Electro-Optical Sciences, Inc. Conference Call
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Corporate Speakers

- Dr. Joseph Gulfo Electro-Optical Sciences, Inc. President, CEO
- Dr. Gary Monheit University of Alabama, Birmingham Associate Clinical Professor of Dermatology, Lead Investigator in MelaFind Study
- Dr. Darrell Rigel New York University Medical School Clinical Professor of Dermatology

Participants

- Dalton Chandler Needham & Co. Analyst
- Matt Dolan Roth Capital Analyst
- Daniel Onsted HQCM
- Ross Shaw RA Capital

PRESENTATION

Operator: Good day, ladies and gentlemen, and welcome to the Electro-Optical Sciences, Inc. Conference Call.

(Operator Instructions)

I would now like to turn the call over to your host for today, Dr. Joseph Gulfo, president and CEO. Please proceed, sir.

Dr. Joseph Gulfo: Thank you, and good morning, everyone.

I'd like to remind everyone that this presentation includes forward-looking statements within the meaning of the Securities Litigation Reform Act of 1995. These statements include, but not are limited to, our plans, objectives, expectations and intentions and other statements that contain words such as expects, contemplates, anticipates, plans, intends, believes, and variations of such words or similar expressions that predict or indicate future events or trends, or that do not relate to historical matters.

These statements are based on our current beliefs or expectations and are inherently subject to significant uncertainties and changes in circumstances, many of which are beyond our control. There can be no assurance that our beliefs, expectations will be achieved. Actual results may differ materially from our beliefs or expectations due to economic, business, competitive, market, and regulatory factors.

Well, I am thrilled to be with you here this morning. My only regret is that we can't do this in person. It's truly a momentous day for us in our quest to improve how melanoma is detected. As you saw in this morning's press release, we announced positive top line

results of the pivotal trial of MelaFind, our noninvasive point-of-care instrument to assist in the early detection of melanoma, the deadliest form of skin cancer.

The study, conducted at seven centers across the U.S., included 1,831 pigmented skin lesions from 1,383 patients, making this the largest prospective study ever conducted in melanoma detection. We're working now to complete our premarket approval application and expect to file it with the FDA shortly.

Based on prior meetings with the agency, we have a binding protocol agreement in place stipulating the endpoints of the study. First is a lower confidence bound of sensitivity higher than 95%, and the second is statistically significant higher specificity than the participating study dermatologists. Improved specificity, the ability to accurately rule out melanoma, is an important concern for patients because melanoma biopsies are invasive and scarring.

I am delighted to report that MelaFind detected 112 out of 114 melanomas that were eligible for a primary endpoint analysis. That equates to a measured sensitivity of over 98%, with a lower confidence bound of 95%. When looking at all the melanomas in the study, the intent to treat population, MelaFind accurately detected 125 of 127 melanomas, which equates to an over 98% measured sensitivity, with a lower confidence bound greater than 95%.

Importantly, almost half of the melanomas were melanoma in situ, the most curable yet most difficult form of melanoma to detect. MelaFind's specificity was significantly superior to that of study dermatologists, who are skin cancer experts. MelaFind had a specificity of 9.5% versus 3.7% for study dermatologists, with a P value of less than 0.02.

Today, physicians rely on surface analysis using the naked eye or, at best, technologies to magnify a suspicious lesion. We developed MelaFind as a tool to help diagnose melanoma at its earliest, most curable stage, using breakthrough technology that allows visualization and evaluation below the skin surface and provides an immediate result that informs the biopsy decision in the moment.

Melanoma kills one US citizen per hour. It is a terrible disease that is on the rise and it knows no age boundary. Of particular concern is the alarming increasing incidence of melanoma in teenagers, according to some, in epidemic proportions. Melanoma is the most common cancer in women aged 25 to 29 and the number one cancer killer of women 30 to 35. We want to help put a stop to this epidemic. We believe that these data provide significant evidence that MelaFind will be an extremely tool in this fight.

I'd now like to introduce Dr. Gary Monheit, the lead investigator in the MelaFind pivotal study and associate clinical professor of dermatology at the University of Alabama in Birmingham, to put these results into perspective. Following Dr. Monheit, Dr. Darrell Rigel, clinical professor of dermatology at New York University Medical School, will

make some comments about the importance of the study and then I will offer further details about our plans going forward. But first, Dr. Monheit.

Dr. Gary Monheit: Joseph, thank you. I appreciate being on this call today, and I really want to congratulate you and the whole team on where this study has come and what it's going to do to help in our practice.

I see a tremendous number of skin lesions and the majority of my practice involves daily binary decisions of whether a pigmented lesion is benign, whether it is potential for malignancy or whether it's malignant. And many of these are soft signs that one has to make a decision in, meaning lots of biopsies, lots of people and lots of skin lesions. Any help we can get in this is going to be of value.

For this I was really happy to participate in the study because this need is growing more and more because of the epidemic that we're seeing in melanoma, younger people, smaller lesions and more subtle lesions we have to make decisions on. And especially when we realize that early detection is our only hope in curing this disease. If we allow it to go and go later, there really isn't much we can do.

