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Zacks Small-Cap Research

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

scr.zacks.com
10 S. Riverside Plaza, Ste 1600, Chicago, IL 60606

# Verisante Technology Inc. (V.VRS)

## *V.VRS: Summary of Recent Activities*

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | N/A |
| Date of Last Change | 02/04/2011 |
| Current Price (04/09/14) | $0.19 |
| **Target Price** | **$2.00** |

## OUTLOOK

Aura officially launched in Canada and Europe. Initial sales commenced in Q1. We expect more substantial revenue going forward. 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 3 years.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$0.51** |
| **52-Week Low** | **$0.15** |
| **One-Year Return (%)** | **N/A** |
| **Beta** | **N/A** |
| **Average Daily Volume (sh)** | **26,185** |
| **Shares Outstanding (mil)** | **79** |
| **Market Capitalization ($mil)** | **15** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **N/A** |
| **Insider Ownership (%)** | **N/A** |
| **Annual Cash Dividend** | **$0.00** |
| **Dividend Yield (%)** | **N/A** |
| **5-Yr. Historical Growth Rates** | |
| **Sales (%)** | **N/A** |
| **Earnings Per Share (%)** | **N/A** |
| **Dividend (%)** | **N/A** |
| **P/E using TTM EPS** | **N/A** |
| **P/E using 2013 Estimate** | **N/A** |
| **P/E using 2014 Estimate** | **N/A** |
| **Zacks Rank** | **N/A** |

| | |
|---|---|
| **Risk Level** | **N/A** |
| **Type of Stock** | **N/A** |
| **Industry** | **Med/Dental-Supp** |

## ZACKS ESTIMATES

**Revenue**
(in '000 of $)

| | Q1 (Sep) | Q2 (Dec) | Q3 (Mar) | Q4 (Jun) | Year (Jun) |
|---|---|---|---|---|---|
| 2012 | 0 A | 0 A | 0 A | 0 A | 0 A |
| 2013 | 235 A | 178 A | 440 A | | 1,925 E |
| 2014 | | | | | 6,149 E |
| 2015 | | | | | 15,141 E |

**Earnings per Share**

| | Q1 (Sep) | Q2 (Dec) | Q3 (Mar) | Q4 (Jun) | Year (Jun) |
|---|---|---|---|---|---|
| 2012 | -$0.01 A | -$0.01 A | -$0.01 A | -$0.02 A | -$0.05 E |
| 2013 | -$0.02 A | -$0.02 A | -$0.01 A | | -$0.05 E |
| 2014 | | | | | -$0.05 E |
| 2015 | | | | | -$0.01 E |

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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## Recent Developments

**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.

**> Additions To Sales Team**

The company recently announced two additions to the sales team including a Director of Sales and a sales rep for Western Canada. As a reminder, in November the company announced that they terminated their distribution agreement with Clarion Medical who was to handle distribution of Aura in Canada as the company decided to handle sales in the Canadian market themselves. Concurrent the February 2014 announcement regarding increases to the sales team, the company noted that they are readying for a full product launch of Aura (skin cancer) in Canada and Europe and working to complete their Core device (lung cancer as well as potentially colorectal and cervical cancers).

**> Verisante Research System**

Verisante unveiled its newest product in February at the SPIE Photonics West conference, where the company is becoming a regular attendee. The company demonstrated its Verisante Research System, a Raman spectroscopy system that uses the same technology as their Aura device but which Verisante designed for the research market.



The Research System product will target the scientific research community and can be launched immediately throughout the world as regulatory approvals are not required. But while the research market is likely only a fraction of the size of the commercial clinical market targeted with the Aura system, the Research System potentially provides another source of near-term income for Verisante.

**> Multispectral Imaging Camera (MSI)**

In September VRS announced that they had completed a phase two prototype of their MSI device. Over the next 24 months they expect to complete laboratory testing for skin cancer, field test for skin cancer, develop an oral cancer probe and field test for oral cancer, apply for regulatory approval, and, if all goes well, launch the device.

**> Capital Raises**

In March 2014 VRS closed a private placement of 2.8M shares (@ $0.17/share) with 100% warrant coverage (24 months, $0.25 strike) for gross proceeds of $481k. In November 2013 Verisante announced they closed on a $1.0 million (gross) capital raise via the sale of stock and warrants. This follows a $943k (gross) raise in May from the sale of stock with warrants. We expect the recent improving financial results as well as the continued progress with the roll-out of Aura and the pipeline to facilitate future capital raises.

**> 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 quarters 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 but in late November announced that they terminated that agreement and will now handle sales to Canada themselves.

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 2013 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. At the time, VRS was shooting 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.

And despite the official launch announcement and initial orders in early 2013, this has not translated into significant sales. In fact it seems Verisante has regrouped to some extent since these announcements, deciding to market in Canada directly with their own sales force and indicating in a February 2014 that at that time they were readying for a full product launch in Canada and Europe.

