Zacks Small-Cap Research

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Verisante Technology Inc. (V.VRS)

V.VRS: Positive 1,000-Lesion Study Results

OUTLOOK

Results of the highly anticipated 1,000-lesion study were presented at SPIE this past weekend. Our take is the data looks very encouraging, especially compared to Melafind's FDA clinical trials. This could bode well for eventual FDA approval of Aura.

Verisante also continues to make meaningful progress on several other fronts including commercialization of Aura in Canada, Europe and Australia, and their initial strategy towards U.S. approval.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	02/04/2011
Current Price (01/23/12)	$0.72
Six- Month Target Price	**$2.60**

SUMMARY DATA

52-Week High	**$1.26**
52-Week Low	**$0.25**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**306,444**
Shares Outstanding (mil)	**60**
Market Capitalization ($mil)	**42.8**
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 2011 Estimate	**N/A**
P/E using 2012 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)
2010	5 A	6 A	0 A	0 E	11 A
2011	0 A	0 A	0 E	0 E	0 E
2012					5,385 E
2013					21,185 E

Earnings per Share

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2010	-$0.01 A	-$0.01 A	-$0.01 A	-$0.01 A	-$0.04 A
2011	-$0.02 A	-$0.01 A	-$0.02 A	-$0.01 E	-$0.06 E
2012					-$0.07 E
2013					$0.04 E

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

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RECENT HIGHLIGHTS

Verisante continues to pump out a regular stream of meaningful news, reflecting progress being made in moving Aura closer towards commercialization and management's efforts in publicizing the virtues of their technology.

The highlight of the highlights was this past weekend's presentation of the 1,000-lesion study data……

1,000-Lesion Study Presentation: The eagerly anticipated statistical analysis of the 1,000-lesion study, Verisante's most pivotal trial to-date, were presented this past weekend at the SPIE (international society for optics and photonics) conference in San Francisco. As a reminder, previously announced preliminary study results on 274 lesions, indicated a sensitivity of 100% and specificity of 70% for Aura in the detection of melanoma.

The study included the measurement of over 1,000 lesions from 848 patients. Dr. Haishan Zeng presented the data at SPIE as an invited keynote speaker. Results showed Aura had a sensitivity of 99% and specificity of 17% in differentiating all major cancers from benign lesions. At 95% sensitivity, specificity in differentiating all major cancers from benign lesions increased to 41%. In differentiating melanoma from benign lesions, the data showed Aura had a sensitivity of 99% with a specificity of 15%. At 95% sensitivity, specificity increased to 38% in differentiating melanoma from benign lesions.

Although the specificity is lower than what the interim data showed, this was not a surprise and there were no realistic expectations that that level of accuracy would carry over to the full data set. In fact the results are comparably 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. The study, which required a sensitivity of at least 95% and included about 1,800 lesions from ~1,400 patients, was the pivotal study Melafind used to support their FDA approval application. FDA approval of Melafind, after long delays, finally came in Q4 2011. Based on the relative strength of Aura's clinical trial data (i.e. - at 95% sensitivity specificity was 41% for all lesions and 38% for melanoma, compared to ~10% for Melafind), this could potentially bode well for eventual FDA approval - although FDA approval may require additional (U.S. based) studies.

Aura also has other advantages relative to Melafind including:

- Aura can be used for the detection of all types of skin cancer, while Melafind is used only for melanoma. While melanoma is by far the most serious and deadly form of skin cancer, it accounts for only about 5% of the disease (basal cell and squamous cell carcinoma account for about 95% of all skin cancer cases). Aura may also have utility in the diagnosis of actinic keratosis, a precancerous skin condition which is estimated to affect about one-half of the global population (i.e. - the target market is enormous)
- Aura's probe is relatively small compared to Melafind's, allowing Aura to scan difficult parts of the body such as around the eyes and ears, where a larger probe can not access
- Aura's scan time is almost instantaneous allowing for full-body scans in minutes whereas MELA's device takes significantly longer (especially when including the patient prep-time). Full body scans are clearly the sweet-spot for skin cancer detection devices as the time-consuming current clinical "ABCD" diagnostic method is not practical for this.
- Verisante's technology is also being developed for derivative applications - including for the detection of lung cancer (and follow-on applications for oral, colon, cervical cancers)