So in practice today, we rely on the physical exam as the traditional ABCDE in evaluating and diagnosing melanoma. There are many patterns that we talk about. There are definitive signs. But then there are more subtle gray zones that sometimes it's very difficult to make a decision on. There's an art to doing this properly. Some are better than others. But even those of us who we feel are the best still have problems with lesions, making that final binary decision yes or no.

And I think that this is where we see a big help with this instrumentation. It's science and it's science that goes not at the skin surface, but we can detect pigment patterns that appear below the surface that we can't see. The incorporation of dermascopy and various wave lengths bring out different colorations and invasiveness that can really tell us if this is an abnormal lesion or not.

That said, we all worry about missing melanomas because it's impossible to diagnose -- it's impossible to biopsy every lesion we see. And in fact, it's impossible as a clinician for us to see on a regular basis all the people who need this kind of evaluation. So the help we can get, both diagnostically and in manpower, is going to really help in this epidemic.

MelaFind sees below the surface, so it adds that extra little bit of science that we need to help in our diagnosis at times. At times, it can prevent a biopsy; and at other times, it leads us to a biopsy. The ultimate decision, though, whether to biopsy or not still remains with the clinician. MelaFind is another tool that helps makes us this decision in detecting melanoma early. So I think that this will be a help for our patients and for the dermatologists.

This study's been fascinating. It's been a test of our own knowledge and ability to diagnose and seeing melanoma as far as whether we're right, whether we're wrong, and the help this machine can give. My own personal observation is that this pivotal trial really will be a big advance. It was easy to fit in and, in fact, our patients got an extra reassurance knowing that we were using the MelaFind in addition to our own observation.

This technology helps us make more efficient biopsy decisions and it really evaluates what we should be doing for our patients when they have their regular skin exams. And I have to tell you the majority of what we see in clinical practice is the evaluation of pigmented skin lesions in a dermatology office. This, I'm sure, mimics itself in all other clinical settings. So this, I think, is a major step upward as a proactive change to help diagnose this disease early and help in the cure of it.

Okay, I'm going to turn this call back over to Dr. Gulfo now. And I hope that I've given you some insight into how this, for us, the clinician, is going to be a help.

Dr. Joseph Gulfo: Thank you very much, Dr. Monheit.

Now I'd like to introduce Dr. Darrell Rigel. Dr. Rigel helped develop the ABCDE method for melanoma detection that is most commonly used today. And as a member of our scientific advisory committee, he was instrumental in advising us on the design of the study and in working with FDA in obtaining the protocol agreement with us. He has offered to discuss his view on this study. Dr. Rigel.

Dr. Darrell Rigel: Thank you, Joe, and I did want to congratulate the team on these results. This is certainly very exciting and I'll go over this a little bit as we talk. But I hope people sense the enthusiasm I have because, in my opinion, this is a very exciting result of a study.

Now why this is important, it's estimated that there are about 650,000 new patients in the US each year that visit dermatologists because they're specifically worried about a mole. And probably there are anywhere from four million to 10 million patients who are at high risk for developing melanoma. So given these numbers, it's clear that we, as dermatologists, need better technology to make us more effective.

It doesn't seem like 25 years ago, but it is that we developed the ABCD, now ABCDEs of melanoma -- asymmetry, irregular border, uneven color and diameter, and whether the lesion has evolved over time. And these were designed as a first cut to help a clinician determine whether something was an early melanoma. But early melanomas can really resemble benign lesions in many ways and it's difficult to identify them. And there also may be many irregular characteristics of a lesion, of a melanoma, that are under the surface that we can't see with the naked eye.

Certainly, you can use a dermascope; and even with experts who use dermascopy primarily, they can still miss up to 40% of melanomas in several of these studies. That's clearly not good enough. And this study is really important on a couple of different levels and it was designed really to deal with that in mind. But I think the most important outcome of this study is there's now evidence to show that MelaFind could be a valuable tool to aid us in early melanoma detection.

Comment [PC1]: This statistic refers to primary care physicians

And given the magnitude of this study, there's really been no other study even close to this, at least in my recollection of looking at melanoma diagnosis. We're going to be able to see new, useful information about -- when sub-analyses become available. I think this information is going to really help advance our understanding of melanoma in certain risk factors and current trends also.

Now I was told that MelaFind was trained and developed and now tested on over 600 melanomas. And just to put that in perspective, the average dermatology resident over three years is probably seeing a dozen or so primary invasive melanomas during their time. So I guess what makes this exciting to me is that it appears that this is the first technology that I've seen that not only offers us a view beneath the skin surface, but really, even more importantly, provides a binary result for us to decide whether to biopsy or not biopsy.

And I think that's the key, not just for the patient with one lesion, but the patient who has multiple lesions where that is even a bigger challenge. To my knowledge, there's no other device that is available or in development that match the potential of MelaFind as a detection tool for melanoma. And I guess that's the real reason that I'm excited that hopefully soon, we'll be able to have this in our armamentarium as dermatologists.

