# Zacks Small-Cap Research

Brian Marckx, CFA bmarckx@zacks.com Ph (312) 265-9474

scr.zacks.com

111 North Canal Street, Chicago, IL 60606

# **Verisante Technology Inc.** (V.VRS)

V.VRS: Overseas Roll-Out Tracking Our Expectations

<b>Current Recommendation</b>	Outperform
Prior Recommendation	N/A
Date of Last Change	02/04/2011
Current Price (09/3/13)	\$0.28
Target Price	\$2.00

# **OUTLOOK**

Aura officially launched in Canada and Europe. Initial sales commenced in Q1. We expect more substantial revenue towards the back half of the year as the roll-out will likely be measured and drawn out. The initial marketing strategy largely consists of placing the units with key opinion leaders and to increase awareness of the device, the technology and the benefit to patients and healthcare practices.

Comprehensive analysis of the 1,000-lesion study were accepted for publication by *Cancer Research*, a peer-reviewed journal of the American Association of Cancer Research and the most widely cited cancer journal in the world. This should provide additional support for marketing purposes as well as potentially to help support the U.S. regulatory program.

Aura continues to be recognized as one of the leading novel medical technologies throughout the world and has racked up several high-profile awards and accolades over the last 2 years.

# **SUMMARY DATA**

52-Week High 52-Week Low One-Year Return (%) Beta Average Daily Volume (sh)	\$0.65 \$0.19 N/A N/A 44,111	Risk Level Type of Stock Industry		N/A N/A Med/Dental-Supp			
Shares Outstanding (mil) Market Capitalization (\$mil) Short Interest Ratio (days) Institutional Ownership (%) Insider Ownership (%) Annual Cash Dividend Dividend Yield (%)	72 20 N/A N/A N/A \$0.00	ZACKS  Revenue (in '000 of \$  2012 2013 2014	~	Q2 (Dec) 0 A 178 A	<b>Q3</b> (Mar) 0 A	<b>Q4</b> (Jun) 0 A	<b>Year</b> (Jun) 0 A 1,914 E 6,180 E
5-Yr. Historical Growth Rates Sales (%)	N/A	2015 Earning	s per Sh	are			15,177 E
Earnings Per Share (%) Dividend (%)  P/E using TTM EPS	N/A N/A N/A		<b>Q1</b> (Sep) -\$0.01 A -\$0.02 A	<b>Q2</b> (Dec) -\$0.01 A -\$0.02 A	<b>Q3</b> (Mar) -\$0.01 A	<b>Q4</b> (Jun) -\$0.02 A	<b>Year</b> (Jun) -\$0.05 E -\$0.06 E
P/E using 2013 Estimate P/E using 2014 Estimate	N/A N/A	2014 2015					-\$0.05 E -\$0.01 E
Zacks Rank	N/A	Zacks Projected EPS Growth Rate - Next 5 Years % N/A					

# **Overseas Roll-Out Tracking Our Expectations**

#### **Q2 Financials**

Verisante filed their financials for the second quarter ending June 30th. Revenue was \$178k from sales of Aura to the company's distributors in Canada and Europe. Revenue came in better than our \$109k estimate. VRS has not disclosed unit sales to date.

Gross margin, at 31%, was a significant improvement from the slim 13% in Q1. We continue to look for GM to firm up and widen with commercialization progress, benefitting from manufacturing volume, reduction of material input costs, sales of the higher margin caps and some pricing gains. Operating expenses were also largely in-line with our estimate (\$1.15MM A vs. \$1.10MM E). Net loss and EPS were \$1.14MM and \$0.02, just about dead-on with our \$1.12MM and \$0.02 estimates.

Cash burn (including capitalized R&D) was \$1.3 million and \$3.1 million in the three and six months ending 6/30/13. VRS exited Q2 with \$1.0 million in cash and equivalents, compared to \$1.2 million at the end of Q1. The current cash balance was bolstered by a \$830k (net) sale of equity and \$284k in proceeds from the exercise of warrants during Q2.

Our near-term outlook remains largely intact with the expectation that VRS books additional sales throughout the current year. We think there remains the possibility of some quarterly variability over the next several periods due to stocking orders and potentially only limited pull-through demand in the near-term. We continue to look for a steepening in the placement curve to materialize in early 2014.

We have made some updates and downward revisions to our mid-term revenue forecasts, mostly reflecting revised assumptions related to the early contribution from the introduction of Aura in the U.S. - which we think could happen in late 2015 or early 2016. We now model negative net income through 2015 with 2016 the first year of positive earnings. We note that while the initial overseas roll-out of Aura was somewhat delayed relative to early expectations, since the commencement of sales in Q1 actual revenue has very closely tracked our estimates and we believe our model represents achievable numbers for VRS.

