Zacks Small-Cap Research

September 18, 2012

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Verisante Technology Inc. (V.VRS)

V.VRS: Field Testing Ongoing / Rodman Presentation

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	02/04/2011
Current Price (09/18/12)	$0.56
Target Price	**$2.70**

OUTLOOK

VRS took delivery of pre-production units in July. Final testing, then production and commercialization should happen by year-end. Management continues to hit milestones and at the same time is driving awareness of Aura. Distributor in place for Canada. Agreements for Europe and Australia expected next.

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. VRS gave an update on commercialization timelines at a Sept 2012 Rodman & Renshaw presentation.

SUMMARY DATA

52-Week High	**$1.13**
52-Week Low	**$0.45**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**101,664**
Shares Outstanding (mil)	**65**
Market Capitalization ($mil)	**36**
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 2012 Estimate	**N/A**
P/E using 2013 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)
2011	0 A	0 A	0 E	2 A	0 A
2012					407 E
2013					8,598 E
2014					26,148 E

Earnings per Share

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2011	-$0.02 A	-$0.01 A	-$0.02 A	-$0.02 A	-$0.06 A
2012					-$0.06 E
2013					-$0.02 E
2014					$0.06 E

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

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Q2 Financials

Verisante filed their Q2 2012 financials for the period ending 6/30/2012 in late August. Operating expenses were $669k, down slightly from the $773k in the year-earlier period. Net loss and EPS were $659k and ($0.01) compared to $759k and ($0.02) in Q2 2011.

Cash burn remains very much in-line with our projections. Management continues to manage capital well, keeping operations lean while continuing to make meaningful progress with product development and pre-launch marketing and investor-awareness activities.

Cash burn (including capitalized R&D) was $1.4 million and $2.6 million in the three and six month periods ending 6/30/2012. VRS exited Q2 with $3.5 million in cash and short-term investments.

Field Testing Ongoing

Verisante continues to make progress with field testing of Aura and last week announced that they placed more beta units in Canada for that purpose. The device is now or has already been tested by doctors and consenting patients in British Columbia, Alberta and Ontario. VRS notes that they expect field testing to continue over a period of about 2 - 4 months during which data and feedback will be collected and used to make any necessary final refinements to usability and the software. This is expected to be the final step prior to commercialization of Aura.

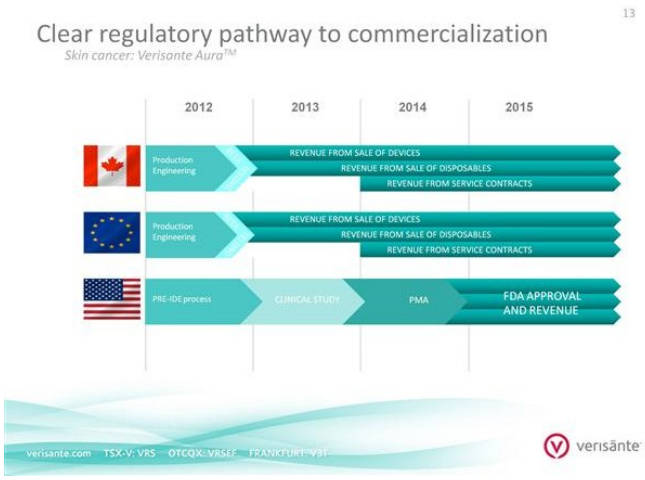
Rodman & Renshaw Presentation

Thomas Braun made a presentation at a Rodman & Renshaw conference held in NYC last week where he outlined the key competitive advantages of Aura and summarized the company's near-to-mid term commercialization strategy. Some of our key take-aways, which mostly relate to timelines, include;

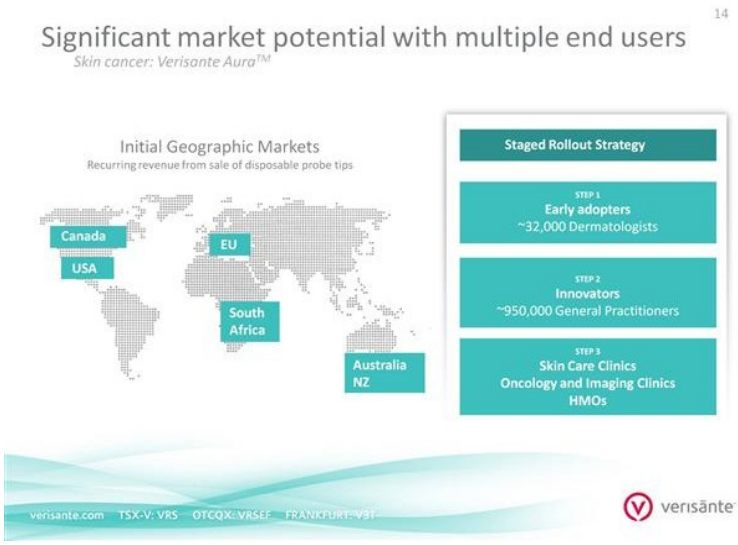
- The clinical study of Core for lung cancer being conducted at the Lung Tumor Center at Vancouver General Hospital should complete by this Summer and results published by year-end

