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Event Transcript

**ISV - CCBN Virtual Healthcare Conference: Co-sponsored by
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CORPORATE PARTICIPANTS

S. Kumar Chandrasekaran

Insite Vision - Chairman and CEO

CONFERENCE CALL PARTICIPANTS

Jim Flanagan

IR Strategic Advisors - President

This question is

PRESENTATION

Jim Flanagan - *IR Strategic Advisors - President*

Welcome to the CCBN Virtual Healthcare conference, co-sponsored by Lippert/Heilshorn & Associates and RedChip Partners.

My name is Jim Flanagan. I'm President of IR Strategic Advisors, a Boston area investor relations and public relations communications firm. I'm also a member of CCBN's advisory board, and I'll be serving as your moderator today for this Virtual HealthCare conference.

For our Webcast participants who are participating live today, you may submit a question at any time by simply typing your query into the question field in the lower left-hand side of the Webcast player. I will present these questions during the Q&A at the end of each company's prepared remarks.

Should I have more questions than time allows, please be sure that we will forward all questions to company management for them to respond to directly.

The following presentation is by InSite Vision, Inc., stock symbol ISV. InSite Vision is an innovative ophthalmic company with a rich pipeline of diagnostic, therapeutic and drug delivery solutions.

Representing InSite is Dr. Kumar Chandrasekaran, Chairman and Chief Executive Officer of InSite Vision, Incorporated.

Please begin your presentation, sir.

S. Kumar Chandrasekaran - *Insite Vision - Chairman and CEO*

Good morning, and good afternoon ladies and gentlemen.

We have designed our presentation, entitled in "Putting the Pieces Together," both for the audience that is new and listening to us totally for the first time, as well as supporters of InSite Vision who want to examine the progress that we have performed since our last presentations to the investment community.

I would like to just inform you that the presentation does contain forward-looking statements, and as a consequence, I have to just let you know that the next slide is relatively self-explanatory, and I'm not going to take the time to read through it. But just to let you know that you should refer to our public filings, the 10-K as well as the 10-Q.

InSite Vision's focus is on ophthalmology. It is traded on AMEX under the symbol ISV. And the mission of our efforts is to bring normal ophthalmic products to market. And we endeavor and are going to accomplish this task by in-licensing promising compounds with potential applications in ophthalmology, and entering out-licensing agreements and corporate partnerships as products reach late stage clinical development.

InSite presents a strong investment opportunity to the community. It presently has a strong product pipeline covering various aspects of ophthalmology.

Ophthalmology today is a large, poorly served market, and it targets patient populations that could benefit from the products under development. The technology is made possible by multiple platforms with broad product applicability.

And the products that I am going to describe to you are supported by intellectual property positions covered by over 65 issued and pending patent applications. Our product pipeline covers three major areas in ophthalmology, anti-infectives, glaucoma products and retinal diseases.

In the area of anti-infective products, we have two under development. ISV-401, which is a broad spectrum antibiotic, we anticipate entering the market in 2005. ISV-403, a fourth generation fluoroquinolone product, we anticipate entering the market in 2006. In glaucoma products, OcuGene, our glaucoma genetic test, is presently being marketed, and 2003 will be the year where we formally launch the product to the eye care community.

ISV-205 is a glaucoma therapeutic product, and I do apologize that instead of reading 2003, it should be reading, entering the market in 2005. ISV-900 is a glaucoma genetic research that would add on products to the genetic test - and I again

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apologize, it should read 2003 instead of 2005, entering the market.

And, of course, tests for primary congenital glaucoma, another genetic condition in infants that we anticipate entering the market in 2003. In retinal device in diseases, ISV-014 is our intra-scleral drug delivery device. We hope to enter the market next year, in 2003.

And looking at 616, looking at angiogenesis inhibitors for retinal disease, our anticipated entry in is in 2006, thereby providing to the investment community a rich product pipeline with entries presently through the next short and medium term time period.