JP Morgan Healthcare Conference: We met up with Thomas Braun at the JP Morgan Healthcare conference in San Francisco about two weeks ago. Although Fair Disclosure rules limit what we could discuss, our take-away feeling is that the status of the major points of interest (product development, regulatory approval progress, integrity of data, commercialization in initial territories, potential demand/pricing for Aura, feedback from conferences/presentations, etc.) is positive.

CE Marking / Australian Approval: November 9, 2011 Verisante announced Aura was CE Marked, allowing the device to be sold throughout the European Union. Australian regulatory approval came in mid-December. This follows on the heels of Health Canada approval which came around mid-October. Aura is now approved for sale in every territory that management had been working towards for the initial (pre-U.S.) roll out of the device. This milestone, in our opinion, is important from not only the obvious standpoint that Aura has regulatory approval in key

skin-cancer markets (detailed in our Appendix), but also from the perspective that management has delivered on a very important goal within their expected timeframe.

Popular Science Award: November 16, 2011 Verisante announced that *Popular Science* magazine awarded Aura a "Best of What's New" award, naming it as a top technology of 2011**.** Editor in Chief of the publication, Mark Jannot, noted that "The Best of What's New Award is the magazine's top honor and the 100 winners, chosen from among thousands of entrants, represent the highest level of achievement in their fields."

FDA Regulatory Process: As we have detailed since initiating on Verisante, FDA approval is expected to be a considerably longer process than was regulatory approval in their initial geographic target markets. Nonetheless, the company is making progress in that direction and in late December announced that they expect to have an initial meeting with the FDA during Q1 2012 to discuss the potential U.S. regulatory approval pathway for Aura. Our initial and current expectations (although we have no particular insight on this) are that approval will need to come via the PMA process and be supported with data from additional clinical testing - this upcoming pre-IDE meeting will hopefully provide guidance on the regulatory pathway as well as what the FDA will be looking for in regards to supporting data/information. Our current (as well as initial) assumptions are that Aura could be on the U.S. market by 2014.

European Distributors: Verisante's late-December operational update press release also noted that the company is in the process of selecting distributors and expects to launch Aura in Canada, Germany, Austria, Switzerland and Australia in the second half of 2012. This is slightly later than our early-2012 prior estimate, although given that we model only minimal sales in 2012 (we have adjusted our near-term revenue estimates) as a whole, the difference at this juncture is relatively immaterial.

1,000-Lesion Data Publication: The article has been submitted for publication and is currently in the peer-review process.

Mexico and Brazil: Verisante has begun the registration process to sell Aura in Mexico and Brazil. The company hopes to obtain registration in Mexico in 2012 and Brazil possibly in late 2013.

High Praise for "Core": The Canadian Cancer Society cited a clinical study using Verisante's laser Raman Spectroscopy in the detection of lung cancer as one of its "Top 10 Canadian Cancer Society Funded Research Stories of 2011" (link here….. http://bit.ly/whcTOI). In the small (26-patient) pilot study Verisante's "Core" cancer (lung, colon, cervical cancers) device candidate was able to detect precancerous lung lesions with a sensitivity of 96% and specificity of 91% when used with existing methods (white light bronchoscopy and autofluorescence bronchoscopy). Results of the study were published in the July 2011 issue of the Journal of Thoracic Oncology. Verisante owns or has rights to all of the technology used in the pilot study including Core's Raman system as well as white light and fluorescence technology. The combination of technologies demonstrated an impressively high level of specificity (low false-positive rate) in the pilot study - which, depending on the success of future larger studies, could be very promising for improving the detection of early-stage lung cancer. However, as we noted when the study results were first announced (in mid-2011), while the results of the study are encouraging, as is Verisante's continued efforts to move their lung cancer detection program forward, we feel it is still too early to reasonably judge the potential for approvability of the device. In addition, management's current major focus is with getting Aura commercialized. As a result, we feel it is appropriate to continue to not incorporate a contribution from Core in our model until there is more information to comfortably judge the probability of regulatory approval and gauge launch timelines. If and when that happens, we will update our model accordingly. This could potentially add significant upside to our current revenue and earnings estimates (especially given the relatively large size of the lung cancer diagnostics market).