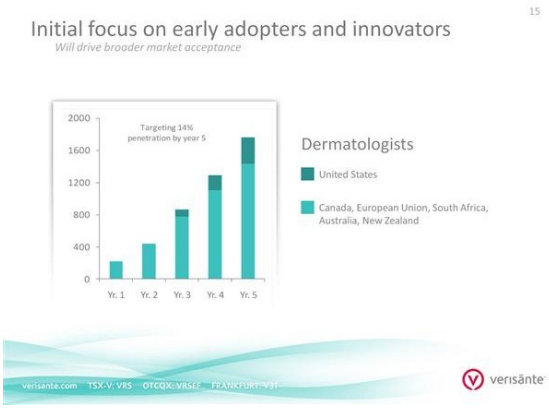
- Registration for sale of Aura in Mexico and Brazil began about 3 months ago (as a reminder Aura is already approved for sale in Europe, Canada, Australia, New Zealand and South Africa)

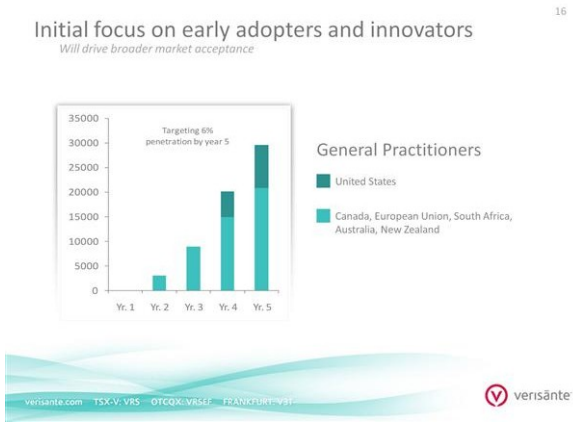
- Commercialization timelines by territory (per a presentation slide);
  - Canada: device sales commence in late 2012. Disposable end-cap sales begin early 2013. Service contract revenue begin early 2014.
  - Europe/Australia/New Zealand/S.Africa/Mexico/Brazil: device sales commence in late 2012. Disposable end-cap sales begin early 2013. Service contract revenue begin early 2014.
  - U.S.: device and disposable sales begin late 2014



- VRS's targeted roll-out strategy remains unchanged. Initially they expect to target dermatologists ("early adopters"), then general physicians ("innovators"), and finally other health care providers including skin care clinics, oncology practices, and imaging centers







- VRS continues to work on the pre-IDE process related to an eventual FDA filing. VRS is working with their U.S. consultant to put together their pre-IDE submission (which should be "any day now"). Following the submission, VRS will meet with FDA (potentially sometime near year-end) where the agency is expected to provide specific guidance relative to the U.S. regulatory approval pathway. The current expectation (which remains unchanged) is that FDA will want VRS to conduct a multi-site clinical trial (n= ~1,000 including at least 100 melanomas) in support of an eventual PMA filing. The trial is expected to take about 1 year to complete. Assuming a 12-month turnaround by the FDA, a reasonable best-case scenario could have Aura on the U.S. market in late 2014. As we note below, given the slight delay in the IDE process (initially an IDE meeting was expected earlier in 2012), we have pushed back our assumed U.S. launch of Aura from late 2014 to mid-to-late 2015, which provides some cushion for further delays.

- VRS expects revenue from service contracts (in all territories) could be meaningful following the expiration of an initial 12-month warranty period

Valuation

We continue to model an initial launch in late 2012 with an immaterial amount of revenue in the current year but showing a steep ramp throughout 2013. We had previously modeled Aura to launch in the U.S. in late 2014 but given the slight delay in the IDE process (initially an IDE meeting was expected earlier in 2012), we have pushed back our assumed U.S. launch of Aura from late 2014 to mid-to-late 2015 (slightly more conservative than

management's late-2014 guidance, which provides some cushion for further delays). Updates to our model mostly effect years 2014 - 2015 with a much more muted impact over the longer-term.

