Transcript of initial interview with Mr. Thomas Braun

President and CEO of Verisante Technology Inc.

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Mr. Thomas Braun - President and CEO of Verisante Technology Inc. Prior to founding the company, Thomas Braun practiced corporate securities law at Braun and Co., specializing in representing small high tech public companies. Mr. Braun is experienced in the management of public companies and has conducted dozens of mergers and acquisitions and going public transactions.

Mr. Braun earned a BA degree from the University of Western Ontario, a Juris Doctor (JD) degree from the University of British Columbia, and a Master of Laws (LLM) degree from the University of San Francisco specializing in International Business Transactions. He is a member of the State Bar of California, and the American Bar Association; and is also a member of the Law Society of British Columbia and the Canadian Bar Association. He is also admitted to practice before the Federal Court for the Northern District of California and the Ninth Circuit Court Appeals.

Smallcaps.us: Hi everyone and welcome to a new Smallcaps.us interview. Today we're speaking with Thomas Braun, the President and CEO of Verisante Technology Inc.

Verisante has developed some promising solutions in the field of cancer detection, and has been turning plenty of heads with positive results from clinical studies and several regulatory approvals.

Verisante is listed on the TSX Venture Exchange with ticker symbol VRS. Mr. Braun, thanks so much for taking the time to speak with us today.

Thomas Braun: No problem.

Smallcaps.us: As this is our first look at Verisante Technology, could you give us a brief overview of the Company and its core activities?

Thomas Braun: Sure. Verisante is a medical device company and we're in the process of commercializing a revolutionary device for the detection of skin cancer that was developed over 10 years by the British Colombia Cancer Agency and tested in a six-year clinical trial at Vancouver General Hospital. And the whole technology platform is also extensible to lung cancer, the whole gastrointestinal tract and cervical cancer.

So the skin cancer study is done, we're in the process of commercializing the device which we call the Aura for skin cancer. The Aura is approved in Canada, Europe and Australia.

And then we have another version for those internal cancers called the Core. And the pilot study for lung cancer was released in July. So that's still in clinical trial.

Smallcaps.us: Thanks. It seems that the Aura device for detecting various types of skin cancer is Verisante's star product for the moment, especially with the recent release of study data collected from tests on 1,000 skin lesions. Can you describe that study for us and how it was conducted?

Thomas Braun: Yes. Well, you're right that the Aura is the number one priority for us right now. Skin cancer is the most common cancer of all. There's more skin cancer than all the other cancers put together, so it's a huge market. Not a lot of people pay attention to it because when they look at cancer they tend to look at mortality rate and how many people die from it. The very thing about skin cancer is that normally you don't die from it, but it still has to be treated. If it's left untreated, some of them can kill you and others can become disfiguring.

As far as the study data goes, what we found was that the device can have 99 percent sensitivity. So basically there are two outputs that the device has. One is to ask whether or not the patient has any kind of a the major skin cancers. So we're looking at actinic keratosis, which is a precancerous lesion, basal cell carcinoma, which is the most common skin cancer, squamous cell carcinoma and of course melanoma. So we ask that question, we have 99 percent sensitivity on the answer to that question.

The other question that we ask simultaneously, and which is in the output of the machine, is that if it's a pigmented lesion, is it malignant melanoma or not. And we also have 99 percent sensitivity there. And what we're doing here is catching a great number of cancers that would otherwise go mist.

An Australian study on 8,600 patients who went to walk-in skin cancer clinic showed that per melanoma, they had 33.8 percent sensitivity. That was a study published in the British Journal of Dermatology. So we're going from 33.8 percent sensitivity in a real world walk-in skin cancer clinic in Australia to 99 percent sensitivity. And as far as the biopsy ratio goes, this Australian study estimated that if all atypical pigmented lesions were to be biopsied to rule out melanoma, the biopsy ratio would be as high as 200 to 1. Using the Aura, the biopsy ratio for cancer versus the nine lesions is 1.03 biopsies for each cancerous lesion found. And those results can be found described in greater detail in a press release that we put out on January 23rd, 2011 which is available on our website.