We also note that MELA Sciences commercialization of Melafind in the U.S. and Europe has been well below MELA management's and analyst's expectations. MELA's unit placement rate and utilization already seemed to have flattened. While there's little insight into the root of the issues, MELA has noted that per-scan pricing may have been set too high and has recently indicated that lack of reimbursement may also hampering greater utilization and unit placements. MELA has since revised their scan pricing. They are also implementing an awareness-building strategy and expect to be actively engaged in pursuing reimbursement in the U.S. In the meantime, MELA has slashed their workforce by about 25% in an effort to conserve resources - which clearly reflects their struggles.

It's impossible to tell if MELA's struggles may be either a harbinger of similar issues for Aura in the U.S. or potentially may translate into a greater opportunity for Aura when it launches in this country. We remain confident that Aura's substantial advantages over Melafind provide it with a meaningful competitive edge and it's possible that those advantages will provide a significantly easier path to commercialization in the U.S. And if reimbursement has been established by the time Aura launches, that will be an obvious benefit to VRS (as well as to MELA). MELA's awareness-building efforts, which management has indicated will largely include messages about the dangers of skin cancer and the benefits of regular screenings, may also directly benefit Aura without the cost to VRS.

And on the macro-level, communications from medical organizations and other groups on the dangers of skin cancer and the importance of screenings continues to build momentum. This is being largely fueled by new studies showing greater incidence of the disease than previously thought and improved patient outcomes from more frequent screenings which can find skin cancer at earlier, more treatable stages. Greater awareness, whether its catalyzed by MELA or VRS or medical organizations and physicians, will increase the chances for a successful launch in the U.S. and provide a stronger tailwind to the ongoing roll-out overseas.

#### **Recent Developments**

Verisante continues to make meaningful progress on several fronts including commercialization of Aura, continued product development, regulatory matters, financing, and product and market awareness initiatives. Below is a quick snapshot of some of these activities over the last several months.

#### > Capital Raise

In mid-May Verisante raised \$943k (gross) from the sale of 2.38 million shares of common stock (@ \$0.40/share) with 100% warrant coverage. The warrants have a two-year term and are exercisable at \$0.60/share. Verisante has the right to call in the expiration dates of the warrants to within ~30 days of the following events; 50% of warrants if Verisante's volume weighted trading price reaches \$0.90 or greater for 10 consecutive days, the other 50% of warrants if Verisante's volume weighted trading price reaches \$1.15 or greater for 10 consecutive days.

Verisante exited 2012 with \$1.7 million in cash and equivalents and has been burning (including capitalized R&D) roughly \$1.3 million per quarter. While this cash raise will provide some operating capital, we expect the company will look to raise additional funds to help catalyze the ongoing roll-out of Aura.

#### > Distribution Further Beefed Up

On the heels of the ex-U.S. launch of Aura Verisante has significantly expanded their distribution. Over the last several months Verisante has penned agreements with several distributors covering large swaths of Europe including Germany, Switzerland, Austria, the U.K. and Ireland. Laserwelt has a substantial footprint throughout Germany, Austria and Lichtenstein and is a top distributor of medical devices. Germany, in particular, is expected to be an important territory for Verisante's Aura as it is the only country with a national skin cancer screening program and one of the largest markets for medical devices in general.

The other recently announced distribution agreements are with Frontiere Medicale Europe for the U.K. and Ireland, Pacifica Handels AG covering Switzerland and an expanded agreement with BO-Pharma which now also covers the Nordic countries of Norway, Denmark, Finland and Iceland in addition to the initial agreement which was for the Benelux region (Belgium, Netherlands, Luxembourg). And as a reminder, Verisante had previously announced a distribution agreement with Clarion Medical Technologies for the Canadian market.

VRS is focused on continuing to expand their distribution footprint and will look to continue to add distributors in other territories.

#### > Aura Launched

In late January 2013 Verisante announced that they received their first orders for Aura from their distributors in Canada and Europe. Manufacturing was up and running and shipping began shortly afterwards.

In March Verisante, in concert with Laserwelt, announced the official launch of Aura in Germany. The announcement was made at the Annual Dermatology Congress "Dermatological Practice", one of the major dermatology conferences in Europe. The German launch was followed in mid-April by VRS's announcement that they were holding an official Canadian launch in Vancouver. VRS expects to have approximately 100 units produced through roughly the end of 2013 or early 2014.