As commercialization (ex-U.S.) is now expected to be a near-term event, we are now using DCF as our valuation methodology. 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 $2.70/share (which is very much in-line with our prior valuation of $2.60/share).

Aura Pre-Production Units



Aura Study Results Published (*from our 4/5/12 update*)

Comprehensive analysis of the 1,000-lesion study were accepted for publication by *Cancer Research*, a peer-reviewd journal of the American Association of Cancer Research and the most widely cited cancer journal in the world. The manuscript, titled "Real-time Raman Spectroscopy for In Vivo Skin Cancer Diagnosis", was first published in the online version of the journal in late March.

As a reminder, Verisante announced the preliminary statistical analysis earlier this year which were presented by Dr. Haishan Zeng at the SPIE (international society for optics and photonics) conference in San Francisco. Data was acquired on over 1,000 lesions from 848 patients. The study analysis focused on only those classes of lesions that are considered to be associated with concern of skin cancer - which resulted in a final dataset of 518 lesions from 453 patients. Specifically, the classes of skin lesions included in the analysis were those diagnosed as malignant or premalignant (i.e. - malignant melanoma, squamous cell carcinoma, basal cell carcinoma, and actinic keratosis - in aggregate, these represent essentially 100% of skin cancers) and benign conditions that look like skin cancer (i.e. - seborrheic keratosis, atypical nevi, malanocytic nevi, compound nevi, and intradermal and blue nevi).

The study focused on three distinct categories, specifically Aura's ability to differentiate; 1) skin cancers and pre-cancers from benign skin lesions, 2) melanomas from non-melanoma pigmented lesions, and 3) melanomas from seborrheic keratoses. Statistical analysis was done using two methods; principal component with general discriminant analysis (GDA) and partial least squares. With sensitivities between 95% and 99%, Aura demonstrated specificities in these three tasks between 15% and 54% with GDA (in most instances using partial least squares resulted in higher specificities) - which resulted in a biopsy ratio (the number of non-melanoma lesions that undergo biopsy for each confirmed case of melanoma) of between 0.77:1 to 5.56:1. Specifically (see Table 3 from the study below) the GDA analysis showed, in differentiating 1) skin cancers and pre-cancers from benign skin lesions, specificity was 17% at 99% sensitivity and 41% at 95% sensitivity (partial least squares showed specificity of 24% at 99% and 52% at 95%) 2) melanomas from non-melanoma pigmented lesions was 15% at 99% sensitivity and 38% at 95% sensitivity, and 3) melanomas from seborrheic keratoses was 25% at 99% sensitivity and 54% at 95% sensitivity. The study authors concluded that, " Raman spectroscopy can distinguish (1) malignant and premalignant lesions from benign disorders, (2) melanomas from benign pigmented skin lesions, and (3) melanomas from seborrheic keratoses."

The biopsy ratio is a metric which helps gauge the accuracy of melanoma diagnosis - the lower the ratio, the more accurate the diagnosis. Misdiagnosis of skin cancer is rampant, often resulting in unnecessary biopsies. Biopsies can be costly, uncomfortable, and result in scarring. If Aura can improve the accuracy of diagnosis (which we believe it can), there should be substantial commercial demand for the device. Relative to the biopsy ratio, for reference the manuscript cites a retrospective study of ~5,000 pigmented skin lesions evaluated by ~500 general

practitioners which resulted in a biopsy ratio between 58:1 and 21:1 (i.e. - 21 non-melanoma lesions biopsied for every confirmed case of melanoma). Other unrelated studies have indicated biopsy ratios in clinical practice may be even significantly higher than these figures. Although it's not necessarily fair (as there could be significant differences in the make-up of the various studies) to make a direct comparison of the biopsy ratios in the Aura study (which appear comparably very strong) with these other studies, at least on the face of it, the Aura data looks potentially persuasive.