Multi-Spectral Imaging License: In July 2011 Verisante entered into a licensing agreement for the global rights to a rapid multi-spectral imaging cancer technology owned by Dr. Haishan Zeng (who is also on Verisante's product development team) and Dr. Yasser Fawzy, both of the British Columbia Cancer Agency. While Verisante's current main focus will be with getting Aura (which uses higher sensitivity/specificity Raman technology) launched, the multi-spectral imaging technology could potentially be used in a lower cost, follow-on device for the detection of skin and oral cancer. The lower cost of a multi-spectral imaging device has the potential to broaden Verisante's potential customer market, especially with dental practices and smaller or rural physician clinics with lower patient throughput. Future derivations could also potentially include a device using both multi-spectral and Raman technologies. Verisante is currently working on a multi-spectral prototype device. If eventually commercialized, the multi-spectral device would compete against a handful of already available products in the oral cancer detection

application (VELscope, Identafi, Vizilite Plus, Microlux, etc.), some of which also use some form of multi-spectral imaging. Despite the competition, there remains a potentially attractive opportunity for Verisante as there is unmet demand for a compact, affordable device than has better accuracy than available products in the early detection of oral cancer. Our model also does not currently incorporate any contribution from a potential multi-spectral device - if and when appropriate, we will update our model accordingly.

Q3 FINANCIALS

Verisante's financial results continue to be very much in-line with our estimates. Results for Q3, ending September 30, 2011, were filed on November 29th. SG&A of CDN $982k was slightly above our $740k estimate as a result of higher stock-based compensation. EPS was CDN ($0.02) on net income of CDN ($988k) versus our CDN ($0.01) and CDN ($710k) estimates. Share count outstanding was 59.5 million, just about dead-on with our 60 million estimate.

The company continues to manage their cash very efficiently. Rates of cash burn have been impressively moderate especially given the progress management has made in hitting development milestones and marketing via attending/ presenting at industry conferences throughout the world. Cash used in operations was a fairly meager CDN $297k in the quarter and just under CDN $800k over the past nine months. Investing activities used CDN $657k and CDN $1,080k over the same periods, mostly reflecting the acquisition of licenses/technology and development costs related to Aura which are being capitalized. Cash balance, including liquid investments, was CDN $6.1 million at the end of Q3, compared to CDN $4.9 million at Q2 quarter-end. The net CDN $1.2 million jump in cash was a result of CDN $2.1 million in proceeds from the exercise of 5.4 million warrants (less the aforementioned CDN $954k used in operating and investing activities).

FINANCIAL MODEL

We continue to value Verisante at $2.60 share……As we have noted in previous updates, our model assumes a selling price for Aura of CDN ~ $45k. This is somewhat conservative compared to management's current expectations - based on their study of the market including in-depth discussions with professionals knowledgeable of the space, Verisante believes a selling price of at least CDN $60k is very attainable. This could potentially provide significant upside to our current financial model, which would in-turn drive valuation higher. As it is now, our long-term revenue estimates and valuation remain unchanged since our previous update.