So again, Joe, I congratulate you and EOS on this important achievement. And I'll turn this back over to you.

Dr. Joseph Gulfo: Thank you very much, Dr. Rigel. Just want to let everyone to know that Doctors Rigel and Monheit are at a dermatology conference, speakers at that conference, and they've taken time out to be with us this morning and I greatly appreciate that.

All right, before getting back to the data, I'd like to provide you with some additional details on how MelaFind works. MelaFind is placed on a suspicious lesion and takes 10 digital images in wavelengths ranging from blue to infrared. The digital images are processed and analyzed using very sophisticated algorithms, developed, trained and tested on a database of over 9,000 biopsied pigmented skin lesions, including over 600 melanomas.

The system provides an immediate result that informs the decision to biopsy. It is completely objective, not requiring any clinical input from the user. The system has a

touch-sensitive screen and a body diagram to indicate the lesion upon which MelaFind is being applied. In the commercial setting, we plan to sell a proprietary digital media card to store the patient's data. The cards, which will be purchased for each exam, allow the physician also to print or archive these reports. And MelaFind was designed with the help of many physicians, including Doctor Rigel and Monheit, to fit easily within a dermatologist office.

So now getting back to the data. The skin cancer experts who participated in the study had previously made the decision to biopsy all 1,831 pigmented skin lesions prior to enrolling the patient in our trial. So this study does not permit us the opportunity to adequately measure physician sensitivity since the biopsy decision was already made. But in order to do that, in order to generate a comparison with dermatologists, their ability to accurately detect melanoma, we conducted a parallel pilot reader study with a different group of 39 dermatologists.

Using images and clinical histories of 23 randomly-selected melanomas from the pivotal study, this group of dermatologists, on average, would have decided to biopsy approximately 18, it's 80%, of the melanomas, whereas MelaFind result would have led to biopsy of 22 of the 23. So over -- that's 96%. A larger reader study is -- will start soon, very soon, to provide additional data regarding the sensitivity of MelaFind relative to physicians, and data from these studies will be submitted to FDA.

All of our energy in the coming weeks will be dedicated to completing and filing the PMA. MelaFind has been granted expedited review status from the FDA, which calls for a 180-day review cycle and team review once the PMA is filed. The agency has indicated to us that we will have a panel meeting to review the PMA package. We would expect it to occur sometime in the middle of the review cycle, but we will update you with more specific timing and further details as soon as we receive feedback from the agency.

In addition, EOS plans to submit the findings from the pivotal study and reader studies to peer-reviewed journals. Study results will also be presented in multiple presentations at the upcoming American Academy of Dermatology meeting early next month, in March. In anticipation of a potential approval, we are beginning to formulate our launch plans. If approved, we intend to pursue a regional launch approach.

Our first area of focus will be the New York, Connecticut, New Jersey region due to the high concentration of top high-volume dermatologists and high melanoma rates within the population. Our goal will be to target these high volume sites that will be able to maximize system usage. Based on our early success, we will optimize our subsequent years' plans as appropriate. We will update you on our strategy as it is further refined and our discussions with FDA as they advance.

As we have previously stated, we expect our burn rate going forward to closely mirror the burn rate during the pivotal trial, which is approximately $1.3 million per month. At the

end of the third quarter, we had $19.57 million in the cash. As always, we will manage our cash judiciously.

In closing, I want to thank Doctors Monheit and Rigel for all their hard work. They both were involved in the program longer than I've been, and I've been with the Company five years. I congratulate and thank all the study physicians, EOS employees and patients who made this all possible. I'm thrilled to see these results and I actively anticipate our discussions with the FDA.

I'd now like to open the call to questions. With me today is Dina Gutkowicz-Krusin. Dina was one of the core founders of the Company and our principle scientist -- and Richard Steinhart, our chief financial officer, to help me answer your questions. Operator, can you announce the first caller?

QUESTION AND ANSWER SESSION

Operator: Yes, sir. Your first question comes from the line of Dalton Chandler with Needham & Co. Please proceed.

Dalton Chandler: Good morning and congratulations. I know it's been a long, tough road. Are Doctors Monheit and Rigel available for questions?

Dr. Joseph Gulfo: Yes.

Dr. Darrell Rigel: Yes. This is Dr. Rigel. We're here.

Dalton Chandler: Great.

Dr. Gary Monheit: -- Monheit.

Dalton Chandler: Great. Thank you. I guess I'd like to just ask how you think this device could change your practices and longer term, as it becomes more widely understood and accepted, how you expect it to be used in the typical practice?

Dr. Gary Monheit: I --

Dr. Darrell Rigel: Well -- go ahead, Gary.

Dr. Gary Monheit: Okay, yes. I can start in that. We have people call in every day with a mole they're frightened about. And when I have a full book, sometimes I have to put them off for six weeks to two months in my own personal practice to fit all these people in for evaluation. And many of them are frightened to death. If they have a mole, they want it to be seen today and they want it competently evaluated.