The initial roll-out and marketing strategy largely consists of placing the units with key opinion leaders and to increase awareness of the device, the technology and the benefit to patients and healthcare practices. Presentations, word-of-mouth, testimonials and recommendations from physicians and key opinion leaders that have already used Aura can be highly influential for promoting the benefits of the device. This, however, will take some time which means the unit placement curve will likely be somewhat drawn out.

#### > Aura Continues To Rack Up Awards

Verisante's trophy case continues to fill up with the latest award coming in April when Aura won the bronze Edison Award. Per the Edison Awards website describing the awards,

"The Edison Awards<sup>TM</sup> are among the most prestigious accolades honoring excellence in new product and service development, marketing, human-centered design and innovation. Unique to the world of award programs, the Edison Awards<sup>TM</sup> are focused on the innovators as much as the innovations. Award winners represent "game changing" products, services and excellence and leadership in innovation around four criteria: Concept, Value, Delivery and Impact. An Edison Award represents significant value to the award winner and to the cause of innovation."

Verisante and Aura were in good company as a finalist for the Edison Award. The other three finalists in their category were; 3M Molecular Detection System by 3M, AccuVein AV400 by AccuVein Inc, and 3-D Motion Capture System by Dynamic Athletic Research Institute.

In February Aura won the 2013 Prism Award in the Life Sciences and Biophotonics category. The award was presented to VRSEF management during the annual SPIE Photonics West conference which attracts over 1,500 companies and 20,000 attendees and which is billed as the world's largest and most influential photonics and optics

event. The award recognized Aura as the best new photonics product on the market and beat out entries from throughout the world including a microscope objective from imaging giant Olympus and an ultrafast laser from Femtolasers, both of which were finalists for the award.

As a reminder Verisante and their cancer detection products and technology have already racked up a number of high profile accolades over the recent past including Popular Science's Best of What's New Award for 2011, being named as a top cancer breakthrough of 2011 by the Canadian Cancer Society and the company being named as the top ranking technology and life sciences company on the TSX Venture 50.

#### > Core for Lung Cancer

Study data using Verisante's exclusively licensed technology which is expected to be incorporated into a lung cancer detection device called Core, affirmed positive results from an earlier pilot study.

The studies used VRS's Raman spectral analysis combined with autofluorescence to detect cancer. The recent data comes from a larger sample size (267 samples) compared to the smaller (129 samples) pilot study and also used the latest generation Raman system technology. The result was an improvement in the already impressive 91% specificity seen in the pilot study with only a slight reduction in sensitivity (which was 96% in the pilot study) in the ability to differentiate localized high grade dysplasia and carcinoma from benign lesions. The new study results were presented by BC Cancer Agency researchers in a poster entitled Characterization of Pre-Neoplastic and Neoplastic Bronchial Lesions Using Laser Raman Spectroscopy at the BC Cancer Agency Annual Conference (Nov 29 - Dec 1) and were also presented at SPIE Photonics West 2013 (Feb 2 - 7, 2013) where VRS was honored with the above-mentioned award. In August 2013 VRS announced that this latest study is now fully completed and statistical analysis is now underway.

As a reminder, results of the small (129 samples from 26 patients) pilot study which used Verisante's Raman system technology, combined with white light and fluorescence bronchoscopy (technology which Verisante acquired in June 2011) for the early detection of lung cancer were published in the July 2012 issue of the *Journal of Thoracic Oncology*. Results showed that when Verisante's Core lung cancer detection device (using Raman technology) is combined with the ClearVu and ClearVu Elite endoscopy system (which Verisante acquired) the number of false positives were reduced by over 75% compared to traditional endoscopic methods.

### > Colon Cancer and Nasopharyngeal Cancer

VRS is also investigating their technology for the detection of other cancers, including colon and nasopharyngeal. Relative to colon cancer, a Raman probe has been developed by the BC Cancer Agency and a clinical study is now underway at Vancouver General Hospital. VRS noted that as of August 2013, two patients had verified the functionality of the probe and the quality of the Raman spectra that were collected.

Relative to nasopharyngeal cancer, VRS announced in August 2013 that they have entered into an agreement with the BC Cancer Agency and Fujian Normal University in China to develop an application for their technology for nasopharyngeal cancer. VRS is providing Fujian Normal with their ClearVu Elite endoscopy system to use in a study to detect cancerous lesions. Nasopharyngeal cancer, a cancer of the upper throat, is more common in China and North Africa.