APPENDIX

A.) Aura's Geographic Target Markets

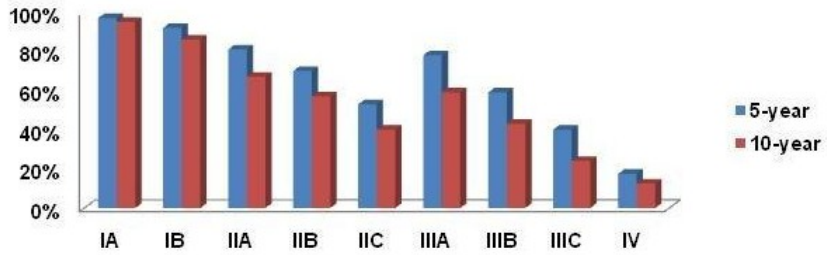
B.) Serious Issue Related to Shortage of Dermatologists as Detailed in *Men's Health* Article

A.) AURA'S GEOGRAPHIC TARGET MARKETS

Skin Cancer
Basal cell carcinoma (BCC), squamous cell carcinoma (SCC), and melanoma encompass the vast majority of skin cancer cases. BCC accounts for about 80% of skin cancer diagnoses. BCC develops in the lowest layer of the skin, tends to grow slowly and only rarely spreads to other parts of the body. SCC accounts for about 16% of skin cancer cases. SCC develops in the upper layer of the skin and tends to afflict fair-skinned people and the elderly with long-term sun exposure. SCC can metastatize (spread) if left undiagnosed and untreated. Melanoma is the most deadly form of skin cancer and accounts for about 4% of all skin cancer cases. It develops in the pigment cells within the skin. Melanoma can be lethal, especially if it penetrates the lowest skin layer and enters the lymph system. While Verisante's Aura is expected to be useful in the diagnosis of all skin cancer types, melanoma screening is where we believe the majority of the opportunity for the device is.

While statistics show that five-year survivability in the U.S. is as high as 97% if melanoma is diagnosed and treated at its earliest stage (i.e. - IA), this drops precipitously as the disease progresses. Worldwide there are approximately 200k new cases of melanoma diagnosed every year and about 50k deaths from the disease. And despite the relatively low incidence of melanoma compared to non-melanoma skin cancers, due to its lethality (causes 75% of skin cancer deaths) and progressive nature, screening for it commands a disproportionate amount of time, money and resources. We believe this provides a significant opportunity for Verisante to exploit the antiquated nature of current screening techniques and at the same time, improve patient outcomes and reduce overall costs associated with melanoma diagnosis.

U.S. Melanoma Survivability by Disease Stage



Source: American Cancer Society

Skin Cancer in Canada Statistics
- Most common of all cancers in Canada
  - 1 in 7 Canadians will develop some form of skin cancer in their lifetime
  - Skin cancer represents 1/3 of all new cancer cases in Canada
- Non-melanoma (BCC and SCC): ~75k people diagnosed each year, ~300 people die each year
- Melanoma: ~5k people diagnosed each year, ~1k people die each year

Skin Cancer in UK Statistics
- Non-melanoma: ~85k – 100k new cases each year, ~1k deaths each year
- Melanoma: ~11k new cases each year, ~3k deaths each year
  - ~85% 5-year survivability
  - Incidence of malignant melanoma has more than quadrupled over the last 30 years
  - Malignant melanoma rates have increased more than any other cancer over last 25 years
  - At current run-rate, in 15 years UK will have ~16k new cases of malignant melanoma per year