Anti-infective products ISV-401 and 403. We use this next transparency, if you would, or the slide, to try and express to you the key attributes of both these product candidates. The indications are designed for bacterial conjunctivitis, an indication that is relatively easy to demonstrate and get to the market as the first entry, and thereby expanding the claims to other indications.

ISV-401 on your right-hand - on your left-hand side, is the first ophthalmic use for an orally active and widely used drug, azithromycin. The target is for the general practitioner, the pediatric and the ophthalmic community marketplace.

The attributes are principally bactericidal. The mode of action - it inhibits protein synthesis. And the activity we are examining is for staphylyus (ph) and other bacteria, including chlamydia, major cause of the blinding disease glaucoma in other parts of the world.

By comparison, ISV-403 is going to be the first ophthalmic use for a totally new product and new drug candidate, thereby entering an ophthalmic market with a new chemical entity.

And the attributes of ISV-403 include both bactericidal and bacteriostatic protection. It inhibits DNA synthesis, and the targets we are examining is pseudomonas and Gram-negative and Gram-positive bacteria.

ISV-401 azithromycin, as I expressed before, is a broad-spectrum antibiotic. We have now formulated this antibiotic in our proprietary drug delivery technology termed DuraSite. It's a time-release eye drop mechanism. And we have now successfully completed both Phase I and Phase II clinical trials with no safety considerations and issues, and good demonstration of efficacy.

Phase III clinical trials are anticipated to begin in the first half of next year. We do anticipate meeting with the Food and Drug Agency during the course of January to present to them the regulatory package summarizing the development activities to-date, and to get their buy-in and support as we move into pivotal clinical trials.

You will be extremely interested in the results of our Phase II clinical trials with ISV-401. This was a multi-center study conducted in sites in various parts of the United States. And for the first time demonstrated that the low-dose requirement of an antibiotic could successfully inhibit and demonstrate efficacy.

Six drops were dosed over five days. Bacterial eradication was seen in 90 percent of the patients. The drug was effective in treating 100 percent of cultured Gram-negative organisms. It was effective in treating 86 percent of cultured Gram-positive organisms.

The ocular comfort and safety profile of azithromycin dosage form was similar to that of vehicle (ph) and provided good ocular and topical comfort.

In contrast, ISV-403 is from a class of drugs called fluoroquinolones. It's a fourth generation fluoroquinolone, and similar to that of azithromycin. It has been formulated in our time-release drug delivery system, DuraSite.

The potential of the product is to treat bacteria resistant to current therapies. We anticipate to receive reduced dosing frequency from this product and to demonstrate broad bacterial sensitivity against Gram-positive and Gram-negative bacteria.

To emphasize these last two points, I would like to just focus on the next slide for a few moments with you. First I should point out that this study was conducted at an external center, done without any financial support from InSite Vision, and was designed to try and evaluate the effectiveness of the ISV-403 dosage form against ciprofloxacin resistant stapholeus (ph) bacteria.

The first two bar graphs, reading it from your right-hand - from your left-hand side, demonstrates at the same concentration of drug A-Q versus B-S, that the drug delivery system, B-S, enhances the effectiveness of the kill. The kill is to try and reduce the magnitude of the bar graph on the ordinate scale.

The second and the third bar graphs demonstrate the effect of the intense concentration of ISV-403, suitably formulated in the drug delivery system, thereby demonstrating almost a

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four-fold log reduction in bacterial kill in a very short time period, giving us confidence that we would like to then move forward with the development of this program, as an effective topical antibiotic.

We are extremely pleased that we do now have the opportunity to co-develop this program with Bausch & Lomb. We executed an agreement with Bausch & Lomb in August of this year, and the licensing agreement was for the treatment of ocular bacterial infections.