This is a way of bringing the evaluation into the office where patients can come in, have a MelaFind evaluation, and if the MelaFind, in fact, shows that this is a lesion that needs

attention now, we will work them in. If it shows that this is a lesion that can wait and come in for a regular appointment, then later, six weeks, then they can come in at that time.

So because of this pressing need of people who need attention on an ongoing basis and right away, I think that this will bring the arm of care and evaluation to the office in a more -- in a quicker way than we have before. It surely will help my practice in getting people in.

Dr. Darrell Rigel: And I'll echo what Gary said. I think it's -- I think it will work for me is exactly that. It's hard to get patients in. It's a way to quickly screen them when they call and it's a very common thing that happens, "I'm worried about a spot." But more -- equally importantly, I should say -- I alluded to this earlier -- this will be helpful when the patient presents not with one lesion, but 5, 10 and 20. And that's not so unusual when that happens.

People with dysplastic nevus syndrome, it's estimated about 6% of the population has that. So it's just a very good screening tool that will make me more efficient in what I do.

I think it will get integrated into the general dermatologist's practice, which is the second part of your question, because the reality is you need an extra tool. Right now, the only thing I have is my good judgment, hopefully which is pretty good. But if I had a tool that would improve my diagnostic accuracy, and that's the importance of what this study basically shows, that I will be more accurate than other comparable studies with dermatologists, then in fact, everybody -- or not everybody, but most everybody -- will opt to integrate this in some way.

And again, the numbers are not going to be that hard from an economic point of view to integrate into a practice. So therefore, I think there will be a large adoption of this once it's available.

Dalton Chandler: Okay, great. And how do you see the workflow when one of these patients calls in and they're very concerned and they want to come in today? Would you have a physician extender do the exam or would you see the patients yourselves?

Dr. Darrell Rigel: Probably I would. And again, we've looked at the model and every practice could be slightly different. And what I would view happening is maybe -- we get a lot of these calls. It's a really common thing when somebody says, "I have a spot. I'm worried about it. I've got to get in." I probably get -- in our practice we have a group of five and a half derms basically. We probably get 20 or 30 of those calls a week. And what I would do is put a morning or two where I have an extender do the screening.

Understand I still have to -- the physicians still have to duck in and tell the extender which lesions to image and screen. But if I had that data, we'd know exactly who to biopsy, what we need to biopsy, and it'll just be much more efficient. So that's how we

envision, at least on the front end, doing this, is using it as a screening tool to have the right people get the biopsies.

But there are other models that you could use, too, and that may evolve over time as we see how it works best in our practice.

Dr. Gary Monheit: And I'll comment on that also. We thought this through. I have a practice of six dermatologists, and we're busy constantly from 7:30 in the morning till 5:30 in the afternoon doing melanoma and mole screenings. And that group of 10 or 15 people who call in -- "I've got a mole that needs to be seen today" -- we would have a dedicated room for the MelaFind and a physician's assistant who would be in charge of it.

She'd have other duties. But when the necessity comes up to do this kind of a screen on it, she would actually activate the screen, put the MelaFind in, and utilize it for those patients who you can't fit into your schedule.

In addition to that, there is a gray zone where even us, as clinicians who are good at diagnosing melanoma, still have that yes or no decision and it is not actually there, they also would be brought into the MelaFind room, have a MelaFind study done, the analysis done, and a yes or no decision from this. This would be conducted by a nurse in the room or/and the nurse practitioner who would carry out that part of the practice.

The physician, though, would do the biopsy and would continue on at that point. So it should be done under the supervision of a physician in an office that is familiar with moles and evaluations of it as an adjunct to help in the vast number of people who need this screening.

Dalton Chandler: Okay, thanks. That's very helpful. If I could ask Joseph a question just about the numbers in the study, we'd always talked about the need to get to 93, wound up at 114. Can you just talk about how that worked out?

Dr. Joseph Gulfo: Right. The way the study works is there's a significant follow-up period interpretation of the pathology. So accrual -- the actual number of melanomas in the trial is delayed coming to us. Second, for a variety of eligibility – evaluability reasons, we assumed a certain number of percentage of patients would not qualify. So we had to over-accrue, and that's standard in trials.

The phenomenal news is we had 21 more melanomas. And to catch 112 out of those 114, and on the intent to treat, the 125 out of 127, it's -- it just makes it all the more compelling. But yes, we had to get at least to 93 in order to show the lower confidence bound of above 95%. That was the magic of 93, not that there was anything else inherent in that number other than the statistical consideration.

Dalton Chandler: Okay, thanks. And I'll just ask one last question and I'll give someone else a shot here. You talked about the process, the filing, the potential panel

meeting. Can you just put maybe some -- a timeframe around when you expect these things to happen and when you might see the final approval?