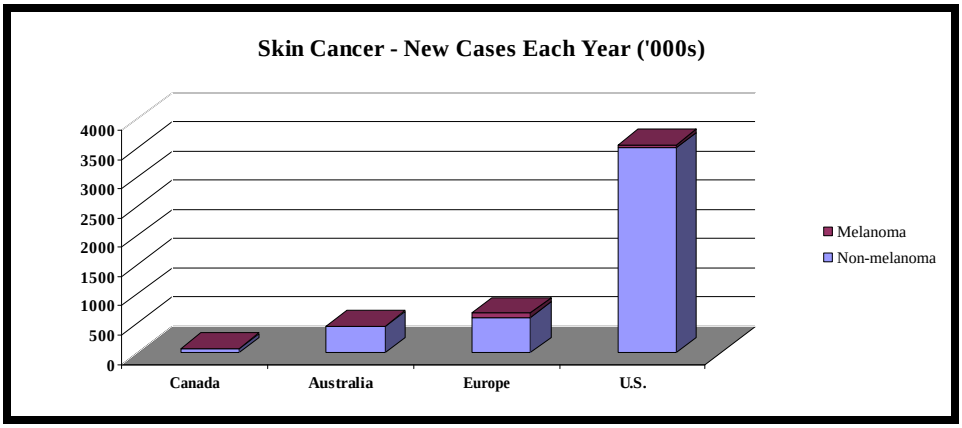
Skin Cancer in Australia Statistics

- Australia has the highest rate of melanoma of all countries
  - Skin cancer accounts for 80% of all newly diagnosed cancers
  - 2 of 3 Australians will be diagnosed with skin cancer in their lifetime
- Non-melanoma: ~450k new cases each year, ~400 deaths each year
- Melanoma: ~10k new cases each year, ~2k deaths each year
- General physicians in Australia have over 1 million patient consultations for skin cancer each year