Bausch & Lomb has exclusive worldwide commercialization rights in all geographies, excluding Japan, and shared rights in Europe. InSite Vision has the responsibility to develop the program through NDA approval. Bausch & Lomb's responsibilities are to take initial preferred equity position and make milestone payments, to manufacture and market the product and make royalty payments from product sales.

We anticipate that the combination between these two antibiotic products will really give InSite Vision and its corporate partners a relatively strong product portfolio in dealing with the whole area of ocular infections.

Turning to glaucoma products, our efforts in the area of glaucoma are designed more from genetic principles, and presently, we have four activities under development and some in the market. OcuGene glaucoma genetic test was pre-marketed during this year and will be formally launched in 2003 with added vigor, which I will describe to you in a short while.

ISV-205 is a glaucoma therapeutic product, the first product designed to address the causes of glaucoma. And it has now successfully completed Phase II trials, which I will also describe to you in a few moments.

Additional genetic research is going to additional genes that will be then incorporated into the OcuGene glaucoma genetic test.

Totally separate from glaucoma in adults is the area of primary congenital glaucoma, a disease genetically driven, affecting infants. And now we have assay development completed for this segment of the genetic endeavor.

To emphasize the whole concept of genetics, if you would, the next slide simply sort of, it totally describes the evolution, if you would, going through a genetic map, cloning the particular gene, which then leads really into three directions.

The direction of diagnostics, which is designed towards preventive medicine. On the other hand, it leads towards a basic understanding of the biological defect that leads to glaucoma therapy. And most importantly, on a later stage, leading to the whole concept of gene therapy.

The two markets that we are addressing today is the diagnostic and the drug therapy market, and the market that we are examining on a very relatively low scale today, but will become active in the future, we hope, is the concept of gene therapy.

I'm happy to report to you that InSite Vision now has almost 30 issued and pending patent applications covering all the glaucoma genes that have been presently discovered. Our goal is to screen for all the major genes that become available to us also in the near future.

Presently, our portfolio consists of three major categories of genes. One that addresses adult onset glaucoma, which is resident in what we call the TIGR gene, as well as a second gene called the optineurin gene. You may see me later address it by TIGR and OPTN.

There's a second section, which is called modifier genes that essentially act as additives, if you would. And we have two genes there, which is the APOE gene and the CY-P1-B1 gene. And in the category of primary congenital glaucoma, we have the CY-P1-B1 gene.

Simply to address to you in relatively brief detail on the next transparency, I just give you pictorially a little bit about the TIGR, which is also called the myocilin gene in other parts of the literature. We examine what's called single nucleotide polymorphisms, called SNPs, but our major consideration in glaucoma and the OcuGene program at the present time deals with what we call the mt-1 variant, which is the gene allele.

We have spent considerable time over the years researching the TIGR gene. And we have a relatively large portfolio of publications and abstracts that have already been out in the literature, and others that are under progress, which I will describe to you in a few moments.

What these results show is that TIGR mt-1 variant is associated with a more rapid progression of glaucoma.

Now, I should also point out right at this moment, which I will then support in a moment, that this is an absolutely new concept in the whole management and treatment and progression of glaucoma. And, of course, has raised some controversy in the

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scientific community. And our efforts have been to try and support, neutralize and normalize such criticism by strong scientific publications and (inaudible) and statistical evidence.

Presently, our statistical evidence show very clearly that the mt-1 variant accelerates disease progression. Analysis with glaucoma patients over the age of 35 years that have been followed up by over 15 years to 30 years follow-up, demonstrates and is the basis of this very strong statistical evidence.

It thereby provides the mt-1 variant as a strong marker for glaucoma progression, and efforts presently are underway to ensure that the scientific and clinical community has access to this information in a timely fashion.

These studies have been performed at extremely well-reputed glaucoma centers in the United States, with complementary work going on in other parts of the world, including Europe and Japan.

These studies have always now brought in the new concept of time. But if you simply examine a slice in a particular time element, the next slide, which then speaks about the association mt-1 with glaucoma severity, demonstrates that people who have the mutation may be having a more severe case of glaucoma.

