

# Jim Little

Vice President of R&D, Second Sight

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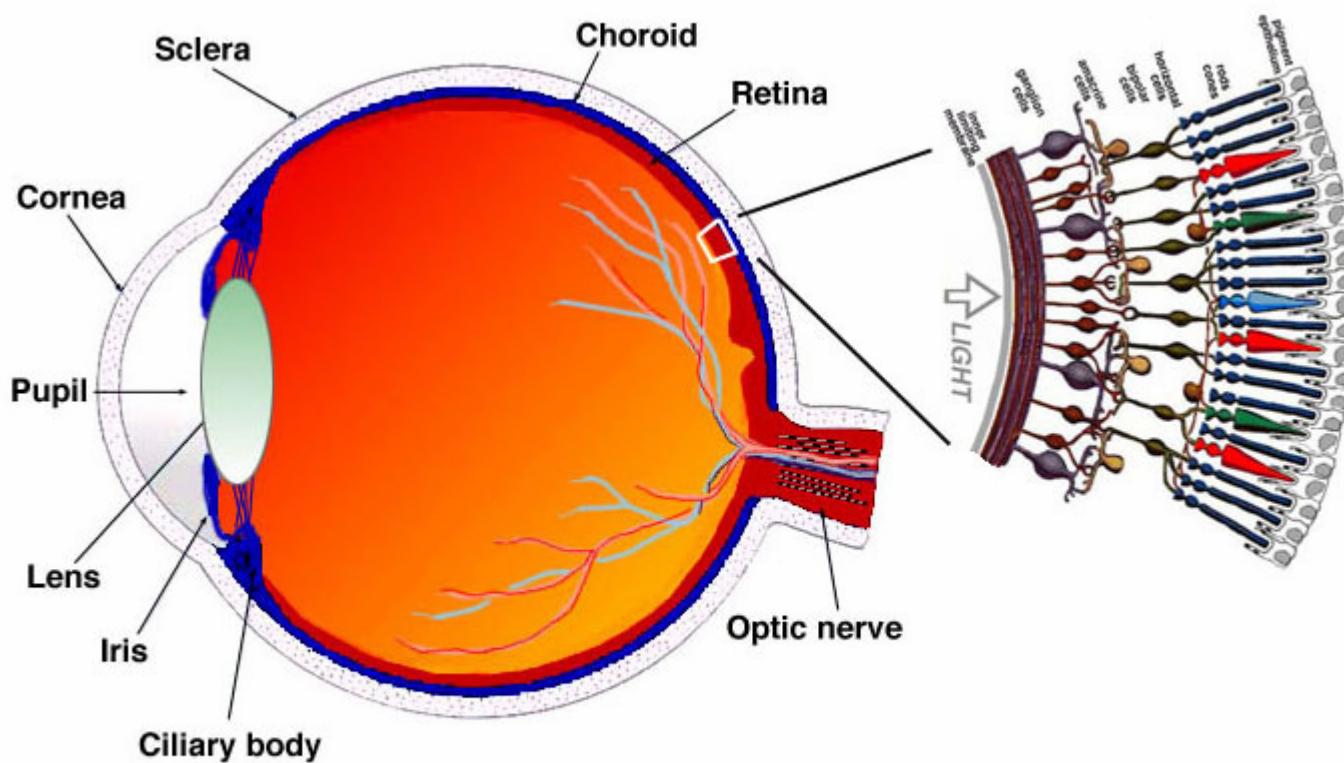
Second Sight

# Second Sight: Providing Vision to Patients Blind from Outer Retinal Degeneration

VM Global Leadership Summit

March 21, 2012

# The Retina



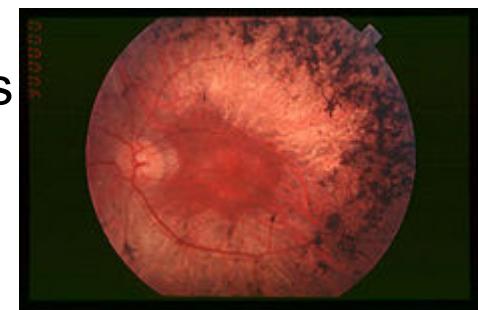
*Fig. 1.1. A drawing of a section through the human eye with a schematic enlargement of the retina.*

From Helga Kolb, Webvision

# Outer Retinal Degeneration

Characterized by loss of some or all photoreceptor cells in retina

- Age-related Macular Degeneration (AMD): affects ~2 million Americans
  - Dry AMD: loss of RPE cells compromises photoreceptors. No known cure.
  - Wet AMD: adds vascular overgrowth. Laser photocoagulation has shown value in early stages of disease.
- Retinitis Pigmentosa: affects ~100,000 Americans
  - Genetic disorder with no known cure