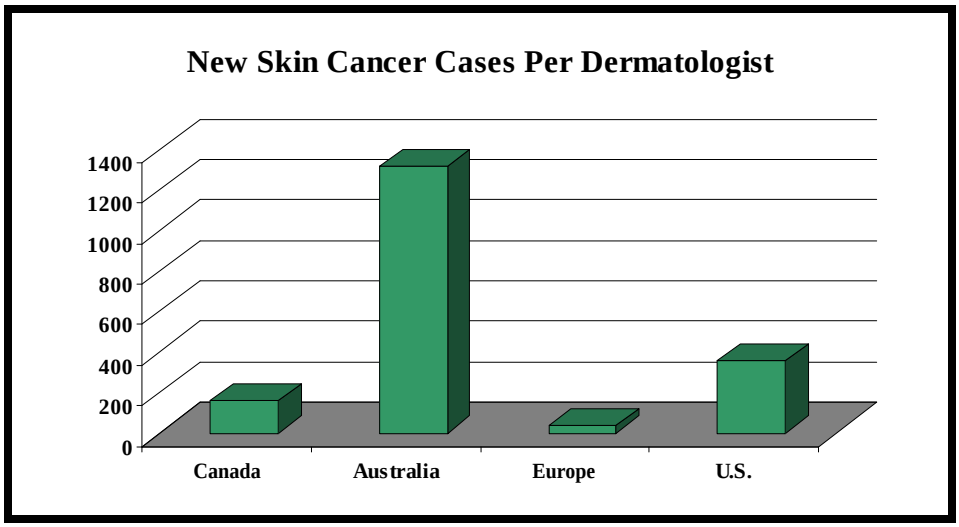
Skin Cancer in U.S. Statistics

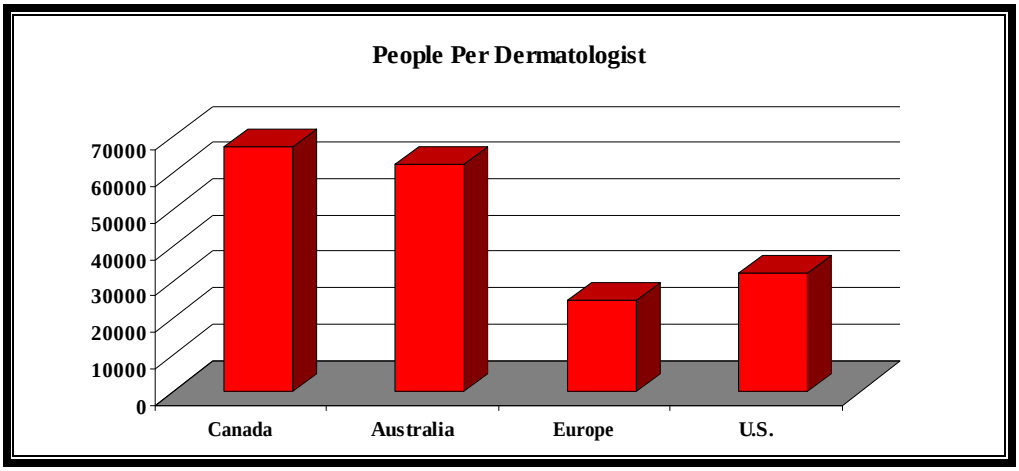
- Skin cancer accounts for about ½ of all cancers in the U.S.
- 1 in 5 Americans will be diagnosed with skin cancer in their lifetime
- Non-melanoma: ~1+ million new cases diagnosed each year, ~3k deaths each year
- Melanoma: ~60k new cases diagnosed each year, ~9k deaths each year
  - Melanoma accounts for about 3% of skin cancer but causes 75% of skin cancer deaths
  - Five-year survivability is ~97% if diagnosed early, this drops to ~15% for late-stage melanoma

Large size of the U.S. and European populations and high incidence of skin cancer could be a boon for Verisante.



With relatively few dermatologists and high incidence of skin cancer, Australia and Canada represent very attractive markets for skin cancer diagnosis. A small number of dermatologists can mean long lead times for patients seeking appointments and melanoma gets more lethal over time. the dearth of dermatologists in Australia has resulted in GPs commonly staffing skin cancer clinics. GPs are less experienced than dermatologists at spotting skin cancer which increases the risk of misdiagnosis.





B.) SERIOUS ISSUE RELATED TO SHORTAGE OF DERMATOLOGISTS AS DETAILED IN *Men's Health* ARTICLE

(From Zacks' July 2011 Blog on Verisante): There was an interesting article in the April 27, 2011 edition of Men's Health magazine which highlighted not only the skin cancer epidemic in the U.S. but also the seriousness of the shortage of dermatologists. For those that do not understand how (life-threateningly) serious the problem is, the article, which documents how two skin cancer victims had to endure month-long waits (as the cancers spread) to see a dermatologist, is an excellent wake-up call (link here: http://www.menshealth.com/health/skin-cancer-appointments).

The problem is two-fold. The first is that the incidence of skin cancer (including melanoma) continues grow very rapidly. In the article Brett Coldorin, M.D., characterizes the growth in U.S. skin cancer cases as "an epidemic." Skin cancer accounts for about one-half of all cancers in the U.S. and roughly 1 in 5 Americans will be diagnosed with skin cancer in their lifetime. Melanoma, while accounting for only about 3% of skin cancer, causes 75% of skin cancer deaths.

The second problem, which likely is largely unrealized by the general public, is that there are not nearly enough dermatologists to handle the skin cancer epidemic. It's estimated there are about 10k dermatologists in the U.S. (and many of these - as much as one-third, only focus on cosmetic procedures and do not screen for skin cancer) with only a slow trickle coming out of medical school each year. This has caused a backlog of patients waiting to see a dermatologist - and the wait can be many, many (as in 6 to 18) months. The problem is especially pronounced in rural areas.

One way dermatologists have been trying to reduce patient wait time and increase throughput is by having a physician assistant see patients. The current "gold-standard" for skin cancer screening ("ABCD" method) is subjective and highly prone to error, especially for less experienced physicians - this poses an especially significant potential problem when non-MD's are the ones doing the screening. Dr. Coldiron notes, "They are not as well trained. They could miss something." The article cites a study that found 23% of dermatologists contacted used an "extender" (i.e. - assistant) to look for skin cancer.