In other words, they are now trying to provide, if you would, a crystal ball, trying to provide additional information to the eyecare practitioner, whereby we can now assess elements of risk, risk factors, risk association – concepts that presently are not available.

Intraocular pressure is one such diagnostic parameter. Visual fields, peripheral vision is a second parameter, which is also expressed in the next transparency, which again demonstrates the severity with people who have the mt-1 variant compared to those who do not. In other words, the essence really is that you are now using the variant for the first time to try and relate to how glaucoma progresses over time – time that could be 15, 20, 25, 30 years in a patient's lifetime.

These concepts are being further strengthened and utilized in what is we now define as the OcuGene glaucoma genetic test. It is the first genetically-based diagnostic test. It is easy to use. It's an active (ph) form. The analysis is provided by Quest Diagnostics, which is one of the largest clinical testing laboratories in the United States. The information regarding the genetic mutation is then provided from these testing lab directly

to the eyecare practitioner. Realizing this concept is a totally new one, education of the eyecare specialist is key.

Our efforts in the coming year is to have a strong strategic marketing plan for the continued launch of OcuGene. I have spoken previously on our efforts to examine opportunities for OcuGene in Europe and in Japan. And we anticipate in the very near future to be able to highlight and inform the investment community on the fruits of these endeavors.

Needless to say, any good marketing plan must have strong scientific data. And presently, we have numerous manuscripts and abstracts submitted to respected peer review journals and conventions. Our efforts are to market OcuGene to ophthalmologists and optometrists, and make our presence known in major conferences.

And I'd just like to start by saying we have a major optometry conference in San Diego at the end of this week, where InSite will be presenting. We also have abstracts presented to the Glaucoma Society meeting, which will be held in San Francisco in March, the International Congress of Ophthalmology and Glaucoma to be held in Barcelona in spring, and the ARVO conference – the major conference for research – that will be held in Fort Lauderdale in May of next year.

We've also made our presence known to the ophthalmic and optometric community by suitable publications in respected journals.

The ISV-205 glaucoma therapeutic product complements OcuGene. It inhibits the expression of the TIGR protein, the protein which is the end of – end result, if you would, of the TIGR gene. It's a diclofenac-based topical therapeutic, again, formulated in our DuraSite system. And InSite Vision has now successfully completed two Phase II trials.

Trial 2A was designed to demonstrate efficacy in blocking intraocular pressurize in patients treated with a steroid and 2B was to demonstrate efficacy in lowering intraocular pressures in patients who test positive with the OcuGene test.

These results are now all being compiled and are being submitted to the Food and Drug Agency, whereby we expect to design with them appropriate Phase III trials necessary for product approval. Active discussions are going on with multiple partners at the present time.

The next two slides very quickly, sort of simply demonstrate to you the difference between the two groups. A group which is

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on vehicle (ph), the other group which is on the drug, and the effect of the mt-1 variant in slide – the first slide.

And the next slide where it talks about the mt-1 variant, as well as the mt-11 variant, simply demonstrating to you a very high significant MT value for pressure measurements taken at time zero, namely the first measurement taken in the day where pressure tends to be the highest, demonstrating in these two slides the importance of the genetic variant marker and the effectiveness of the drug.

Of course, we are trying to keep our pipeline fertile (ph) on genetic information, so our efforts go towards extensive genetic research. The optineurin, OPTN, the APOE gene are complementary to OcuGene. InSite Vision has exclusive worldwide diagnostic and therapeutic rights to these genes, and Quest Diagnostics is presently developing tests to incorporate both these genes.

A few words about each of these genes for clarification. The optineurin gene was licensed in from the University of Connecticut Health Center. It is related to a subset of glaucoma which is called normal tension glaucoma.

Normal tension is usually difficult to detect, as loss of vision occurs without elevated pressure, used as a surrogate marker. Normal tension is found quite extensively in the United States, and to a very high percentage in the Japanese population.

