Company: MELA Sciences
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Speaker: Joseph V. Gulfo, M.D. - President and CEO

All right, welcome to the MELA Sciences presentation. We have the President and CEO, Dr. Joseph Gulfo, with us today. I will turn it over to him and let him tell you what I think is a great story.

Dr. Joseph Gulfo

Thank you, [Dalton]. Thanks for inviting us here today. Appreciate people coming out in person and listening to this webcast. The company is MELA Sciences. We are public. I refer you to our public documents for forward-looking statements, which we will be making today, for a complete description.

OK. This slide represents, from my point of view, a disturbing paradox. I was just chatting about this slide with one of our new board members, David Stone. As you see, the fundamentals of the company have been increasing, but you're not seeing that in the valuation. Two years ago, right, two years ago almost today, January 14th, we hit $12.00 a share. Closed that day at $11.67. Yet, we are where we are today.

When the markets were expecting a panel meeting in the first quarter of 2010 we did not get that panel meeting. We got a non-approval letter which, a year and a half later, was admitted by the FDA at a congressional hearing to be the wrong call. As you can see, not withstanding the FDA approval, CE Mark approval, and now having imminent market introductions in both U.S. and Europe we aren't anywhere near where we were. As David put it, from the Molly Hatchet song, "one man's pain is another man's pleasure." I'm in pain and maybe some fundamental investors are going to have some pleasure.

I'd like to examine a little bit why this might be the case. I think the first is the gun smoke from the FDA process. We did the largest study, prospective study, ever done in melanoma. Sectioned every end point. Had a binding agreement before. Did everything the FDA has said it wants from companies. To meet with us early and often. Do meaningful studies, meaningful differentiated claims. We did all that, yet we had an arduous process. The internet is a wonderful thing. Sometimes. The gun smoke from that process is still readily available. People who want to make a case against us can easily go and find that.

I think that's issue number one. Issue number two is related to it. The financing. Because of that FDA process, we had built a nice war chest, very opportunistically, and we spent quite a bit of it dealing with the FDA. That required us to raise more money. A combination of burning through money that we had accumulated to fund the launch and the commercialization and the effect of devaluation from FDA was a real double whammy. We did a financing. We did it at the end of last year. We raised $16 million.

We had more than enough money to achieve our goals. But I think that the devaluation at which we did the financing is another weight on us.

Third that I hear from investors quite often is launch overhang. They tell us there's been a number of launches recently of products that were over-hyped and didn't live up to the hype. Therefore, based into your valuation is an assumed poor launch. Thank you very much. What I hope to do today is make David Stone's words a reality. I hope by the end of the presentation I will cover those three points to your satisfaction and not only will you find this slide appealing, you'll find it tantalizing.

OK. Along the lines of more fundamentals, better and better fundamentals, in the last month we've been pretty active. We added top notch individuals to the board in the fields of the commercialization of dermatology products, public relations, business strategy, business development. We're very excited about our new board members. We raised additional money, as I just alluded to, in December.

Then just yesterday we announced an expanded agreement with Askion, our provider. We've been working with Askion for quite a while. We went to Askion to develop our commercial manufacturing methods. We then used the systems that were produced by Askion in the pivotal trial. We had a manufacturing agreement that provided for them producing systems that they now are doing to build inventory and for the early commercialization. We are happy to expand the supply agreement for another three years.

OK. I did a little bit of this already. As I said to an investor who came into the room a little earlier. He said, "Boy, what an exciting ride." I said, "Yeah, it's putting time." We're there. We have the approvals. Launches are imminent. I hope that the product does what it did on the pivotal trials. That is detect melanomas at the absolute earliest stages.

If it does, that will translate into better outcomes, saved lives. I hope all the market research that we did in coming up with the business model, an approach to the doctor's office so that he and she can incorporate it into their practice as well and be successful in using MelaFind from a business point of view, we hope that comes to be. That's really what we have to achieve this year.