Because this is such a game-changing technology, I'll reference some of the awards that we've been getting. The most important one is that the editors of Popular Science named the Aura one of the most innovative medical devices that came out in 2011 and we received a "Best of What's New" award in November of last year. In other words, this has been recognized as a game-changing technology.

Smallcaps.us: Great. Is it correct that based on this study you received regulatory approval for the Aura in Canada, the European Union, and Australia?

Thomas Braun: That's right. This was the clinical study that was used to receive those regulatory approvals. And the results showed that it was safe and effective. And an important thing to remember is that in the European Union and Canada there are some similarities. For example, both require that you have ISO 13485:2003 certification and so we're ISO certified as the medical device developer and manufacturer.

In Europe, they require that you demonstrate the product is safe as well. And in Canada, there's an additional requirement that you show that it's also effective. So Canada is a little bit more like the United States in that we require that you show a product is safe and effective.

So the analysis that Health Canada did of our statistical result from the clinical study concluded that it was safe and effective and they approved the device to assist doctors in detecting skin cancer. And what's important is that they also approved it for use by all medical professionals. And so it's not just for dermatologists and it's not just for doctors. This is important, because in Canada there's a shortage of dermatologists and there's also a shortage of doctors.

So to address this shortage, which is going to get worse as the population ages, what we need are these new technologies that don't just save money and save lives but they can be used by non-doctors like nurse practitioners or medical imaging technologists who can then do the initial scanning and triage patients for the dermatology clinic.

Smallcaps.us: I see. And how big would you say are the markets for the Aura in each of the regions where you received regulatory approval?

Thomas Braun: Well, the market is pretty huge. There's different ways of looking at it. On the one side, you can look at how patients there are potentially. Skin cancer can happen to anybody. Typically it happens to very light-skinned people who may be blonde or redhead, those are the people who are most at risk. But it's important to remember that it can happen to anybody. Bob Marley, for example, died of melanoma. So to be safe, really everybody should get screened.

In Europe, you've got approximately 350 million people so that's a huge market. If you break it down by country, in Germany, you have a

population of 80 million people. They have 20 percent more skin cancer than the rest of Europe. In fact, they are the only country that has public reimbursement for skin cancer screening. So their Krankenkasse (German health insurance service) will actually pay 150 euros to doctors for skin cancer screening. So you've got reimbursements and you've got 80 million people. That's one way of looking at those markets. In Canada, we've got 35 million people, in Australia now 22 million people. Australia is the skin cancer capital of the world. In Queensland, Australia, which is their sunshine state, something like 70 percent of the population gets skin cancer in their lifetime. And in Canada, if you're born today you have a lifetime risk of 1 in 6 will get skin cancer. So huge populations of people, all of whom should be screened to make sure that they don't have it, particularly the high risk people. But I can tell you in the United States, the American Cancer Society says everybody should get screened because it can happen to anyone.

Now, the other way of looking at the market is to say how many dermatologists are there. Because right now, dermatologists are the only people who have the training to do a clinical diagnosis of skin cancer. It's not really covered in medical schools, most general practitioners don't really know much about it. So right now it's a market that's pretty much owned by the dermatologists. And in Europe, there are approximately 21,000 dermatologists, in Canada there are 500, in Australia there's about 300. In Germany alone, which is the main market in Europe for us to start with, there are 5,500 dermatologists.

So it's a huge market no matter how you look at it. If you look at it by the number of patients who need to be screened it's huge, if you look at it by the number of doctors and dermatologists it's huge.

We then, after marketing it to the dermatologists first, plan on also marketing it to general practitioners, hospitals, cancer agencies and medical imaging laboratories. In the United States, the market is very big. In the U.S. there are 10,000 dermatologists. You have a population of about 330 million people. Every year they diagnose 2 million people with skin cancer in the United States. We're not approved in the U.S. yet, but we're looking forward to that in the future. So those are going to be our main markets, Canada, Australia, Europe and the United States.