The APOE gene relation of this gene to the optic nerve and visual field damage is extremely important in glaucoma patients.

Finally, congenital glaucoma simply shows a little picture of an infant with bulging eyes, sometimes mistakenly to show that the eyes look extremely beautiful. And in this particular case it's a genetic disease where the pressure starts to really increase. And it's one of the largest cases of misdiagnosed infant diseases.

It is a significant cause, which is shown in the next slide, of infant blindness. And InSite Vision presently has the exclusive rights to all the gene mutations associated with this disease. Development of a commercial test is in the initial phases with Quest Diagnostics. And early diagnostic diagnosis of this disease is going to allow for early treatment. It's going to reduce a vision loss, and it's going to prevent misdiagnosis.

Then the whole area of retinal disease, which primarily is focused in what we call the posterior segment of the eye, the back of the eye. It affects diabetics and a significant portion of diabetics will develop indications such as diabetic retinopathy.

It affects a large percentage of people with presymptomatic AMD, and it's projected to increase significantly over the next 20 years. And a good number of people in the United States have some vision loss related to AMD and diseases of the retina.

InSite's efforts are two-fold. ISV-014 is an intra-scleral device, and I briefly show in this slide to you the comparative efficacy of steroids in preventing retinal damage.

I'm not going to take you through the slides, but the end results of these experiments do demonstrate that one could use the device which I'm going to share with you in the next couple of slides for the delivery of steroids in a relatively non-invasive fashion to the ocular compartment.

The next slide, which demonstrates and pictorially shows you an intra-scleral drug delivery device – it's for animal use – which generated the results shown in the previous slide, whereby we had a pump, a handle, a platform, a micro needle, for relatively innocuous delivery of drug to the sclera of the eye – the outer surface of the eye.

The animal model now and the information used from these animal studies have been incorporated in the next slide, which is the design for human use. In our efforts for the human use for the eyes, is to try and get regulatory clearance.

And in the next slide, we sort of demonstrate to you our overall what they call the 5-10-K strategy. Designs for human device are in progress. We are building human devices for functional and clinical testing. Collaborative agreements with potential development partners are ongoing, and our efforts are all directed towards submitting regulatory documents to the Food and Drug Agency.

In our ISV-616 – and I apologize for the slide, it should be 616 – the whole goal is to try and see if one could relatively innocuously deliver drugs to the retina. And our efforts here is to try and use our proprietary drug delivery system, DuraSite, for drugs to be delivered topically as eye drops, and using some active transport mechanisms to carry the drug to the back of the eye.

Presently, we have successfully formulated compounds that prevent angiogenesis. These are being designed to treat retinal diseases, including diabetic retinopathy and macular degeneration. And initial studies indicate that sufficient drug reaches the retinal tissue from eye drops in concentrations and drug levels necessary to prevent angiogenesis.

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Presently, discussions are ongoing with potential corporate partners, with the further development of this product.

Many of you may have heard our quarterly call that we shared a few weeks ago. But for those who may not, we just present to you selected financial data. And at the present time, one of the major efforts ongoing at InSite Vision is to strengthen our balance sheet. And I have described previously to you efforts that are going on towards discussion with potential corporate partners, looking at selected M&A activities, et cetera.

We are extremely hopeful that the fruits of these efforts will be very productive to InSite Vision going forward.

As potential investors, what you can expect from InSite as the new year comes upon us, is to try and eliminate some of the corporate partnerships. I do hope to be able to share something with you in the very short time period of this year.

We hope to initiate and anticipate initiating pivotal Phase III trials with azithromycin in the first half of next year. We anticipate initiating clinical trials with ISV-403 in the first half of next year.

We hope to generate significant revenue from OcuGene during the course of next year. And our hope is to introduce a totally new genetic test for the infant marketplace in the form of an assay for primary congenital glaucoma.