As I alluded to earlier, this is the paper from the pivotal trial. It's published in the Archives of Dermatology which is the premier journal of dermatology. It's the largest prospective study ever done in the disease. Both primary end points were met. We showed that MelaFind sensitivity was over 98%, lower confidence (inaudible) yet at that high sensitivity we had higher specificity than even the studied dermatologists. That was the dual end point.

We have additional data. I'll take you through some new data that is under peer review right now. We're generating, excuse me, we're conducting another large study in Germany. A large reader study in Germany. A large reader study in Germany that we should be completing soon. I hope later in the year to be reporting on it. We are committed to research. We are committed to doing things right. When we do something

we do it with numbers, we do it with appropriate power and we have the right people involved with us.

OK. Melanoma, just in the news again a few days ago, that incidence is rising much to the chagrin of dermatologists. Especially in the women in the 30-to-50-year group. The real problem is catching it early. If you try to catch it when it's curable, limited to the epidermis, it is extremely difficult. How difficult you might ask? Well, here is a dermatologist. Her name is Elizabeth Tamsey, a board certified dermatologist.

She tells her story of missing a melanoma on her leg, a very, very obvious part of her body. Not on her back, difficult to see, but on her leg. A year before she biopsied her lesion she noticed it. She asked her partner about it. Both she and her partner felt it was nothing to worry about. They asked another individual outside the practice, another dermatologist. Same thing. A year later she felt that it changed a little bit. She even tells me I wasn't quite sure but I just felt it had changed. She performed the biopsy and it was stage I.

So, she missed her melanoma when it is was melanoma when it was melanoma in situ and it’s curable. The moral of the story is if a board certified dermatologist can miss a curable melanoma on her own body, on a very obvious part of her body, this is a disease where dermatologists need help and we want to provide that.

How did I meet Dr. Tamsey? My wife came with her Shape Magazine and said to me, "Joe, do you know this doctor?" Of course I made it my business to know her. If you catch melanoma early it's 100% curable. If you catch it when it's a stage I, stage I means it's just minimally in the dermis, your five-year survival drops to 93%. Interestingly, in a video that Dr. Tamsey was on she said I'm now four years out and still cancer-free. She has to keep talking like that, right? Because it's not 100% curable for her disease. 93%, at her stage it goes just a millimeter deep, a millimeter into the dermis and you drop survival down to 68%. Then deeper and it gets worse.

Even though we've been reading about advances in late stage treatments if you look at the addition to life span you're seeing maybe four months of survival, maybe five months for those who respond in a couple of the new, approved products. If you catch a melanoma here versus here you can add 40 years of life. That's really what we're trying to do.

Also, if you catch melanoma early the surgery is extremely cosmetically appealing. This is the surgery after a melanoma in situ. You see just a hint of a scar. This is the surgery, this is the result after a Stage III melanoma. Disfiguring surgery, not even showing you the area of the lymph node dissection. Biopsies, a lot of people say if in doubt cut it out. OK, well, a few phenomenons with biopsies. One is on a significant number of patients the healing process doesn't go as smoothly as one would like. This is a patient, young patient, 13, who developed hypertrophic scars after every biopsy. Most people get scars like this. All right, so at the minimum you will have hypopigmented areas you will see most upon sun exposure.

Interesting phenomenon in dermatology because the name of the game is catch melanoma early. Dermatologists do as many biopsies as they think they need to do, but patients exhibit biopsy avoidance behavior. They don't want to be carved up. We hear this time and time again. The dermatologists have adopted as minimal a biopsy as they can. The problem with that is if you were to cut through a melanoma you wouldn't know you did and you'd put the patient at a great risk.

You see the problem. It's a many levels. It's missing it when it's curable. Its biopsying so much that patients don't want to come in. It's performing a biopsy that, and it's all too often heard of, actually cuts through a potential melanoma and you have a horrible outcome. They need help.

When I talked about MelaFind initially to a number of dermatologists one of them said something to me that really stuck in my mind. He said to me, "Joe, this is going to be, for me a dermatologist, what an echocardiogram is for a cardiologist." Just the perfect example. Cardiologists, when you go to a cardiologist, they use their stethoscope and they use maybe an EKG for screening. Then, if they hear something, they hear a murmur or by talking to the patient they think there may be decreased cardiac output or something, or on EKG they might see a slight ST elevation or something, what do they do? They want to look at the way the heart is pumping. They want an echocardiogram. They want to look at the wall motion.