Dr. Joseph Gulfo: I've not been too good at that. So when I -- at the conference in January, I was asked when would we have data and I said "in weeks." And it's been about a month. So why don't we say for PMA filing a month or so? Then from the date of filing, with expedited review, it's a six-month review; it's a 180-day target.

So somewhere near the middle of that, we would expect a panel meeting with FDA. And certainly, we need to be prepared to launch the product at that 180-day mark. But I can't comment on really what happens during that period. That's in the, as you know, in the purview of FDA. But that's what we're planning and what we have to be prepared for and will be prepared for.

Dalton Chandler: Okay. Thanks a lot and congratulations again.

Dr. Joseph Gulfo: Thank you, Dalton.

Operator: Your next question comes from the line of Matt Dolan with Roth Capital. Please proceed.

Matt Dolan: Hey, guys. Good morning. Congratulations, everybody.

Dr. Joseph Gulfo: Thanks, Matt. Good morning.

Matt Dolan: Just a follow-up for Doctors Monheit and Rigel if they're still on. Maybe -- and you gave some good color on how this would fit into not only an expert's practice but a more typical dermatology practice. Can you -- can you talk to us -- we've had some question in terms of the practical side of biopsies and making biopsies more efficient. Are biopsies, if you reduce the number, are they ever concern -- considered to be somewhat of a money-maker for a practice? Do you truly want to reduce those from an economic standpoint?

And --

Unidentified Speaker: (inaudible - microphone inaccessible)

Matt Dolan: And secondly, as you look at the -- some of these reader studies, you actually end up biopsying more patients. Is there any concern there that true efficiency may or may not be found or is the clinical value outweighing any of those financial or practical concerns?

Dr. Darrell Rigel: Well --

Dr. Gary Monheit: So --

Dr. Darrell Rigel: I'm sorry, Gary. You go ahead.

Dr. Gary Monheit: You go ahead. Well, I was just saying that we are all so overwhelmed with the number of people we evaluate that I don't think it'll have a clinical impact on our practice whatsoever. In fact, it'll make it much more efficient because as both Darrell and I have said, there are many, many people who need to get in and this will help the efficiency of the office and its evaluation of it and really direct us towards biopsying those that are really of need.

Go ahead, Darrell.

Dr. Darrell Rigel: Yes, I would just echo what Gary said. We're very fortunate in dermatology; with this economy our practices are booming. We still have big delays, especially on the medical side of things. Maybe a little different on the appearance side. But on the medical side, it's really pretty good. So bottom line is I think that if we can make sure that we have this tool, it'll make us more efficient.

I'm not worried about the number of biopsies changing one way or the other. You could argue we may do a few more or a few less, but we'll be more efficient at it. And I think that's what the biggest value we have in our practice is, is the efficiency because we just have limited time and limited resources to see these patients. It's a good problem but it's a problem not just for us but virtually every dermatologist.

Matt Dolan: Okay. And just to reiterate from the patient's perspective, it sounds like that you'd have no problem generating interest from that side. That seems – today, there's actually even -- just through the pivotal study there's patients almost actively seeking the MelaFind.

Dr. Darrell Rigel: Yes, I think so. I mean there are going to be -- patients will really like this. First of all, it's smooth, it's small, it looks good when you see something visual happening. Some patients actually enjoy when you play with this. But the reality is that I think that's the easiest side of it. It will help my practice be more efficient and more effective and for those reasons, I think it's going to be a winner, at least in my practice.

Dr. Gary Monheit: I can also say from patients who've been in this study, many of them are coming back now and asking for a MelaFind to be done on their other moles. And those, when you're actively doing the procedure who are looking at the screens, seeing the pigment pattern evaluation, are really getting into it and actually learning how to evaluate their moles better themselves.

So in addition to that, it's becoming a teaching tool for their self-examination. They say, "Oh, is that what you're talking about," as they look at the various patterns that appear on

the screen. So they're intrigued with it. They love it. And I think once they have it done, when they come back for repeat evaluation, they're going to be asking for it.

Matt Dolan: Okay, great. Thanks a lot, guys. That's helpful.

Joseph, on the data itself, just a couple of questions. Looking at the confidence interval, and this may be splitting hairs, but confidence interval of 95% versus the endpoint of greater than 95%, are we literally on 95.00% or how does that -- how do you expect that to be perceived?

And secondly, on the reader studies, were those originally expected to be included in the submission? And the rationale behind those would be great.

Dr. Joseph Gulfo: Right. So, the protocol agreement on all sensitivity endpoints is that we want to show greater than 95% lower confidence bound. So let's not just look at the protocol agreement that was signed in October of '04, but the history of it, which was about a year prior. We proposed to FDA -- we combed the literature with the help of our expert friends and associates here and found the best paper on melanoma up to that point.

And that was a group did a retrospective study, not prospective like ours, retrospective study in a pigmented skin lesion -- in the pigmented lesion clinic in the UK. And they showed that they detected their sensitivity was a measured 94% and that was the best number in the literature from the best study in the literature.