As we noted in our previous updates, the Aura data does look to be very compelling relative to clinical trial data from MELA Sciences Melafind device which showed a sensitivity of 98% and specificity of about 10% in the detection of melanoma. Aura's biopsy ratio appears similarly relatively strong. Also noteworthy is that MELA opted to use a statistical method different than either GDA or partial least squares, both of which are considered conservative. As such, it's possible that Aura's specificities may have been relatively even stronger than Melafind's had the statistical methods used for both devices' studies been the same. Also as we've previously explained, Aura has other advantages to Melafind including a significant speed advantage (allowing for full body scans) and the ability to detect of all types of skin cancer whereas Melafind is used for only melanoma.

Table 3. Summary of Raman spectroscopy diagnostic parameters derived from ROCs according to various levels of sensitivity.

Diagnosis classification task	Sensitivity level (95% CI)	Principal component analysis (GDA[a])				Partial least squares			
		Specificity (95% CI)	PPV [b]	NPV [c]	Biopsy ratio	Specificity (95% CI)	PPV	NPV	Biopsy ratio
Skin cancers + Actinic keratosis *vs* Benign lesions	0.99 (0.98-1.00)	0.17 (0.13-0.21)	0.49	0.95	1.03:1	0.24 (0.19-0.29)	0.51	0.97	0.95:1
	0.95 (0.92-0.99)	0.41 (0.35-0.48)	0.57	0.91	0.77:1	0.52 (0.48-0.58)	0.62	0.93	0.62:1
	0.90 (0.86-0.94)	0.64 (0.58-0.70)	0.67	0.89	0.49:1	0.66 (0.61-0.71)	0.68	0.89	0.47:1
Melanoma *vs* Benign pigmented lesions	0.99 (0.96-1.00)	0.15 (0.11-0.19)	0.15	0.99	5.58:1	0.14 (0.10-0.18)	0.15	0.99	5.65:1
	0.95 (0.89-1.00)	0.38 (0.32-0.44)	0.19	0.98	4.24:1	0.44 (0.38-0.50)	0.21	0.98	3.83:1
	0.90 (0.81-0.99)	0.68 (0.63-0.73)	0.30	0.98	2.31:1	0.63 (0.57-0.69)	0.27	0.98	2.67:1
Melanoma *vs* Seborrheic keratosis	0.99 (0.96-1.00)	0.25 (0.17-0.33)	0.34	0.98	1.96:1	0.46 (0.37-0.55)	0.41	0.99	1.41:1
	0.95 (0.89-1.00)	0.54 (0.45-0.63)	0.44	0.97	1.25:1	0.52 (0.43-0.61)	0.43	0.96	1.31:1
	0.90 (0.81-0.99)	0.68 (0.59-0.77)	0.52	0.95	0.92:1	0.66 (0.57-0.75)	0.51	0.94	0.98:1

[a] GDA: general discriminant analysis.

[b] PPV: positive predictive value, the ratio of true positives to the total of true positives and false positives.

[c] NPV: negative predictive value, the ratio of true negative to the total of true negatives and false negatives.

FINANCIAL STATEMENTS

INCOME STATEMENT (CDN $)

Verisante Technology

	2010 A	2011 A	2012 E	2013 E	2014 E	2015 E
Device sales	$0	$0	$378	$7,403	$20,475	$45,360
% total sales	-	-	*92.9%*	*86.1%*	*78.3%*	*77.4%*
Cap sales	$0	$0	$29	$1,195	$5,673	$13,263
% total sales	-	-	*7.1%*	*13.9%*	*21.7%*	*22.6%*
Revenue	$11	$2	$407	$8,598	$26,148	$58,623
YOY Growth	*-62.5%*	-	-	*2013.5%*	*204.1%*	*124.2%*
Cost of sales	$8	$0	$190	$3,761	$10,521	$23,343
Gross Income	$3	$2	$216	$4,837	$15,627	$35,280
Gross Margin	*26.0%*	-	*53.2%*	*56.3%*	*59.8%*	*60.2%*
SG&A	$1,435	$3,435	$3,839	$6,322	$7,700	$12,265
% SG&A	-	-	*943.8%*	*73.5%*	*29.4%*	*20.9%*
R&D	$215	$7	$0	$0	$0	$0
% R&D	-	-	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Interest expense (income), net	$0.4	($41.0)	($28.2)	$0.0	($5.0)	($50.0)
Operating Income	($1,648)	($3,399)	($3,595)	($1,485)	$7,932	$23,065
Operating Margin	-	-	-	*-17.3%*	*30.3%*	*39.3%*
Total Other Income	$163	($153)	($80)	($516)	($1,569)	($3,517)
Pre-Tax Income	($1,485)	($3,551)	($3,674)	($2,001)	$6,363	$19,548
Taxes (benefit)	$0.0	$0.0	$0.0	($500.3)	$1,717.9	$5,864.3
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*25.0%*	*27.0%*	*30.0%*
Net Income	($1,485)	($3,551)	($3,674)	($1,501)	$4,645	$13,683
Net Margin	-	-	-	*-17.5%*	*17.8%*	*23.3%*
EPS	($0.04)	($0.06)	($0.06)	($0.02)	$0.06	$0.16
YOY Growth	*30.4%*	*54.3%*	*-13.2%*	*-65.0%*	*-390.4%*	*180.7%*
Diluted Shares O/S	35,159	54,651	65,167	76,000	81,000	85,000