It's exactly what MelaFind is. Patient comes in. The doctor looks at it, not quite sure. Rather than guessing, which is what they do now, and in that guessing of gee, this looks a little peculiar to me. In that guessing of does peculiar mean do I need to biopsy it, that's where 30% of the earlier stage melanomas are being missed. That's where these excessive biopsies in pursuit of the melanomas are happening. It's a perfect analogy. That's how I'd like you think of MelaFind. It's an echocardiogram for pigmented skin lesions.

Actually, it goes a step further. That is even with an echocardiogram you need interpretation. Right? You need to look. Is that normal wall motion, is it not? Is that normal motion of the valves? Is that a vegetation or is it just the rotation of the body and inadequate study? With MelaFind you don't have that. You get a result. You get a positive or a negative. No interpretation required. Just incorporation required. Dermatologists are armed with their eyes. Occasionally, some of them use what's called a thermascope. Which provides an image that's very difficult to interpret. It's awkward. You see this, very awkward to use. Then you have some digital thermascopes where you could look at the image on the screen. Still, interpretation is required.

What does MelaFind do? When you put MelaFind on the skin, it looks like a radar detector. You put it on the skin, you push the button. In 2-1/2 seconds, we've slowed this down, so I can explain it. It takes 10 pictures, 10 different wave lengths of light. From blue which give the surface hue. Down to three infrared bands which gives information down to 2-1/2 millimeters.

Physicians' eyes cannot see 2.5 millimeters deep. Once that information is obtained, our

automated algorithms take over. They calibrate the image. They perform quality control. They make sure there wasn't too much hair over the lesion. If there, was, it would tell the operator you need to clip more hair. If there were too many bubbles, you need to reapply.

It tries to be user friendly. It doesn't let garbage into the algorithms by identifying quality control issues. Next, it then identifies these key features. MelaFind is a resolution of three cells. The human eye of course and the human brain, does not.

They can see patterns of growth on the surface, below the surface, in different planes, in different directions. The human eye can't get the information and the human brain can't process that. It can appreciate 5,000 different characteristics.

In the final algorithms, to separate the positive class [??] from the negative, 75 characteristics made it into the final algorithm. The human brain can appreciate 75 different characteristics and use them in differentiation.

The other thing about MelaFind is that it was developed, trained and tested on 10,000 biopsy pigmented skin lesions, over 600 melanomas. One of our key investigators once did a survey. He asked how many early stage melanomas, [??] stage one, did residents see before they graduated. It was below a dozen. MelaFind has been developed trained and tested on over 600 early stage melanomas.

The other thing I'd like to say is that this technology is completely objective. What does objective mean? Objective means it will give the same result Tuesday at 8:30 on a lesion as it will on Thursday at 4:30.

Why is that a big deal? Because dermatologists don't. The practice of any aspect of medicine is very subjective. Dermatologists are influenced by the last patient they saw.

I had one dermatologist tell me that he's in a three man practice. If one of them has a patient with a melanoma, for the next three months, they're biopsying everything that walks in the door. No melanoma, they stop biopsy. That's not objective.

The dermatologists tell me things that I look at, again, at one part of the day I know I make different decisions than another part of the day. MelaFind won't. It doesn't care that the prior lesion it saw might have been a positive call. It doesn't care what time of day, what season. That's what it means to be completely objective. That objectivity will level the playing field. Will make that determination of whether a biopsy is needed more uniform across all dermatologists. I have a slide on that in a little while to show you.