So we went to FDA and said, Look, the best way to do this study, you can't really do a controlled trial. So number one, FDA had to accept the fact that we used the literature comparison, and they did. And number two, we said, Well, it's the best study in literature; it was a 94%. We'll show you that we're better; we'll do 95%. Okay?

So Matt, where we're literally at on the intent to treat, which is the analysis that always carries the most weight in every program I've ever been involved in, right, it's basically anyone who signed an informed consent and has a measurable observation. We are 125 out of 127, which is just, you know, I'm thrilled. And on the specific primary endpoint group, and I'll explain what group is left out of that, we're literally right at the 95%. So I am extremely confident and thrilled and feel that we have an extremely strong dossier to present to FDA.

Let me talk about the difference between the primary endpoint patients and the ones in the intent to treat. There was a group that had a clinical diagnosis of ‘definitely melanoma’ and that was the group left off. And it's a reflection of the intended use that we proposed because one would argue, well, gee, if you're calling it a definite melanoma, you wouldn't need to put MelaFind on it. And that's not true, actually. There are many reasons, especially as dermatology has evolved in the last several years, of why you'd put MelaFind on that.

One of the biggest reasons is deciding the biopsy approach. If you have something that you think is a melanoma and MelaFind confirms it, a biopsy approach you would definitely do an en toto deep biopsy with generous margins. The other important thing to know, and this is what Dr. Rigel and Dr. Monheit told me, is definite melanoma to one doctor is not definite melanoma to another doctor. So there's tremendous heterogeneity of observer observation -- excuse me, of observer heterogeneity in this disease. And that wasn't known before, really, before we came along.

We now have an 1,831 lesion trial. We have these reader studies, I won't forget that question either, and what we're showing within our trials, in this rigorous exacting trial is tremendous heterogeneity. So I think when you -- when I sit here and think about the dossier that we will present to FDA, I am extremely confident and I see multiple bases of approval within the protocol agreement.

All right, now, the reader studies. When we went to FDA and proposed the protocol, one of the comments they made, they made a number of great comments, and one of them was we'd like you to take pictures. So we incorporated into the trial pictures with a clinical camera, with a very high-end camera from about 18 inches away, the same camera about six inches away, and even a separate dermascopic camera. MelaFind can give a beautiful dermascopic image but we used a separate dermascopic camera, provided this to all the sites, standard protocol, the whole bit.

So FDA asked for these pictures. Now that's -- you do reader studies from these pictures. So to answer your question, a reader study is not an endpoint of the trial, certainly included in the exploratory secondary endpoints, ok, where we left ourselves open to do a number of analyses with the data, but it was actually indirectly something that FDA asked for. So I think they will be extremely interested in the reader study and the information that we -- that they provide.

Thirty nine dermatologists, I've never seen a reader study with 39 dermatologists. We're about to do one twice that size and we're working with probably the biggest name in reader studies who's going to do that for us. So I just -- again, I keep saying this with this grin on my face -- the dossier we have, what we've accomplished with the help of, number one, the patients, number two, our expert dermatologists, what we've been able to do is just really unprecedented and extremely exciting.

Matt Dolan: Okay, great. And just one last one and I'll jump off. The panel expectations, do you -- can you give us a feel for what that could be comprised of? There's not -- it's not wildly common to have a dermatological device on your panel. So is it an oncology panel, a derm panel, a new mix of the two? And then I'll drop off. Thank you.

Dr. Joseph Gulfo: It's a great question and thank you. So when we submitted the -- when we obtained the expedited approval, I discussed -- excuse me. When we submitted

for a pre-PMA meeting and FDA called me and they said, well -- at least we had it by phone, they didn't feel the need for a face-to-face meeting. But during that, I said to them, Look, I'd also like to discuss panel composition. And because you had told us we could go into a panel. So this is what we believe will happen. The device division has what they call a super-panel. They have a number of experts outside the agency that have been vetted and are available to serve on a number of different panels. So they will pick from that panel.

We certainly want people conversant in sensitivity and specificity of imaging products, and there's plenty of that in the device division. We also want dermatologists. I could see FDA borrowing from the drug side for dermatologists. There are a number of very well-known experts in the dermatology world that, frankly, we purposely haven't gone to in order to keep some extremely well-regarded and knowledgeable thinkers in the disease basically free from interaction with us so that they could serve, if invited by FDA.

So I've been thinking about panel for a long time. I'm very experienced in advisory committee meetings on the oncology side and I understand their importance. So this is something we've been thinking about for a long time.

Matt Dolan: Great. Thanks a lot for the time, guys, and job well done.

Dr. Joseph Gulfo: Okay, thank you.

Operator: Your next question comes from the line of [Daniel Onsted] with [HQCM]. Please proceed.

Daniel Onsted: Yes, hi. Thanks very much. Congratulations, Joseph, and everybody on the great results. I have a question for the experts, if they're still on the line. And obviously this result is going to be great for your patients and I can see definitely how it would be a benefit both medically and financially for your practice. I have a more -- an out-there question about the use of this device. Given the demographics and how busy you guys are and the way patients go, do you see anywhere in the future of the possibility where a device like this might be used by PCPs when they give their annual physical to most people?