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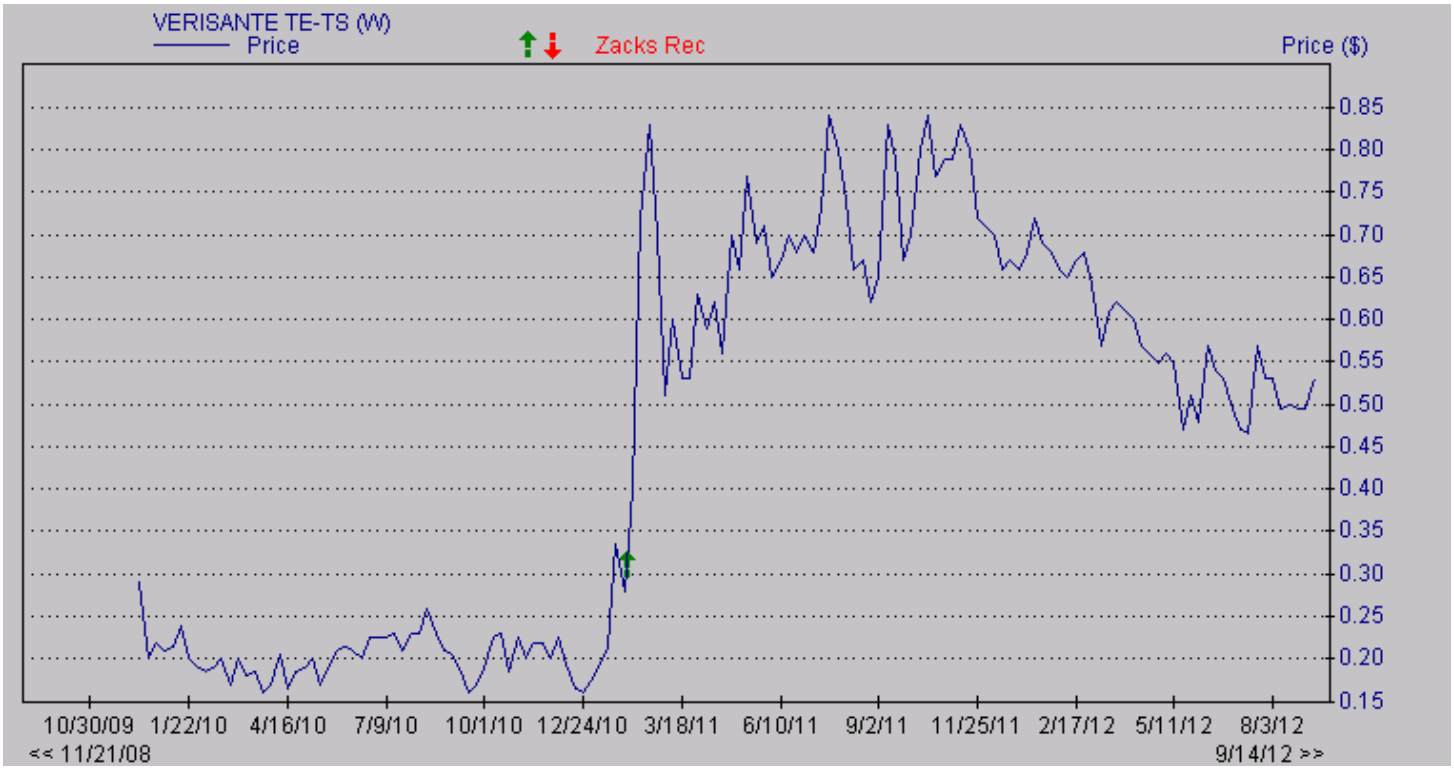

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