OK. You can't judge a book by its cover, right? Everyone would look at these two lesions and think that the lesion on the left needs to be biopsied to rule out melanoma and the lesion on the right looks perfectly benign. It looks symmetric and everything. We have a paper on this. Ten of North America's top dermascopists all got this wrong. The lesion on the left was on a 12 year old boy, he'd had it since birth. His new dermatologist wanted to biopsy it until it got on our trial. The lesion on the right, I actually forgot the details of

that, but it was on the trial and biopsied. In reader studies later every dermatologist felt the lesion on the left did not need to be biopsied and the lesion on the right did. Of course, MelaFind was negative on the left and positive on the right.

Why? Because the dermatologists can't see below the surface. On the surface there was great atypicality but below none on the left. On the surface here it looks quite run of the mill but below the surface was where the atypicalities had occurred.

How is MelaFind used? Very easy. It sits right in the doctor's office. You see it there. It has no wider footprint than a stool. The doctor would first examine the patient. Decide which lesions are clinically atypical and which of those he'd like more information on. Put it on the lesion, literally hold it there for two seconds. In under a minute per lesion we get the unequivocal results. That then needs to be incorporated into a decision.

The clinical study that we performed, we set out to show that MelaFind was very, very sensitive. Literature had established physician sensitivity in the 70% for very early stage lesions, 80% range. We said at the FDA we want to show that MelaFind is at least 95% but also, simultaneously, we'll show the specificity is superior to dermatologists. What did we show? We showed just that. We had a 98.3% measured sensitivity, lower confidence down at 95.1%, and a specificity higher than the dermatologists.

In corollary studies, I jumped to reader studies, where we can measure physician sensitivity in a subset of lesions. We took 65 of the melanomas on the trial, there were 114, and a balanced number of other lesions. We showed that the dermatologists, consistent with the literature, for early stage lesions had a sensitivity of 72%. MelaFind 97% and a p-value of .001.

Now we've done, oh, excuse me, very, very important here, is, again, the stage that we're detecting this. Forty-five percent of the melanomas on our trial, who were melanoma in situ and 55% were minimally invasive. How minimally? Well, .365 millimeters, so one full millimeter is the breakpoint between Stage I and Stage II. So, I like to say these were stage half. There's no such thing as stage half, but I'm just trying to dramatize that they were early Stage I lesions. This is just when you want to catch the melanoma.

So we've provided images for a number of reader studies, this was the definitive reader study we called [??] about 110 dermatologists, 130 lesions, and we reported on that and data and a paper on that is being prepared. But there have been other reader studies that show again, between 70% to 80% sensitivity.

So, I'd like to talk about this one. This was done, two years ago, 216 dermatologists at a continuing medical education meeting, immediate response system. The physicians were shown very high quality images from a camera, Fuji camera, $3,000 Fuji camera from 22 inches away, 8 inches away dermascopic image and complete medical history, and they detected 80% of the lesions.

So this investigator at the very next year at the same meeting, did a study for us. He wanted to assess whether knowing the MelaFind information would improve their performance. So why did he think of this, he thought of this because, when you look at the results of this study, you see that, of the 110 dermatologists, four of them actually performed at the level of MelaFind. They had very high sensitivity and they matched the specificity. But the bulk of them did not. They performed here. And he question he posed to me was, what will be great, is if when MelaFind is on the market we see, that MelaFind moves these dermatologists to these dermatologists. Right, these are the four you want to go to.

So he did a study, a year later, at the winter derm meeting, 179 dermatologists, I'd like you to ignore this column for the moment, and what did he show? First of all, what we've seen before. Sensitivity around 70%, 69%. OK. They were asked what they would do with each lesion first, and then they were then told what the MelaFind result was.

So, after being told what the MelaFind result was, now MelaFind caught all the melanomas so it was 100%. The sensitivity increased to 94%, not 100. Few of them still didn't believe it. OK? Thirteen percent of them, of all those dermatologists would have caught all the melanomas in the sample before knowing the MelaFind information. That jumped to 70%. Caught all five. Now there's a price to pay.

When you're detecting only 69% of the melanomas, your specificity will be at one level, when you're detecting 94% it's gonna drop a little. OK? That's an accepted tradeoff in dermatology. This is very interesting, on the number of lesions that were MelaFind called negative and were truly negative. So 42% of the dermatologists, before knowing MelaFind felt that it was negative, would not have biopsied those lesions. Therefore they felt it was negative and that number didn't drop to zero when they were told the MelaFind. It they should have, if they listened blindly to it. It dropped to 25%.