Verisante Technology is specifically addressing the issues of rampant skin cancer growth and too few professionals to handle the epidemic. Their Aura skin cancer detection device has shown in preliminary data to be more accurate than "ABCD", even when "ABCD" is performed by a dermatologist. The device, which provides yes-no diagnosis (i.e. - non-subjective), has the ability to revolutionize skin cancer diagnosis and, even in the hands of "extenders", would allow for more reliable screening than the current gold-standard.

With no end in sight to the dearth of dermatologists and continued escalation in the number of skin cancer cases, more and more general physicians (i.e. - non-dermatologists) will need to be able to accurately diagnose skin

cancer - and Aura could be the way to do it. With high-throughput scanning (under 1 second per lesion), Aura also affords accurate full-body scans in just minutes, an impossibility with "ABCD".

FINANCIAL STATEMENTS

INCOME STATEMENT (CDN $)

Verisante Technology

	2010 A	Q1A	Q2A	Q3A	Q4E	2011 E	2012 E	2013 E	2014 E
Device sales	$0	$0	$0	$0	$0	$0	$1,890	$14,175	$36,855
% total sales	-	-	-	-	-	-	*90.8%*	*82.6%*	*77.6%*
Cap sales	$0	$0	$0	$0	$0	$0	$192	$2,976	$10,632
% total sales	-	-	-	-	-	-	*9.2%*	*17.4%*	*22.4%*
Revenue	$11	$0	$0	$0	$0	$0	$2,082	$17,151	$47,487
YOY Growth	*-62.5%*	*-100.0%*	*-100.0%*	*#DIV/0!*	*#DIV/0!*	-	-	*723.8%*	*176.9%*
Device COGS	$0	$0	$0	$0	$0	$0	$945	$7,088	$18,428
Cap COGS	$0	$0	$0	$0	$0	$0	$10	$149	$532
Cost of sales	$8	$0	$0	$0	$0	$0	$955	$7,236	$18,959
Gross Income	$3	$0	$0	$0	$0	$0	$1,127	$9,915	$28,528
Gross Margin	*26.0%*	-	-	-	-	-	*54.1%*	*57.8%*	*60.1%*
SG&A	$1,435	$639	$753	$982	$850	$3,224	$3,222	$3,718	$4,012
% SG&A	-	-	-	-	-	-	*154.8%*	*21.7%*	*8.4%*
R&D	$215	$7	$0	$0	$0	$7	$2,720	$1,055	$1,010
% R&D	-	-	*4.9%*	*4.7%*	*5.1%*	-	*130.6%*	*6.2%*	*2.1%*
Interest expense (income), net	$0.4	$0.0	($13.5)	($14.8)	$0.0	($28.3)	$0.0	$0.0	$0.0
Operating Income	($1,648)	($646)	($739)	($968)	($850)	($3,231)	($4,815)	$5,142	$23,506
Operating Margin	-	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	-	-	*30.0%*	*49.5%*
Total Other Income	$163	($93)	($20)	($20)	($25)	($158)	($25)	($979)	($2,799)
Pre-Tax Income	($1,485)	($739)	($759)	($988)	($875)	($3,389)	($4,840)	$4,163	$20,707
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,040.7	$5,590.8
Tax Rate	*0.0%*	*0.0%*	*40.0%*	*40.0%*	*40.0%*	*0.0%*	*0.0%*	*25.0%*	*27.0%*
Net Income	($1,485)	($739)	($759)	($988)	($875)	($3,389)	($4,840)	$3,122	$15,116
Net Margin	-	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	-	-	*18.2%*	*31.8%*
EPS	($0.04)	($0.02)	($0.01)	($0.02)	($0.01)	($0.06)	($0.07)	$0.04	$0.19
YOY Growth	*30.4%*	*78.8%*	-	-	-	*44.6%*	*10.4%*	*-161.1%*	*354.3%*
Diluted Shares O/S	35,159	43,109	56,897	59,508	63,200	55,678	72,000	76,000	81,000