**> Aura Continues To Rack Up Awards**
Verisante's trophy case continues to fill up with the latest award coming in April 2013 when Aura won the bronze Edison Award. Per the Edison Awards website describing the awards,
*"The Edison Awards™ 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™ 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.

## Q3 Financials

Verisante filed their financials for the third quarter ending September 30th. Revenue was $440k from sales of Aura to the company's distributors in Canada and Europe. Verisante also noted that some of the revenue in Q3 was from sales that were made directly by the company. In the earnings release Verisante announced that they have cut ties with their Canadian distributor, Clarion, and will now handle sales to the Canadian market themselves. Q3 revenue was the highest since VRS initiated sales of Aura in early 2013, was up almost 150% from Q2 and came in better than our $355k estimate. VRS has not disclosed unit sales to date.

Gross margin continues to improve and came in at 57% in Q3, up from 31% in Q2 and just 13% in Q1. VRS noted that they continue to leverage efficiencies from their production and manufacturing processes. While we think there may be some q-to-q variability in gross margin, we expect it 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 also came in better (i.e. - lower) than our estimate ($966k A vs. $1,190k E). Net loss and EPS were $749k and ($0.01) versus our $1,126k and ($0.01) estimates.

Cash burn (including capitalized R&D) was $821k and $3.8 million in the three and nine months ending 9/30/13. VRS exited Q3 with $288k in cash and equivalents, compared to $1.0 million at the end of Q2. Subsequent to Q3, Verisante raised an additional $1.0 million (gross) through the sale of common shares with warrants.

Our near-term outlook remains largely intact with the expectation that VRS books additional sales in Q4. 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 no material changes to our model following Q3 results. 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. And despite Aura currently only available ex-U.S. and the roll-out commencing less than a year ago, Verisante's financial results have already been significantly better MELA's through the first nine months of 2013.

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 in the U.S., 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.

**MSI Camera**



Meanwhile, Verisante expects to exploit the advantages of Aura outside of the U.S. The initial roll-out already appears promising. They will also be actively engaged in pursuing reimbursement. The company also will look to bring derivative products to market over the near-to-mid term. In addition to Core, which is still being used in clinical studies for the detection of lung cancer, the company has other products under development. This includes their Multispectral Imaging Camera (MSI) which has potential applications in detection of skin and oral cancers. In September VRS announced that they had completed a phase two prototype of the device. Over the next 24 months they expect to complete laboratory testing for skin cancer, field test for skin cancer, develop an oral cancer probe and field test for oral cancer, apply for regulatory approval, and, if all goes well, launch the device.

VRS envisions the MSI skin cancer device will be targeted towards general physicians (Aura is targeted towards dermatologists). A diagnosis indicating suspicious for skin cancer would then be referred to a dermatologist to make a diagnosis. The device is expected to be compatible with smart phones and tablets as well as with a laptop. And with a small footprint, the MSI camera is potentially easy to integrate into almost any physician (or dentist's, for the oral cancer application) practice.

A device for oral cancer would significantly expand Verisante's total target markets. Over 40k new cases of oral cancer are diagnosed in the U.S. every year. That figure is over 600k worldwide. While there are other oral cancer screening devices and products already commercialized that VRS's device would compete with, the market is still very much unsaturated. The typical method to check for oral cancer involves the dentist visually examining and feeling the inside of the mouth. VRS believes their device will provide advantages such as a lower rate of false negatives compared to currently available oral screening devices and products. And unlike skin cancer detection, there is already reimbursement in place for oral cancer screening.
As we have noted before, we have yet to model any contribution from products other than Aura. 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 products. We will, however, include a contribution from these derivative products if and when it's appropriate.

## Valuation

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 | 2016 E |
|---|---|---|---|---|---|---|
| Revenue | $2 | $0 | $1,925 | $6,149 | $15,141 | $33,824 |
| *YOY Growth* | - | - | - | *219.4%* | *146.2%* | *123.4%* |
| Cost of sales | $0 | $0 | $1,283 | $3,317 | $6,123 | $13,398 |
| Gross Income | $2 | $0 | $642 | $2,832 | $9,018 | $20,426 |
| *Gross Margin* | - | - | *33.4%* | *46.0%* | *59.6%* | *60.4%* |
| SG&A | $3,435 | $3,201 | $4,400 | $6,050 | $8,705 | $13,470 |
| *% SG&A* | - | - | *228.5%* | *98.4%* | *57.5%* | *39.8%* |
| R&D | $7 | $52 | $88 | $225 | $275 | $325 |
| *% R&D* | - | - | *4.6%* | *3.7%* | *1.8%* | *1.0%* |
| Interest expense (income), net | ($41.0) | ($33.6) | ($13.6) | ($20.0) | ($20.0) | ($35.0) |
| Operating Income | ($3,399) | ($3,219) | ($3,832) | ($3,423) | $58 | $6,666 |
| *Operating Margin* | - | - | *-199.1%* | *-55.7%* | *0.4%* | *19.7%* |
| Total Other Income | ($153) | ($291) | ($160) | ($369) | ($908) | ($2,029) |
| Pre-Tax Income | ($3,551) | ($3,510) | ($3,993) | ($3,792) | ($851) | $4,636 |
| Taxes (benefit) | $0.0 | $0.0 | $0.0 | $0.0 | $0.0 | $370.9 |
| *Tax Rate* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *0.0%* | *8.0%* |
| Net Income | ($3,551) | ($3,510) | ($3,993) | ($3,792) | ($851) | $4,265 |
| *Net Margin* | - | - | *-207.4%* | *-61.7%* | *-5.6%* | *12.6%* |
| EPS | ($0.06) | ($0.05) | ($0.05) | ($0.05) | ($0.01) | $0.05 |
| *YOY Growth* | *54.3%* | *-17.0%* | *1.4%* | *-16.5%* | *-78.6%* | *-584.6%* |
| Diluted Shares O/ S | 54,651 | 65,112 | 73,008 | 83,000 | 87,000 | 90,000 |

