which immediately precedes such exhibits, and is incorporated herein by reference.

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 thereunto duly authorized.

TranS1 Inc.

Date: August 10, 2011

By: /s/ Ken Reali
Ken Reali
President and Chief Executive Officer

Date: August 10, 2011

By: /s/ Joseph P. Slattery
Joseph P. Slattery
Executive Vice President and Chief Financial
Officer

**TranS1 Inc.
Exhibit Index**

Exhibit No.	Description
31.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(a) / 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) / 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of Chief Executive Officer Pursuant to Rule 13a-14(b) / 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.
32.2	Certification of Chief Financial Officer Pursuant to Rule 13a-14(b) / 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.

CERTIFICATION

I, Ken Reali, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TranS1 Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 10, 2011

/s/ Ken Reali

Ken Reali

President and Chief Executive Officer

CERTIFICATION

I, Joseph P. Slattery, certify that:

1. I have reviewed this quarterly report on Form 10-Q of TranS1 Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting

Date: August 10, 2011

/s/ Joseph P. Slattery

Joseph P. Slattery
Executive Vice President and
Chief Financial Officer

CERTIFICATION

I, Ken Reali, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that the Quarterly Report on Form 10-Q of TranS1 Inc. for the quarterly period ended June 30, 2011 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of TranS1 Inc.

Date: August 10, 2011

/s/ Ken Reali

Ken Reali

President and Chief Executive Officer

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference.

CERTIFICATION

I, Joseph P. Slattery, hereby certify pursuant to Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, that the Quarterly Report on Form 10-Q of TranS1 Inc. for the quarterly period ended June 30, 2011 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of TranS1 Inc.

Date: August 10, 2011

/s/ Joseph P. Slattery

Joseph P. Slattery
Executive Vice President and Chief Financial
Officer

This certification accompanies the Report pursuant to Rule 13a-14(b) or Rule 15d-14(b) under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350 and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liability of that section. This certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Company specifically incorporates it by reference.