OPTOBIONICS STAYS FOCUSED AS RETINA IMPLANT PROCESS PLODS ALONG

By Elizabeth Gardner
Small Times Correspondent

June 16, 2003 – When your goal is to make the blind see, the last thing you want is hype.

Optobionics Corp. is doing its best to avoid hype these days as it shepherds its Artificial Silicon Retina, a 2-millimeter-wide chip packed with 5,000 tiny photodiodes, through the arduous process of regulatory approval. A decade of safety tests on animals was followed by three years of safety testing in humans, and another two or three years of testing is coming up – this time to establish how well the chip works as well as how safe it is over several years.

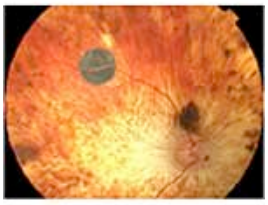
The latest results are promising: None of the 10 patients in the safety test have had any problems so far with the implant, which is inserted under the damaged area of the retina. All 10 upgraded their vision, said company co-founder Alan Chow, a pediatric ophthalmologist. One who had seen only darkness can make out blurry shapes; another who had been at the blurry-shape stage can distinguish between the teams at a basketball game. Another who had only been able to make out his hand in front of his face can read 25 letters on an eye chart and see cars well enough to comment on how ugly they've become. The results will be published later this year in a major peer-reviewed ophthalmology journal.

The Naperville, Ill.-based company has moved with deliberation since its official founding in 1997 by Chow and his brother Vincent, an electrical engineer. "The company was in the basement of Alan's house until last year," said acting Chief Executive Officer Stuart Randle, who came on board to manage the company from one of its investors, Advanced Technology Ventures.

Photos courtesy of Optobionics

Vincent and Alan Chow, Optobionics co-founders

Vital facts about Optobionics Corp.



An Artificial Silicon Retina implanted in a human eye.

A magnified image of an Artificial Silicon Retina chip.

The brothers have been working since the late 1980s on a way to use electrical stimulation of the retina to help patients with retinitis pigmentosa (RP) and age-related macular degeneration (AMD), two conditions where retinal cells are damaged and for which there is currently no cure. Such stimulation produces flashes of light even for people with vision loss, and the Chows designed an implant that can create thousands of flashes that function like the pixels in a television screen to create a picture. The microphotodiodes in Optobionics' implant are powered by the light that comes into the eye, like solar cells.

All the patients in the trials have RP, but AMD is by far the more common of the two diseases, with 10 million victims in the United States. alone. Clinical trials with AMD patients are in the company's long-term plan.

Among the company's investors are venture capital firms like Arch Venture Partners and Polaris Venture Partners, and Medtronic Inc. and Ciba Vision, powerhouses of medical implants and vision care respectively. They've committed a total of $30 million so far.

It's the right set of backers to take the product to market, said Robert Paull, a managing partner at the nanotech venture firm Lux Capital, who has been following Optobionics' fortunes. "There's a reason the guy was called 'The Six-Million-Dollar Man' – these devices are expensive," he said. But if insurers can be persuaded to pay for the device, "Optobionics may really have something."

Medtronic, the world's largest medical implant company, has contributed a member to Optobionics' board: Steve Oesterle, senior vice president of medicine technology. He offers the benefit of Medtronic's experience in areas like designing an effective controlled study for a medical device (where insertion of a sham device – the equivalent of a placebo in a pharmaceutical study – may be impractical or ethically unacceptable), and how to made the device economically viable. "The FDA only evaluates safety and efficacy, not whether a device is cost-effective," he said. "We have to clearly think through how to design a trial that will convince CMS (Medicare's governing agency) to reimburse for it."

Chow estimates that at least a dozen groups around the world – many of them academic researchers – are working on some kind of retinal implant technology. Only one U.S. company, Second Sight LLC in Sylmar, Calif., has gotten as far as clinical trials, and it has put implants in two patients so far.

The most promising development is one that Chow didn't expect: The chip seems to stimulate the retinal cells around it, so that the improvements in vision come as much from the patients' own cells as from the implant, or maybe even more.

"It now seems to be a therapeutic device," he said. "If it's implanted early enough, it could stop the impact of these diseases."

Company file: Optobionics Corp.
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Company
Optobionics Inc.

Headquarters
850 East Diehl Road, Suite 120
Naperville, IL 60563-9386

History
Optobionics was incorporated in January 1990 by Alan and Vincent Chow, but sat dormant until 1997, when it received outside funding.

Industry
Implantable medical devices

Employees
15

Small tech-related products and services
Optobionics is developing an artificial retina that is currently in clinical trials. The silicon-based surgically implantable chip contains thousands of ultraminiature diodes that react to light levels and emit appropriate voltage levels to induce visual signals.

Management

- Stuart Randle: acting chief executive officer
- Alan Chow: chief scientific officer
- Vincent Chow: vice president of engineering
- Peter Lord: vice president of development

Investment history
In mid-June 1997 Optobionics picked up $750,000 in seed funding from ARCH Venture Partners, Polaris Venture Partners and Advanced Technology Ventures and Polaris. Second-round funding was completed in June 2000, in the amount of $4.4 million. Polaris, ARCH and ATV all participated, as well as newcomer Ciba Vision, which led the round. Optobionics garnered an additional $20 million in December 2001, with funding from ATV, ARCH, Medtronic and Polaris.

Barriers to market
Like other firms in the medical device sector, Optobionics has to deal with extensive FDA testing – more than 10 years with animal trials and five or six with human clinical trials. On top of that, Optobionics needs to find a way to determine the cost-effectiveness of their product.

Selected competitors
Second Sight LLC, a California-based company, is also testing a retinal implant. VisionCare Ophthalmic Technologies, also headquartered in California, is in clinical trials with an implantable ophthalmic telescope to address macular degeneration.

Goals
Short-term: To work with the FDA to design a clinical trial to prove the safety and efficacy of the Artificial Silicon Retina in patients with retinitis pigmentosa. Long-term: To market a working retinal implant for patients with both RP and age-related macular degeneration, a much-more-common condition with a huge potential market.

Why they're in small tech
"An 11-year-old boy came into my office thinking he had gotten

something in his eye, and it turned out to be RP," said Alan Chow. "It was frustrating – there wasn't much I could do for him except watch him go blind."

What keeps them up at night
Acting CEO Stuart Randle: "Being on completely new frontiers in both technology and medicine. " Alan Chow: "Sheer excitement. I can start an operation at 8 a.m., finish it at 3 am, and go out and talk about it afterwards."

Relevant patents

- Artificial retina device with stimulating and ground return electrodes disposed on opposite sides of the neuroretina and method of attachment
- Multi-phasic microphotodetector retinal implant with variable voltage and current capability

Relevant articles
Obstacles clutter path for implant sector
Implanted microsystems are key to restoring sight to the blind
Company sees success and funding in helping to give sight to the blind

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