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Zacks Small-Cap Research

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Verisante Technology Inc. (V.VRS)

V.VRS: 2013 Annual Filing

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	02/04/2011
Current Price (05/06/14)	$0.15
Target Price	**$1.25**

OUTLOOK

Aura officially launched in Canada and Europe. Initial sales commenced in Q1 but have been lackluster. 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	**$0.48**
52-Week Low	**$0.14**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**20,221**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**12**
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 2014 Estimate	**N/A**
P/E using 2015 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)
2013	235 A	178 A	440 A	-78 A	775 A
2014					1,322 E
2015					4,180 E
2016					9,648 E

Earnings per Share

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2013	-$0.02 A	-$0.02 A	-$0.01 A	-$0.01 A	-$0.07 A
2014					-$0.05 E
2015					-$0.04 E
2016					-$0.03 E

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

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2013 Annual Filing

Q4 Financials

Verisante filed their financials for the third quarter and year ending December 31, 2013. Q4 financials were largely unremarkable with "low-lights" consisting of revenue coming in negative ($78k) and the company taking a large bad debt expense, the latter related to uncollectable receivables. 2013 net revenue came in at $775k, well below our $1.9M estimate. The difference partially a result of the surprising $508k bad debt expense as well as continued delays with the full launch of Aura.

Excluding the bad debt expense, Q4 operating expenses were $1.1M and very much in-line with our $1.1M estimate. Q4 net loss and EPS (ex-bad debt) were ($1.3)M and ($0.02) compared to our ($902)k and ($0.01) estimates.

Cash burn (including capitalized R&D) was $750k and $4.5M in the three and twelve months ending 12/31/2013. VRS exited the year with $455k in cash and equivalents. Subsequent to year-end the company raised an additional $481k via the sale of equity with warrants.

We have made significant downward revisions to our near-to-mid term revenue forecasts as a result of the slower than anticipated roll-out of Aura. While several distribution agreements have been penned over the last several quarters, production of up to 100 Aura units was underway, significant effort was put into awareness-building activities and the official launch announced in early 2013, this has not translated into consistent and measured sales growth like we had anticipated. The reasons behind the roll-out headwinds are not entirely clear, although the cancellation of the Clarion distribution agreement for Canada (where VRS will now sell direct), negative revenue in Q4 and the large bad debt expense may indicate initial expectations may have erred on the too-optimistic side. The company also notes in the annual filing that they will be reviewing their relationships with all of their distributors in Europe and expects to be ready for a full launch of its products (Aura and the research-use product) via their direct sales team (which currently is focused only on Canada) in Q3 of this year - which we think may indicate less-than-robust revenue expectations for at least the next couple of quarters. We also think the language indicates that they may look to sell direct in other areas that they had previously signed distribution agreements - which if so, could be a positive development as the company will have direct control over the selling efforts. However, ramping a sales force will require additional capital.

Our current 2014 revenue estimates include mostly only sales of Aura (with a minor contribution from the research-use product). We think 2015 could be the first year of contribution from sales of Core for an initial indication - likely lung cancer - which is dependent on positive data from the ongoing statistical analysis from the recently completed ~300 patient study - as well as requisite regulatory clearances. The data is expected to be available during the current year. While we believe Core could hold significant revenue opportunity given its potential wide-ranging applications and their related sizeable markets, we have yet to incorporate an assumed contribution from the device in the clinical market - eventual attainment of requisite regulatory clearances, compelling clinical data and commercialization would likely provide upside to our current model.

Near-to-mid term revenue could also benefit from VRS's complementary-type products - including the research-use only version of Aura as well as the recently unveiled MSI camera. Similarly, Core may initially be offered to the research market - which could also contribute to near-term revenue.

Relative to the U.S. market - there has been little in the way of updates from VRS relative to their progress towards regulatory approval - although we think the lack of news likely relates to the company's focus on commercialization of Aura in Europe and Canada. VRS has recently indicated that they will submit request to FDA to follow a 510(k) regulatory pathway - if granted this would significantly reduce the regulatory burden (in terms of time and cost) and could conceivably put Aura on the U.S. market as early as next year. We continue to assume that the FDA approval pathway will be PMA - which likely would mean a potential U.S. launch would not happen prior to late 2016. A 510(k) clearance route, if approved, would also likely provide upside to our model.

The updates to our model resulted in a downward revision to our DCF-generated price target. Our price target has moved from $2.00/share to $1.25/share. We are maintaining our Outperform rating.

Recent Developments

> 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 2013 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). We think VRS will add additional sales reps as they begin to sell direct in other territories where they had previously signed distribution agreements.

> Verisante Research System

Verisante unveiled its newest product in February 2014 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 18 - 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.

> 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.

> 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 also noted in their 2013 annual filing that they will be reviewing their relationships with all of their distributors in Europe - potentially indicating that they may look to switch to a direct sales model in areas of Europe as well.

> 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. The regrouping effort also looks like it will include selling direct instead of using a third-party distribution sales model.

> 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. We think the data will read-out and be published sometime during the current year which could provide better insight into the utility of Core for lung cancer.

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 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 $1.25/share.