I can add to that that the Health Canada approval gets it into Mexico, without having to do any further studies. They accept the Health Canada approval, so we just have to do a registration. And Mexico has about 80 million I believe and they have a growing middle-class with more and more disposable income. And Brazil also accepts the Health Canada approval and you have to go through a registration process there. Brazil has something like 190 million people now and they have a tremendous amount of skin cancer. So those are also markets that we'll be looking at in the future.

Smallcaps.us: Okay. Now you just mentioned the United States. From what I understand, Verisante has also taken steps towards obtaining FDA approval. Is there anything you can share with us about that?

Thomas Braun: Sure. What the FDA likes to see in the normal course of business is that if you are a non-U.S. company, you first get approval in your own country and the CE Mark and then you apply to the FDA.

So in our case, we got Health Canada approval in October, we got a CE Mark in November, we did the Australian registration in December and then we began the process immediately thereafter of putting together the required information that the FDA needs in order to give us guidance and make some initial determination.

We've hired a very good regulatory consultant that is based in Austin, Texas, called the Emergo Group and they have been working on the putting together a large technical file of information that's required by the FDA. We will be submitting that very soon and then the FDA requires some time to read through that material and digest it.

Then you have what's called the pre-IDE meeting. IDE stands for Investigational Device Exemption where we plan on having a determination made by the FDA that we are a non significant risk device and that we can either go right into filing our PMA, which stands for Premarket Approval application, or they may say to us that they want us to do a clinical study in the United States first before we file a PMA. Those are the different outcomes, and we'll have that formal guidance from them in about three months from now I assume.

And as far as having to do a study, which is the worst case scenario for us, it's not that bad because the estimate of the cost is about $1,000 per patient. The way these studies are done, is that before a patient, who's going to be biopsied anyway, gets scanned with our device, which takes one second to produce the result, and then subsequently they're biopsied. Then the result of our scan is compared to the pathology report, which is the current gold standard. So if we had to do say 1,000 patients, we're estimating the cost could be in the neighbourhood of $1 million, maybe $1.5 million. And if we did the study at a handful of different sites that have a high flow through of patients, we could potentially collect sufficient data in a matter of a few months.

Smallcaps.us: Given the large market potential in the areas where the Aura already has been approved, is it true that, at this point, FDA approval would be more of a bonus than a true necessity for Verisante?

Thomas Braun: The reality is that the world medical device market is divided between the United States and the rest of the world roughly, because the United States consumes approximately 40 or 50 percent of all the world's medical devices. We're already approved in these other countries, so we've got half of the world taken care of and the reality is the United States is the other half.

So it's our intention to pursue FDA approval and to try and get it as soon as possible. I think it's good that we have our Canadian and Australian approvals first because that way Canada will become some sort of a test market for the United States if we can show that patients are coming out to get skin cancer scans, that they're willing to pay for it, that governments are willing to reimburse for it.

By the time we get the U.S. approval, we'll have a lot of evidence as far as marketing studies go. That way, when we get U.S. approval, we'll hit the ground running. We're not just starting from a complete stop. We'll already be manufacturing, we'll have distributors, we'll have figured out any potential problems that we have before we hit the U.S. market. So that even if, let's say that FDA approval takes two years, in that two-year time we'll have enough marketing data to show potential American customers that the whole system works and that they can make money off of this machine so that it will result in immediate orders.

So I wouldn't downplay getting FDA approval, we are pursuing that vigorously. And between now and then, we're going to spend the next two years, proving that this device works and that the business of skin cancer detection is very worthwhile and that purchasers of our device can make money off of it.

Smallcaps.us: It's also important to take a look at your primary competitor, which is MELA Sciences, the developer of the Melafind. How does this product compare with the Aura?