*Brian Marckx, CFA*

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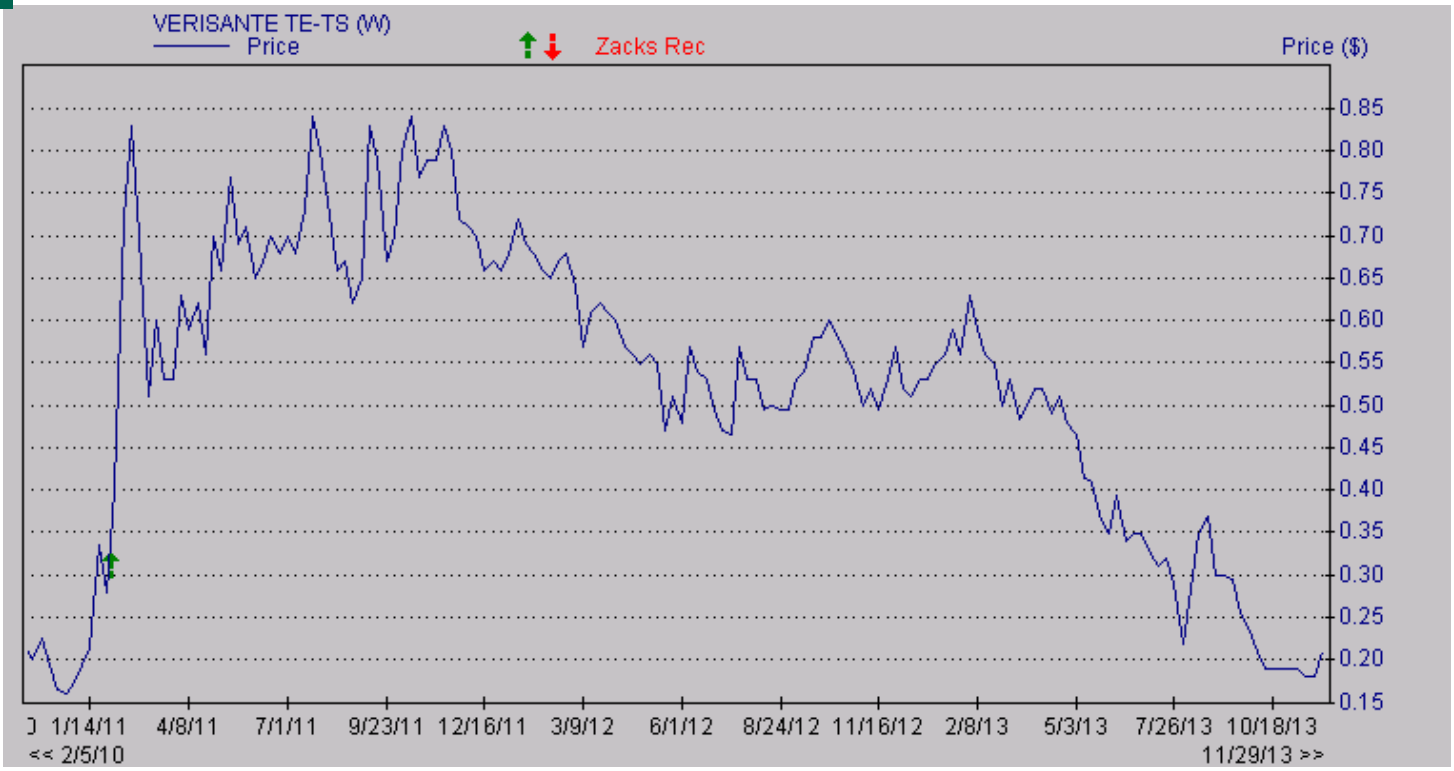
## HISTORICAL ZACKS RECOMMENDATIONS

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