FINANCIAL STATEMENTS

INCOME STATEMENT (CDN $)

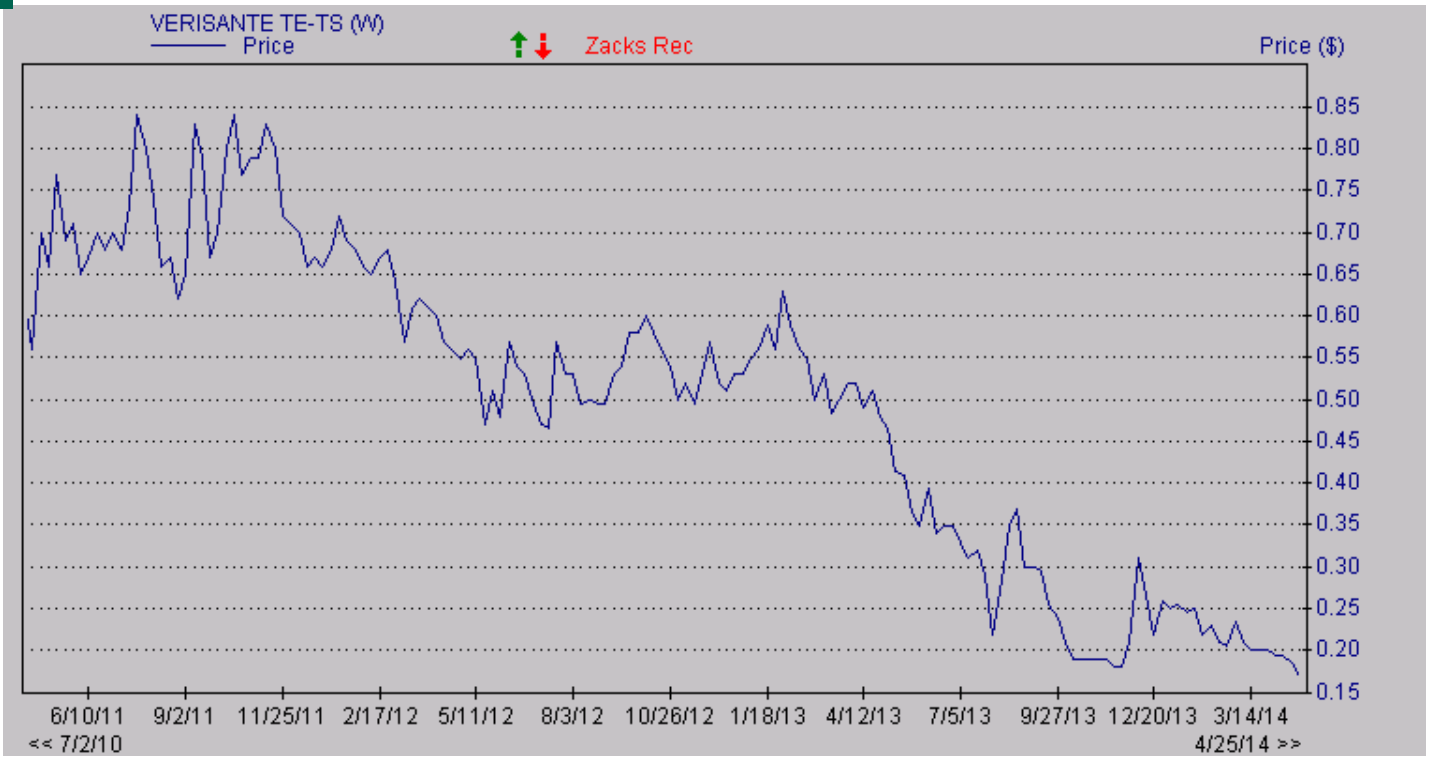
Verisante Technology

	2012 A	2013 A	2014 E	2015 E	2016 E	2017 E
Revenue	$0	$775	$1,322	$4,180	$9,648	$21,918
YOY Growth	-	-	*70.5%*	*216.2%*	*130.8%*	*127.2%*
Cost of sales	$0	$505	$907	$2,273	$4,566	$8,735
Gross Income	$0	$270	$415	$1,907	$5,082	$13,183
Gross Margin	-	*34.9%*	*31.4%*	*45.6%*	*52.7%*	*60.1%*
SG&A	$3,201	$4,874	$4,570	$5,740	$7,240	$10,750
% SG&A	-	*628.7%*	*345.7%*	*137.3%*	*75.0%*	*49.0%*
R&D	$52	$109	$175	$275	$325	$425
% R&D	-	*14.0%*	*13.2%*	*6.6%*	*3.4%*	*1.9%*
Interest/ Div expense (income), net	($33.6)	($12.3)	($10.0)	($10.0)	($15.0)	($20.0)
Operating Income	($3,219)	($4,700)	($4,320)	($4,098)	($2,468)	$2,028
Operating Margin	-	-	-	-	-	*9.3%*
Total Other Income	($291)	($196)	($160)	($251)	($579)	($1,315)
Pre-Tax Income	($3,510)	($4,896)	($4,480)	($4,348)	($3,047)	$713
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($3,510)	($4,896)	($4,480)	($4,348)	($3,047)	$713
Net Margin	-	*-631.5%*	*-338.8%*	*-104.0%*	*-31.6%*	*3.3%*
EPS	($0.05)	($0.07)	($0.05)	($0.04)	($0.03)	$0.01
YOY Growth	*-17.0%*	*25.3%*	*-22.8%*	*-17.5%*	*-32.6%*	*-123.0%*
Diluted Shares O/ S	65,112	72,453	85,875	101,000	105,000	107,000

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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 is as follows: Buy/Outperform- 16.3%, Hold/Neutral- 75.2%, Sell/Underperform – 7.3%. Data is as of midnight on the business day immediately prior to this publication.