# Treatment Possibilities on the Horizon

- Pharmaceutical treatments
  - Anti-VEGF therapy. Injected into eye, may slow progression
  - Avastin, Lucentis, etc. (already in use)
- VisionCare: IMT telescope for treatment of AMD
  - Implanted in capsular bag
  - Magnifies 2.2-2.7x: allows central image to be projected on healthy perimacular retina
  - Market approved by FDA, CE, Israel
- NeoVista: focal delivery of radiation for treatment of subfoveal choroidal neovascularization from wet AMD
  - Study enrollment completed 10/09, results due 3/12



# Treatment Possibilities (cont'd)

Advanced Cell Technology: Stem cell therapy study for AMD

- First ever FDA approval of trial using human embryonic stem cells
- RPE cells are grown from embryonic stem cells, then injected into the back of the eye.

All are aimed at slowing progression of the disease or maximizing utility of remaining visual function. None are “cures”, nor do they replace function that has been lost.

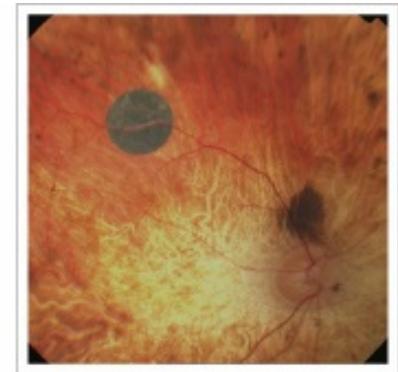
AND NOW, RETINAL PROSTHESES.....

# Retinal Prostheses

University research projects at Johns-Hopkins, USC, Harvard/MIT, Stanford, Wayne State, several international universities. Common objective is to bypass damaged photoreceptors and stimulate remaining neurons.

## Optobionics

- Subretinal silicon chip to convert incident light directly to electrical stimulation
- Feasibility US clinical trial beginning in 2000 failed to show visual benefit; company failed



ASR® device implanted in the human eye

## Intelligent Medical Implants

- Spun out of German consortium/ University of Bonn
- Active EU clinical trial of epiretinal device, but not recruiting. On hold following device issues in patients.

# Retinal Prostheses (2)

## Retina Implant AG

- Spun out of German consortium/ University of Tübingen
- Amplified subretinal chip with external power source
- Seven subject short-term clinical study in Germany completed. Enrolling a second study (45 subjects)

## Second Sight Medical Products Inc.

- US commercial effort, collaboration with Johns-Hopkins and USC
- Investor and NIH funding, DOE collaboration. Total >\$100 million
- Completed clinical studies, CE-Marked epiretinal product, in commercial distribution in EU
- Applied for FDA approval



# Second Sight History



- Founded in 1998 to develop, manufacture, and market implantable prosthetics to help overcome visual impairments.
- 100 employees in US and Europe
- More than 150 issued patents (110 in the US)
- Developed and clinically tested Argus® I prosthesis for proof of concept in 6 US subjects (2002 – 2004).
- Developed and clinically tested Argus II prosthesis as a marketable device for severe to profound outer retinal degeneration.
  - Clinical trial showed positive safety and reliability profile in 30 subjects at 10 clinical sites in US and Europe.

# HOW THE DEVICE WORKS

Subject  
Date 4/2/2012

# Performance Demonstrated in Clinical Trial



Performance	% of subjects who perform better with System ON versus OFF
<b>Visual Function Test</b>	
Visual percepts	100%
Square localization	96% perform better ON vs. OFF
Direction of motion	57% perform better ON vs. OFF
Grating visual acuity	23% measured 2.9 logMAR or better ON vs. 0% with OFF
<b>Orientation / Mobility</b>	
Following a line	54-82% avg. success ON vs. 15-26% OFF
Finding a door	52-60% avg. success ON vs. 8-44% OFF
<b>Character Recognition</b>	
Letter / word recognition	53-74% avg. success ON vs. 10-16% OFF

Trial also demonstrated a clear and significant improvement in visual function, both in the clinic and in patient's daily lives.

# Blind Subjects Reading with Argus II

# Argus II: Making a difference

# Market launch

- A European notified body approved application of the CE Mark in 2011 based upon results of the clinical trial and a comprehensive review of the device and our quality system.
- Second Sight launched the Argus II in Europe during the 4<sup>th</sup> quarter of 2011. The system is already reimbursed at \$100,000 in Germany and Italy. We are working on reimbursement in other countries.
- Second Sight submitted a market application to FDA in 2011, and we hope for US approval during 2012.
- We're looking for a commercial partner for faster global launch scale-up.



Second Sight



# Thank you

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