We currently do not model a contribution from any of VRS's ancillary applications (i.e. - cancers of the lung, colon, nasopharynx) as while we think these applications have potentially significant revenue potential, we feel it is still too early to reasonably judge the approvability or utility for these applications. Additional clinical data and future publication of the data should provide more insight into approvability, utility and potential demand.

#### **Valuation**

We model more substantial sales towards the back half of the current year as we expect the initial roll-out to be somewhat slow and measured. Pre-IDE submission package related to the U.S. regulatory program and pathway is in process of being finalized. We model an assumed U.S. launch in late 2015 to early 2016.

We use 10-yr DCF to value VRS. Key inputs to our 10-year DCF model include a 10% discount rate and 2% terminal growth rate. Our DCF model values VRS at about \$2.00/share.

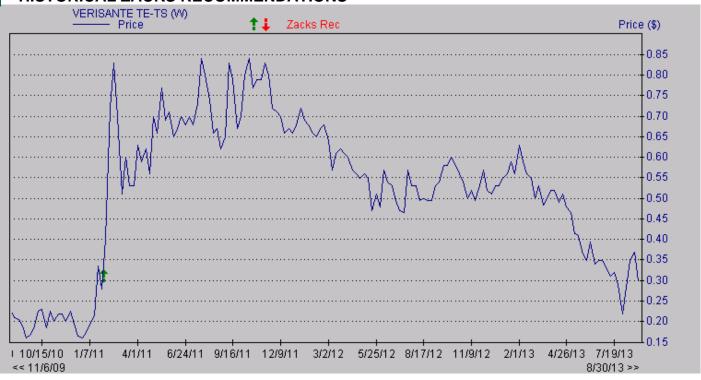
# **FINANCIAL STATEMENTS**

# **INCOME STATEMENT** (CDN \$)

## Verisante Technology

	2011 A	2012 A	2013 E	2014 E	2015 E	<b>2016 E</b>
Revenue	\$2	\$0	\$1,914	\$6,180	\$15,177	\$33,854
YOY Growth	-	-	-	222.8%	145.6%	123.1%
Cost of sales	\$0	\$0	\$1,378	\$3,320	\$6,125	\$13,400
Gross Income	\$2	\$0	\$536	\$2,860	\$9,052	\$20,454
Gross Margin SG&A	\$3,435	\$3,201	<sup>28.0%</sup> \$4,592	\$6,050	<sup>59.6</sup> % \$8,705	\$13,470
% SG&A R&D	\$7	\$52	239.9% \$135	97.9% \$225	57.4% \$2 <b>7</b> 5	<sup>39.8%</sup> \$325
% R&D Interest expense (income), net	(\$41.0)	(\$33.6)	7.1% (\$16.6)	3.6% (\$20.0)	1.8% (\$20.0)	1.0% (\$35.0)
Operating Income	(\$3,399)	(\$3,219)	(\$4,174)	(\$3,395)	\$92	\$6,694
Operating Margin	-	-	-218.0%	-54.9%	0.6%	19.8%
Total Other Income	(\$153)	(\$291)	(\$171)	(\$371)	(\$911)	(\$2,031)
Pre-Tax Income	(\$3,551)	(\$3,510)	(\$4,345)	(\$3,766)	(\$819)	\$4,663
Taxes (benefit) Tax Rate	\$0.0 0.0%	\$0.0 0.0%	\$0.0 0.0%	\$0.0 0.0%	\$0.0 0.0%	\$373.0 8.0%
Net Income	(\$3,551)	(\$3,510)	(\$4,345)	(\$3,766)	(\$819)	\$4,290
Net Margin	-	-	-227.0%	-60.9%	-5.4%	12.7%
EPS	(\$0.06)	(\$0.05)	(\$0.06)	(\$0.05)	(\$0.01)	\$0.05
YOY Growth	54.3%	-17.0%	8.2%	-22.2%	-79.3%	-606.5%
Diluted Shares O/S	54,651	65,112	74,515	83,000	87,000	90,000
		Brian Marckx, CFA				

# HISTORICAL ZACKS RECOMMENDATIONS



#### **DISCLOSURES**

The following disclosures relate to relationships between Zacks Investment Research ("ZIR"), Zacks & Company (ZCO") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned.

ZCO and Zacks SCR are separate legal entities. ZCO is U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the Financial Industry Regulatory Authority and the Securities Investor Protection Corp. This report is for your information only and is not an offer to sell, or a solicitation of an offer to buy, the securities or instruments through ZCO.

Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1028 companies covered: Buy/Outperform- 14.9%, Hold/Neutral- 78.0%, Sell/Underperform – 6.0%. Data is as of midnight on the business day immediately prior to this publication.