I know that when I go to the -- for my annual physical, they do a physical inspection. I'm not sure how good the quality of that is and they certainly don't get paid anything. So it would seem to me it would be a benefit for the patients who don't go through the effort of seeing you guys on a regular basis to get a preliminary read by a device like this in the doctor's office and then you get -- and then you get referred more patients than you otherwise might because things are found by MelaFind that they wouldn't normally see.

You get a biopsy, they get a fee, patients get treated. Is that a -- is that too out-there and wild to think about and would it threaten you guys? Or how do you see a model like that?

Dr. Gary Monheit: Well, first, we're so over-jammed with what we're doing now, we welcome the device in to help us with what we're seeing. I think like anything just to prove, once we get it into the population of dermatologists, then we're going to really be able to evaluate at that point whether it can be diffused out beyond our own practices. It's kind of like post-marketing on a device or drug, you really see more of the efficacy, the efficiency and also the safety of that as it is used in a much larger sense.

I think the dermatologist's office is a testing ground. We're going to see whether this should maintain its confines within our practice or whether it will be valuable in primary care practices. And this is something that probably would help the whole medical field. But I think that we're going to have to see how it's handled by us first.

Daniel Onsted: So subject to that, you don't find that model either medically or technically unfeasible or problematic for you guys? It's perfectly reasonable to assume that might happen at some point?

Dr. Gary Monheit: Well, I still think we're going to be getting those patients, either later for biopsies or for follow-up, especially as Darrell had mentioned, many, many of these people have 15, 20 lesions that can't really keep backing up in a primary care doctor's office. And once they see them, they're going to want us to follow them on a regular basis.

Daniel Onsted: I totally agree. So I'm just suggesting it's also additive. Great, so it's reasonable. Okay. Thanks so much.

Operator: Your next question comes from the line of Ross Shaw with RA Capital. Please proceed.

Ross Shaw: Hi. Thanks for taking the question and congratulations on the data. I was actually curious as to how you distinguish between the 114 melanomas that were eligible and evaluable for primary sensitivity endpoint analysis versus the 127 melanomas overall. I guess, what was unique about the 13 that were not included in the primary sensitivity analysis?

Dr. Joseph Gulfo: Sure. So there are three ways you could get on this study. The final common pathway was the dermatologist decided the lesion was being biopsied. So the three reasons for the biopsy that were possible were 'melanoma cannot be ruled out' – overwhelming majority. 'Not melanoma' – I'm taking it off for patient concern, I'm taking it off because I think it's a pigmented basal cell, whatever, but, "It's pigmented and this is the protocol I'm running and we're enrolling you." And then the third: 'definitely melanoma'.

So in our discussions back in 2004 when we proposed a labeling for the product, which, when you broker with FDA, you propose a protocol and they ask you, "Okay, that's a nice protocol. What are you trying to achieve?" So you discuss your labeling. We said,

"Well, MelaFind will be indicated to assist in the evaluation of suspicious lesions when a decision to biopsy has not yet been rendered."

So on the basis of that last part, FDA said, "Well, is it reasonable to say if a doctor has made the biopsy decision already, they wouldn't put MelaFind on it?" And as time has gone on, five years has passed, thinking on that has evolved. So those are the 13 patients and MelaFind caught them all. But what's interesting is that a melanoma that Gary Monheit or Darrell Rigel says is definitely a melanoma, another doc – probably good chance many docs – would not feel it's definitely melanoma. So the observer heterogeneity argument really takes that away.

And then you consider also that there are plenty of times where even when the doctor feels it's definitely a melanoma, you'd still want to put MelaFind on it and that is to guide the biopsy approach, right, MelaFind can tell you -- if MelaFind were positive and the doctor has a -- feels it's definite, you definitely need an *in toto* biopsy with generous margins.

Right now, what's happened the last five years, the cosmetic craze. I have doctors telling me that patients don't want the biopsies, don't want the scars. So I had doctors tell us, "Gee, when I have MelaFind, it's going to help me convince the patients they need this biopsy."

So I am extremely confident and, based on the discussions we had with FDA, I feel that the basis of approval that we've come out of the study with, with these compelling data, are such that the intent-to-treat analysis of all comers will really carry the day because it is most appropriate. And both analyses actually beat what the goal of the study -- of what the underlying, the underpinning really, of the protocol agreement – the "Bataille et al" study. So I'm extremely confident.

Did that explain the -- did that satisfy your question?

Ross Shaw: Yes. Yes, that's very helpful. I guess I was just going through some of the numbers as well and I was curious, what was the false positive rate for the dermatologists as well as for MelaFind?