Thomas Braun: Well, I think our product compares quite favourably, because Melafind is only approved for melanoma and the way their technology works it could only ever work for melanoma. So they have no hope of ever expanding their label to include other cancers. While our device covers all of the major cancers. Melanoma is only 4 percent of skin cancers. We do that as well but we also do other 96 percent. So just based on the number of skin cancers, our market is 25 times bigger. So that's the first major distinguishing factor.

The second one is that their label says that the Melafind can only be used by board certified dermatologists. Our label says that it can be

used by any medical professional. So that means that even if you are selling to a dermatology clinic, the dermatologist can have physician's assistant do the screening and then he just goes in to do the biopsy and the treatment. In the stand alone imaging laboratories, the imaging is all done by licensed technologists, like medical radiological technologists. And in the United Kingdom, for example, the government announces they're switching to a system of nurse practitioners where the frontline healthcare people will be nurse practitioners. In Canada, the frontline are general practitioners (GPs). My understanding is that about 65 percent of biopsies are being done by GPs in any event. So if you cut out all those other people, you've made your market very, very small compared to what it could be.

So the major distinction is that we do all major skin cancers, they only do melanoma. We can be used by any medical professionals, while they can be only used by board-certified dermatologists.

The other thing is that their device takes two minutes for one lesion, our device takes under one second. So if you've got an at-risk patient who has a hundred moles on their body, with our device you can do the person's whole body in 15 minutes. With their device, you can't.

Then as far as cost goes, they are charging $50 per patient. So the doctor has to pay Mela Sciences $50 every time he images a mole. So if he images one mole, he has to pay them $50, which cost he passes along to the patient. With ours, we have a disposal tip which gives us recurring revenues and we're looking at charging may be $10 for the tip and one tip is given out for the whole patient. So in 15 minutes the patient has to pay $10 for a disposal tip and we can do their entire body. While with the Melafind, you pay $50 per mole and you have to wait two minutes for each one. So these are huge differences.

And then finally the last major difference is that our biopsy ratio is much better. I believe the Melafind's biopsy ratio is about 7.6 biopsies for every true melanoma, ours is 1.03 for every true melanoma. So our results from our statistical analysis of the clinical study are much better than their statistical results.

Smallcaps.us: And can you give us an idea of how, and at what price, the Aura will be sold in those regions where it already has been approved?

Thomas Braun: Right now, we have only announced one distributorship which is for Canada, which is our country of origin. We've said before that we're looking at a price of about $60,000 over a period of five years. If you amortize that over 60 months, that comes out to $1,000 a month. So usually medical devices such as these are leased and you have to have a business case that the purchaser can make more money than the lease costs him. So that's one of the ways we determine the purchase price and that we think it's very reasonable for it to be $1,000 a month.

In Germany, for example, where we are approved and where they have reimbursement of 150 euros. Your first four or five patients would pay for that month's lease. And then everybody else you do is 'gravy'. In Germany, a busy skin cancer specialist can see 25 patients a day or more. So basically he would pay for the device before he has his first coffee break on the first day of the month, and the rest of the month is gravy. And then for us, we get the recurring revenue from the tip, the disposal tips which are $10 each.

Now we haven't set a price exactly for Europe yet and we have not announced the distributor for Europe or for Australia. It could be that the device will cost more in those jurisdictions simply because we pay higher costs ourselves for the warranty coverage. The other thing is that you've got higher costs with transportation, potentially having to translate things and for other reasons.

Next to device itself and the disposable tips, there's a third revenue stream which is that after the one year warranty runs out, during which we fix anything for free, the lease company requires them to go onto a service plan. And the industry

standard for such a service plan is 10 percent of the capitalized cost of the equipment. So we'll be charging approximately $6,000 a year for the service plan.

With some companies, for example the aesthetic laser company Syneron, which is public, gets almost half of their revenue from service contracts. So that really adds up. Our projections show that within the first few years when we have enough machines in place, the recurring revenue from the disposable tips starts to overtake the revenue from the sale of the machines. When you add to that the service contracts, we'll probably get one-third of our revenue from the sale of the machines, one-third from the tips and again one-third from the service contracts.