So what are we seeing in this data? We're seeing that knowing the MelaFind information before it's even out, before they've even had experience with it, this is just being told the results of a published paper, knowing the MelaFind information did indeed affect decision making. It increased the sensitivity. It decreased the specificity a little bit, but at a tremendous gain and we see fewer biopsies on MelaFind negative lesions. So it's very interesting. These data has been submitted for publication and when they're published we will let you know.

So how do you use MelaFind? Right now, dermatologists use the ABCDs. In fact, this company was basically started by the three gentlemen who popularized the ABCD method and they use some other parameters to help decide whether something is atypical and now what you will use is MelaFind in addition, and you will get an objective piece of information that does not require interpretation. It requires incorporation, like the slide I just showed you.

OK. So the way MelaFind can be used; patient in the clinic, average Caucasian middle-aged male would have about 50 to 60 pigmented lesions on the body, the bulk of which

are totally benign, just like these three. Like freckles. Dermatologists have no problem with any of these. One might, unfortunately, look like that. Dermatologists have no problem with that either. He knows he's going to take it off. And two, three, four look like this. They're a little atypical, right? And the question is what do you do with this?

So where do you MelaFind? If it were a screening device, you use it on all 60. It's not a screening device. If it were a confirmatory diagnostic, you'd use it only there. It's not for that. It's to be used when there's a question.

All right. So we have done a lot of market research and now, as I said, it's putting time. So when preparing our launch strategy and commercialization strategy, we looked at what makes for a successful product and what doesn't. It's very simple. One, it's the product. Two, its respect for the fact that doctors are running businesses and they have to have the use of your product incorporated into that. And that's really where we focused. So doing a larger study, getting results we did, we feel we have a highly differentiated product that could provide great benefit.

Now let's talk about the fact that we're respecting the doctor's business. So, I think the biggest lesson we've learned from these is the importance of being deliberate, focusing on training, and making sure that the earliest users have phenomenal experiences. That's the approach we've taken.

The way we've addressed the business concerns in the practices is follows. Basically say to the dermatologists we would like to place this system in your office, here it is, and for $7,500 we will place that as your contract. We will train your entire staff how to use it. Every time you want to use it you buy a card for $50 from us. This is not reimbursed yet.

Reimbursement is something that could be considered a few years from now when it's in widespread use, is one reimbursement requirement. Another is robust literature, which we don't have yet. You don't want to rush reimbursement. Because if you get reimbursement too early and the use is not totally established.

Let's say early on they use it on one lesion but five years from now a number of papers come out and say no, the right way to use MelaFind is, the heck with everything else, the heck with everything else we've taught, just examine a patient and the eight more peculiar lesions put MelaFind one. Well, guess what, if your reimbursement is based on using it on one and the literature, a few years later, tells you the best way to use it is eight, people aren't going to use it.

OK, so the worst thing you can do is rush the reimbursement. What we did, rather, is understanding how dermatologists work and understanding patients who go to dermatologists are accustomed to paying out of pocket for valuated services, is we keep the price low. Very low price. The dermatologists actually have advised us for that. Our goal is, initially, we will focus on the Northeast and some other sites outside of the Northeast that are familiar with MelaFind based on what we did in the clinical trials. We want to place 200 systems in the first 12 months on the market. That's not at 200

practices. That might be 60, 80, 90 practices. We want to focus on the high volume opinion leaders.

We want to do a similar thing in Germany. Germany, there's 75 systems we want to place. Again focused on a number of high volume opinion leaders. Deliberate approach, make sure that they have excellent experiences with MelaFind. Know when to have a conversation with the patient. Know what type of system they should adopt in the practice. Should they have a dedicated exam room? Should they have MelaFind in three exam rooms? What should they do? Should they set up MelaFind Thursdays?