Dr. Joseph Gulfo: Okay, so, the answer is I can give you specificity of the doctors, which was 3.7%, and MelaFind was 9.5%. Now, technically 'false positive rate' is a different calculation that I can't give you yet because I don't have the full data. I have just top-line data. So I'd need all the numbers from the statistician to be able to give that to you. And someone is writing me a note that they came up with the number, but I think I need to wait till I get the final report from the statistician, okay?

Ross Shaw: Okay. Well, I guess I mean the false positive rate would be 90.5%, right, for MelaFind. And so my understanding is that the specificity would simply be the number of true negatives over the number of true negatives plus number of false positives?

Dr. Joseph Gulfo: That is specificity. False positive rate is the number of true positives over all positives. So you're going on the row, the diagnostic information, not pathologist information, which is the column, if you will, on a classic 2X2 grid of sensitivity and specificity. That's why I don't want to answer your question. I don't have all the inputs into the table.

Ross Shaw: I see. Okay. When do you guys expect to put that out?

Dr. Joseph Gulfo: The statistician needs just a little more time, okay, so I'm trying not to give too much numbers. We certainly need to have it before we file the PMA, right?

Ross Shaw: Right. Right, okay.

Dr. Joseph Gulfo: I look to have more data soon and I'd expect to have some more data for the AAD meeting, but I don't know if I'll have all of the data, okay?

Ross Shaw: Okay. No, fair enough. And then just the last question I had, and this might be something that may be well addressed by the physicians, is I guess what percent of all the people coming in to see a dermatologist asking about an anomaly would get biopsied?

Dr. Gary Monheit: I would say probably it's well over 50%.

Ross Shaw: Okay.

Dr. Gary Monheit: There are some very obvious things that we wouldn't consider. But there are subtleties – and there are some who just want to biopsy as Joseph said – who want something removed. So I would say maybe probably closer to 60% of people who come in with something will have that biopsied. And I'm sure if it's just out of fear, some of those biopsies will be alleviated with the help of MelaFind.

Ross Shaw: Right. No, exactly. So about 60%. So the other 40% are told, "Let's watch and wait"?

Dr. Gary Monheit: Exactly. Now, that may be a wise decision or it may be a decision which both patient and doctor feel a little uncomfortable about, even though they're watching. And then you're assuming the patient – one other tool we use is time, change in time, that the patient will come back if there is another change that tips the scale. Well, MelaFind, because it can see more than what we see on the surface, can actually predict a change that will occur by the pigment pattern below the surface.

So where we're saying, “Well, it hasn't quite reached that ABCDE level, we're not going to take it off now. I want you back, though, in six weeks or a month to see if that change occurs.” They may come back, they may not come back. And if they come back a year later with massive change, it may be too late. Well, MelaFind might, because of its ability to see below, pick up a subtler change that would tip the scale and allow that patient to have it removed right then rather than have to come back for a second appointment.

Ross Shaw: Right. No, so I appreciate the sort of 98% sensitivity. I guess what I'm trying to figure out is, is there any clinically relevant consequence to the 2% false negative rate and whether not biopsying some melanomas is worth the risk of missing those 2%.

Dr. Gary Monheit: Yes. Well, you know what? We have a greater percent that we don't and are coming back to see. So I think we've upped our ability to diagnose it correctly with --

Ross Shaw: Right.

Dr. Gary Monheit: -- help of MelaFind.

Ross Shaw: I see. Okay.

Dr. Joseph Gulfo: I think, Gary, too, one of the great outcomes of the undertaking is these reader studies where we're -- the paper by Friedman, et al last year looking at small melanomas, you led off with that, Gary, that melanomas above 2 mm, we had 49 melanomas with a median diameter dimension of 4.5 mm. There were 29 melanomas in that category, 40% of those --

Unidentified Company Representative: (inaudible - microphone inaccessible)

Dr. Joseph Gulfo: I'm sorry, 40% of those 49 melanomas were invasive. So small does not mean biologically benevolent. And MelaFind detected 48 out of those 49 and the experts detected just 71% of the small melanomas. And these were North America's top dermascopists giving dermascopy lectures. So the reader studies are really showing how difficult it is for dermatologists to detect disease.

So to the caller's question, MelaFind has this 98% measured lower confidence bound of at least 95% in an extremely rigorous trial where not much is known about what's happening through the eyes of physicians and we're elucidating that with our reader studies. And the numbers are coming in between 70%, 80%. So that's really the trade-off.

Ross Shaw: All right. Okay, well, thank you very much. I appreciate it.

Operator: At this time, there are no further questions. I would now like to turn the call back over to Dr. Joseph Gulfo for closing remarks.

Dr. Joseph Gulfo: All right, I want to thank everyone for calling in and sharing the excitement with us and we certainly look forward to more data, we look forward to a lot more events and sharing that with you. I just read a book on Winston Churchill and when London got bombed, he said to his population, "This is not the end, this is not the beginning of the end, but it is the end of the beginning." And I really believe at long last, this is the end of the beginning for us and there's great excitement ahead. So thank you all very, very much.

Operator: Thank you for your participation in today's conference. This concludes the presentation. You may now disconnect and have a good day.