Smallcaps.us: Okay, that's good to know. In terms of manufacturing capacity, what has Verisante done to ensure it will be able to meet demand?

Thomas Braun: Well, we are teamed up with an OEM which is a very good one, probably the best in Canada or one of the best. They have a very good size facility and a large staff. They estimate that they could manufacture approximately 40 units per month. Once we surpass that, they will then assist us to transition to a larger OEM. Typically, the larger OEMs want a larger contract. And so when you have a new product and you don't know exactly how many you are going to sell and you're still in the stage of ramping up, you have to start with a small one.

But there are many such companies around the world. I would think that if two years from now we have FDA approval we will probably also have an OEM in the United States that does all of our manufacturing, at least for the United States if not the whole world, and also takes care of the servicing and the distribution.

Smallcaps.us: And what are the upcoming milestones for the Aura?

Thomas Braun: Well, the major milestones for the Aura are going to be signing up distribution agreements for Australia and for Germany and other countries. We're also looking forward to the publication of the article drafted by the principal investigator at the University of British Colombia that covers our clinical study. That article is certainly something people are looking for because although we did release the bottom line results on January 23rd, 2012 in a press release, some investors want more detail.

We will also be going into manufacturing. We're just in the process of putting together the first 10 data units, which will be field tested and safety tested. Then in the second half of the year, we're going to be going into full production and actually delivering units that are being sold.

So those are the major milestones for this year. And then of course, something we already mentioned which is the pre-IDE meeting with the FDA where we'll get formal guidance from the FDA on what we need to do. Then we'll have a clear regulatory pathway for the United States.

Smallcaps.us: Let's take a look at the other Verisante product, the Core. A pilot study was recently conducted to test this device for early lung cancer detection. Can you describe this study for us and its results?

Thomas Braun: Sure. The Core uses what is mostly the exact same device, the guts of the device are the same, it's also based on Raman, near infrared Raman spirometry. But the difference is the probe. The probe is a fiber optic probe, which sits down the biopsy channel of a bronchoscope or any endoscope. So there's a 2.2 mm channel in a bronchoscope. The bronchoscope is put down your airway, down your throat into your lungs and the doctor uses the bronchoscope for field viewing. They're using something called autofluorescence that helps occult lesions stand out. When they see that lesion, they can then go up to it with our rapid Raman system and take a point measurement that will tell them whether or not it's malignant or benign tissue.

The pilot study result showed 96 percent sensitivity and 91 percent specificity. This is a

massive increase from just using autofluorescence by itself which had specificity of about 60 percent.

So we have a massive reduction in false positives and that's really important because with skin cancer, false positives are not so important. What you really want to do is make sure you don't miss the melanoma. But with the lungs, you don't want to be doing unnecessary biopsies because it can lead to infections. The biopsies on your skin can be stitched up with suture, you get one or two stitches and then you can put some Polysporin on it, some kind of antibiotic cream and a Band-Aid and it's easy to monitor if it gets infected or not. With something that's in your lungs, there's no way to stitch it up or to put a Band-Aid on it or Polysporin. And if you get a lung infection as a result, you can end up in the hospital and in rare cases you can die from it. So doctors really don't want to be doing unnecessary biopsies in the lungs. The Core will help eliminate that and speed up the whole process of lung cancer detection.

Smallcaps.us: How would you discribe the Core's market potential?

Thomas Braun: The market potential is pretty good. Lung cancer is the biggest cancer killer. Worldwide there's an estimated 1.4 million deaths per year from lung cancer. And people who are at high risk are people who have been chain smoking their whole life. And we know that there's lots of those people, millions and millions and millions of them. Each one of them should probably be having a bronchoscopy.