And in conclusion, to all of you, the investment considerations for InSite Vision is still simply driven by us having a rich pipeline of innovative ophthalmic and diagnostic and therapeutic products that are designed to serve a large, poorly served population.

And everything that we do have is supported by technologies with broad applicability, strong intellectual property, and agreements with recognized industry leaders in this segment and the overall segment of the pharmaceutical marketplace.

So, collectively, for those listening to InSite today for the first time, and those who have been supportive, many thanks to all of you. And our efforts are all designed to demonstrate progress and "Putting the Pieces Together" moving forward.

We do appreciate your attention and your continued support. Thank you, ladies and gentlemen.

QUESTIONS AND ANSWERS

Jim Flanagan - *IR Strategic Advisors - President*

And thank you, doctor. We'll move now to the first of our questions. And from one of our audience participants today.

This question is

Why do you anticipate such a lengthy timeframe to begin Phase III trials for ISC-401?

S. Kumar Chandrasekaran - *Insite Vision - Chairman and CEO*

It's a very good question, and I don't think the time is lengthy from the standpoint the Phase II results have all now been summarized. As we speak, the package of information that covers everything from pre-clinical work, Phase I results, Phase II results, Phase III protocol plans, will be now submitted to the agency during the course of this week, to permit us to have a discussion with the Food and Drug Agency round about the middle of January.

Our efforts here is to ensure that between us and the Agency there are no surprises, and to ensure that we do have buy-in from the agency on the clinical trials and the results necessary for product approval.

The product and clinical units are going to be manufactured during the first quarter of next year, once we have the buy-in from the agency. And our efforts after that is to rapidly go into clinical trials.

So, our efforts are to try and see if we can initiate. There is one Phase I, Phase III clinical trials. Both in the United States as well as in the international arena before the first half of next year. And it could be as early as end of March or early part of April.

But I think any circumstances, that's a relatively rapid timetable.

Jim Flanagan - *IR Strategic Advisors - President*

Thank you for elaborating on the timeline. That was one of the follow-up questions.

Just a point of confirmation. At one time was 401 to be on the market in 2004, and is that still the case?

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S. Kumar Chandrasekaran - *Insite Vision - Chairman and CEO*

I'd just put in here between - we have just put in 2005. It may be 2004. It all depends how quickly we can recruit the patients and get volume from the agency towards the product launch.

So, we always said, it's going to be somewhere between the end of 2004, and 2005. So, it's in that general timeframe.

Jim Flanagan - *IR Strategic Advisors - President*

Thank you. We have time for only one more question. And that's, could you provide for our audience the size and growth rate of the ophthalmic anti-infectives market? And what factors are going to drive this growth going forward?

S. Kumar Chandrasekaran - *Insite Vision - Chairman and CEO*

It's a wonder question. I would be happy to do so. The anti-infective market today is round about 750 million. It is growing, and we anticipate that within the next few years, it will be close to a billion dollar market.

It's growing because of the advent of not really new antibiotics. Antibiotics that is going to prevent resistance - antibiotics that's being designed to be more user-friendly (ph).

And in our particular case, we hope to really tap a significant part of this market by addressing the pediatric and general practitioner market, especially with the ISV-401 azithromycin, the product attributes really permitting good pediatric use by its infrequent dosing opportunities.

Jim Flanagan - *IR Strategic Advisors - President*

Excellent. That's all the questions that we have time for. We remind our audience and our company presenter that any additional questions will be forwarded on to company management for a direct response.

We thank Dr. Kumar Chandrasekaran today from InSite Vision, Inc., stock symbol ISV. For our real-time Web participants, we'd like to thank you for your time. For our participants, to listen to the next Webcast, please close your media player and return to ccbn.com, redship.com or lhai.com, and click on the agenda URL for the CCBN Virtual Healthcare Conference.

S. Kumar Chandrasekaran - *Insite Vision - Chairman and CEO*

Thank you.

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