Source: Zacks Investment Research *Brian Marckx, CFA*

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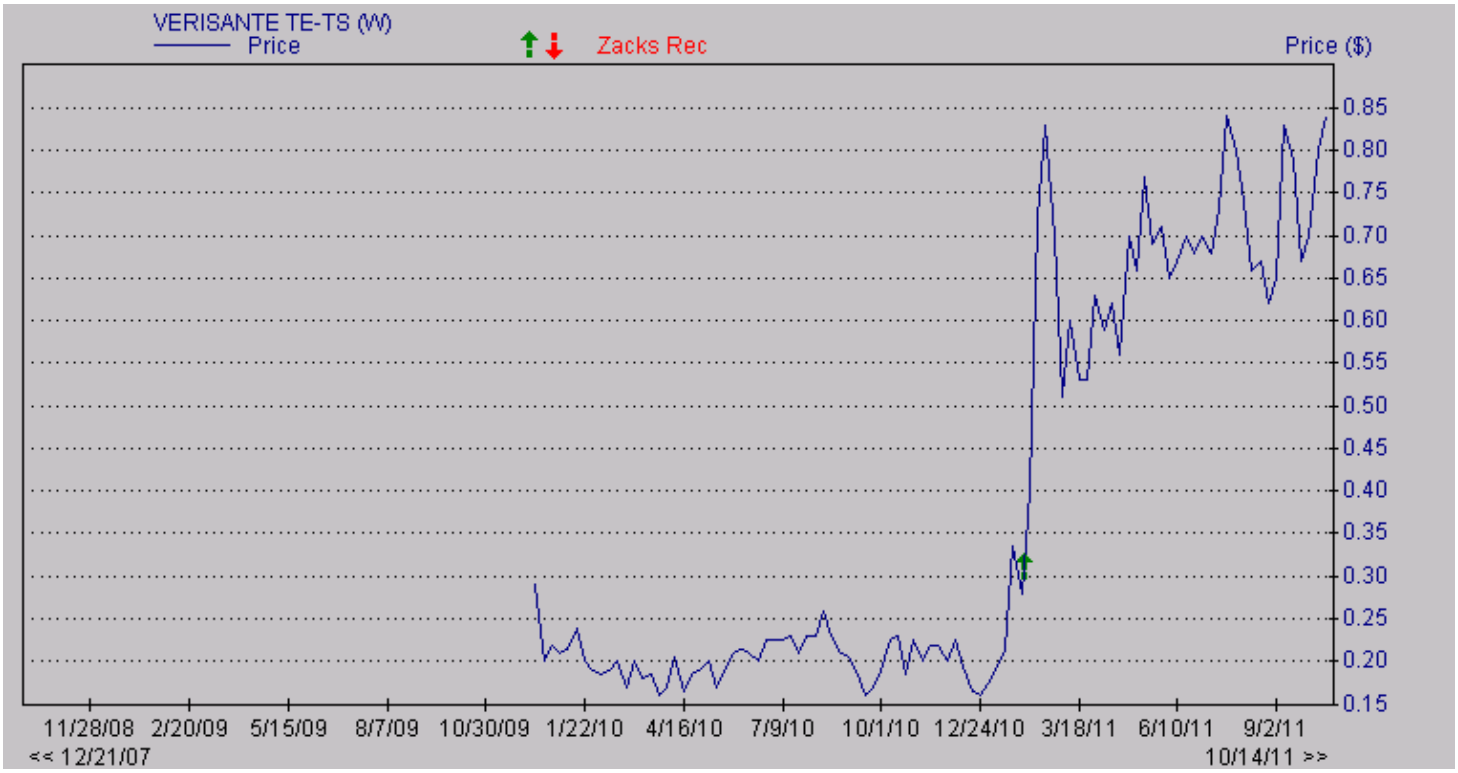

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