We also think that this will be a very big market in places where they have less skin cancer but they have plenty of lung cancer like in China, for example. In China, you have 1,000 tier 1 hospitals that are not price sensitive, they just want to have the best in the world and they don't even want to buy things that are made in China, they want western-made equipment. The Chinese government just announced that they're spending an additional $136 billion building more hospitals in China. I heard from the Vice President of Eli Lilly at a China biotech form I went to that cancer rates in China have been increasing with about 43 percent a year for the last five years. Because of industrialization, increased smoking, adopting the western diet, their cancer rates are skyrocketing.

So we think that not only can we sell this to all of the medical major centers in Canada, the United States, Europe but it'll let you be very popular in Asia. In the United States, there's around 4,000 hospitals. But because not all of them do bronchoscopy, we would have over a thousand hospitals in the United States and probably a similar number in Europe that are potential customers.

So the Core's market is pretty broad. We're also looking at making that fiber optic probe a disposable, so we would also have recurring revenues. And we would also have the service contracts or other servicing income.

Smallcaps.us: And what do you see down the road for the Core in the short to medium term?

Thomas Braun: The clinical study that's currently underway at the Lung Tumour Center at Vancouver General Hospital is scheduled to be completed around this coming summertime. And then they will do statistical analysis of the result and there will be a publication.

Once we have the statistical analysis of those results, we can then follow the exact same regulatory pathway that we've followed for the Aura. So we can then get approval in Canada from Health Canada, the CE Mark in Europe and Australian registration.

And I don't think that it will take very long either because, similar to the Aura, this is a device which is just helping doctors see things better. It is not a therapy, it is not a drug. These kind of things typically don't take that long to get these approvals.

We'll already be in manufacturing then for the Aura. The industrial engineering that we had to do in order to bring the costs down so that we have a good profit margin has already been

done. The ISO certification has already been done. So I think that the time to market for the Core will be very quick.

Smallcaps.us: Okay. Well, that's good to know. Now, before we close out, would you tell us a little bit about Verisante's management team?

Thomas Braun: Sure. I'm the CEO of the company and my background is as a securities lawyer. For those who don't know what a securities lawyer is, he is basically a stock market lawyer. So I represented small high tech companies that we're going public on the stock market and raising money. I owned my own law firm for 10 years before I chose to work fulltime for Verisante. So I've done many going public transactions and corporate finance transactions of all different types. I have a Juris Doctor degree from the University of British Colombia and a Master of Laws from the University of San Francisco and my undergraduate degree is Bachelor of Arts in History from the University of Western Ontario. And in San Francisco I studied Intellectual Property Law and Technology Licensing at the University of San Francisco School of Law. So that's my background.

Our CFO Anna Trinh has a Bachelor of Commerce degree and a Juris Doctor degree from the University of British Colombia and is also a member of the Bar.

So we are well-versed on how to manage public companies and how to do technology licensing deals and other transactions like we're managing right now.

On the engineering side, we have two project managers. One of them is Branko Palcic who is the founder of the BC Cancer Agency Imaging Laboratory and he also founded their technology development office. He is retired from the BC Cancer Agency and he now works for us a Project Manager and he's put together the team of engineers who all have history and experience building devices for cancer detection and cancer imaging.

One of our other project managers, Dr. Haishan Zeng who is one of the three inventors of the device. His main job is with the BC Cancer Agency as a senior scientist and he's also professor of dermatology at UBC. Under the rules that govern faculty members, he is allowed to spend 20 percent of his time consulting, and so we have acquired that 20 percent.

Between the two of them, they have put together a terrific team of people who have combined decades of experience of building devices. These are people who actually build things that are used in clinical studies and then ultimately commercialized.

Smallcaps.us: Excellent. Thanks so much Mr. Braun. We'll be sure to keep an eye on Verisante as it moves forward with these exciting developments, and of course we'd be glad to have you back for an update interview.

Thomas Braun: Well, that sounds great. So thanks a lot for having me and I hope I've answered all of your questions clearly and concisely. And I'd like to also thank your listeners for taking the time and taking an interest in Verisante. We appreciate it.

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We welcome your questions and feedback regarding this interview at:
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