When Botox first started one of the early promotions was Botox Fridays for lunch. They had quite a hurdle, just think of that. You want me to inject Botulism toxin in my patients' faces and don't go too deep? OK, it started slow. Now it's every second of the day. Same thing.

Germany is very attractive. There are 5,000 German dermatologists. 10% of our database actually comes from das country, a site we had in Grouts, Austria. We've done a lot of work already there. We're doing a large study there. We know the key opinion leaders in Germany. 10% of the German population has added insurance on top of the state insurance which pays for tools to be used in the evaluation of pigmented lesions. We feel very confident.

We do not have a selling challenge. I'm asked this all the time. We get an email a day. Today we got two, this morning actually, of dermatologists that want MelaFind. We know the names. We know who's going to get these. That's not the challenge. The challenge is to bridle ourselves and focus and partner with the practices, work with the different type practices, because you need different practice archetypes, and really methodically determine what makes for an optimal use of MelaFind.

Optimal use to us is use once an hour. Dermatologists see five to ten patients per hour. Market research tells us they'll use it once an hour. At least once an hour. If they do that the metrics on a hypothetical machine are very, very favorable. One use per hour is 40 uses a week. Times $50, times 50 weeks, we just keep the numbers simple for now, its $100,000 in revenue per machine. Useful life at three years. Manufacturing costs are about $35,000.

If we achieve our goals and we end those first 12 months at 275 systems out working at one an hour the run rate for the following year is over $25 million. Even though a lot of people say to me why so slow? Why so deliberate? Why so this? When you think of the business model that's a heck of a run rate to have at the end of your deliberate approach year, commercial development year.

We're doing things we do prior to launch. Mostly it's the training program that's rate limiting. Doing these other things. We'll be starting a beta study very, very shortly. Then we'll launch.

I already talked about Germany. We will continue to attend the big meetings and the most valuable meetings for us. There's one happening actually next week. The big annual meeting, the Academy of Dermatology meeting, is happening March 12th in San Diego. We talked about new board members. I discussed their backgrounds and we're just thrilled to have them guiding us. We raised $131 million in the public markets in 2005. We just completed a financing of over $16 million. We have plenty of cash to achieve the objectives that I just set out.

The market for melanoma continues to grow. Which is good news and bad news. It's a disturbing trend for the disease but a great opportunity. Having now achieved CE mark approval and FDA approval, with launch imminent, as I said its putting time. We're very excited about that. Having just raised money we're well capitalized to achieve the goals.

Questioner

[??]

Dr. Joseph Gulfo

So we will address that because they don't want to feel the Geek Squad, because that's what it would take, right? The patient card, the EMR card has been coded so that it's readable by the major EMR systems. So if they have one all they need to do is put it in any computer, we will give them a proprietary reader, and the information can be incorporated in their EMR.

Down the line we want to make the handheld wireless and maybe even partner with one of those type companies to make it seamless. But I am so worried about trying to make it compatible with the people systems. We made a decision a while ago to stay away from things like that for the time being.

Questioner

[??]

Dr. Joseph Gulfo

Well, Askion produces the handheld for both the U.S. and Germany, but interestingly you ask, we want the Askion to make the card as well for the German market and that's part of the agreement. The other is we want to work with Askion over time to now start optimizing manufacturing and reduce cost and we want their commitment to produce the supply that we project and [non-compete] and things like that. That's really the essential element of the expanded agreement.

Questioner

[??]

Dr. Joseph Gulfo

Right. So, a few things; the German leader study will answer two questions. What is the base line performance of the German dermatologist on the U.S. data is very important. We know that melanomas are caught at later stages in Germany than they are in the States. To have data for that market with their own eyes is very, very important. So, number one is baseline what their sensitivity is versus MelaFind. The other is built into that study will be an assessment of what does the MelaFind information do to their performance.

It's a large study. We'll have baseline performance and then we'll have performance once knowing the MelaFind information so the implications of the data. I think that's very important for the marketing in Germany. I think you are showing respect for them and having data on their own soil. In one study, all those answers. If you noticed, we had all those pieces of information in two studies, we'll have it all in one.

Thank you.