# From a Napkin to the OR: Developing a New Product

Lessons learned along the way.

**BY DONALD SCHWARTZ, MD**

At 7 o'clock in the evening on July 30, 2006, I decided to act on an idea that had been kicking around in my head for a while. I know that is when this process started, because so many people have asked how long I have been working on my company, Eye Sonix, that I went back through my e-mails to find the answer.

## BACKGROUND

It is commonly accepted that modern cataract surgery, performed with ultrasound, decreases IOP. If one could determine the reason for this effect, one might be able to refine the cause and use it to develop a way of treating glaucoma. Conventional wisdom has pointed to the increase in the anterior chamber's depth as the reason for the decrease in IOP. I do not doubt this factor's importance in eyes with narrow angles, but recent studies indicate no correlation between widening of the angle and the observed decrease in IOP after cataract surgery in eyes with open angles.[1-3] I therefore concluded that it is probably the use of ultrasound that reduces the IOP in glaucomatous eyes.

Throughout the summer of 2006, I researched possible mechanisms of ultrasound and their potential role in glaucoma. There appeared to be three specific ways in which ultrasound energy might treat glaucoma: (1) the sonomechanical or vibratory effect of ultrasound could have an impact, (2) the hyperthermia induced by ultrasound could be helpful, or (3) the specific induction of integrins could trigger the release of beneficial cytokines.[4-6]

> "I wondered if there might be a common pathway leading to the cascade that was independent of the type of energy applied."

## A LITERATURE SEARCH

Using the Internet and depending on whether the search was via Google or the National Library of Medicine, I entered various terms to find any connection between the effects of ultrasound and the physiology of glaucoma. An article by Schuman and colleagues that found phacoemulsification causes a cascade of cytokines struck me as worth exploring.[7] I read this article about the time that I was beginning to use selective laser trabeculoplasty, and I wondered if there might be a common pathway leading to the cascade that was independent of the type of energy applied.

Work by D. Jackson Coleman, MD, resulted in the use of cyclodestructive ultrasound to decrease aqueous inflow.[8-12] I did not believe that the phaco energy imparted to the ciliary body during cataract surgery was sufficient to obtain the same outcome; rather, I suspected that phacoemulsification affects aqueous outflow.

Articles published in the oncology literature indicate that induced hyperthermia can trigger inflammatory cytokines at a temperature just below that which causes cellular death and pain.[13-15]

## LABORATORY WORK

It took five prototypes using varying frequencies and powers to reach and maintain the ideal temperature at the proper depth below the surface of the limbus of a porcine eye. In an animal testing laboratory, I performed studies on swine and rabbits. The histopathology confirmed that inflammation located within the outflow pathway was minimal.

I approached an institutional review board in hopes of testing the tolerability of my device on subjects with blind eyes. The device was considered by the institutional review board to be associated with an insignificant risk, and the patients tolerated the procedure well. I developed a protocol to treat eyes with glaucoma, and my 1-year results from this study are exciting. I presented the results at the ASCRS meeting in Chicago.[16]

The journey has been exciting, frustrating, expensive, and energizing. I have had to juggle concerns regarding intellectual property, research, and fundraising. I have used my own savings to pay for patent rights, prototypes, and the studies, among other items. I have converted appointments with paying patients to "study follow-ups" in which I reimburse individuals to be a part of the investigation.

## SEVEN LESSONS LEARNED

I have learned a several things from my experience.

No. 1. For intellectual property, one must have a device that is novel, useful, and not obvious. One must therefore review the prior art carefully.

No. 2. Today, the regulatory route is bifurcated with most device companies' seeking initial approval outside the United States. I hope the FDA's goals of increased transparency and clarity will allow for a more secure route in this country.

No. 3. Persistence is king.

No. 4. Investors are leery of being first. They like to see more than one person with a stake in the company before they invest.

No. 5. A "single-man company" is a double-edged sword. One can make decisions rapidly, but investors are concerned that this person may be unwilling to "let go" eventually. One must gather an advisory team for its science and business acumen.

No. 6. Investors evaluate hundreds of deals each year, so it is wise to keep one's presentations to them short and interesting. The details can be filled in later.

No. 7. The hallmarks of a good investment are secure intellectual property and a clear pathway to the market. One must keep these goals in mind from the first day.

## CONCLUSION

Every day, I wake, pick up my 30-pound rock, and move it down the road a bit farther. It is neither easy to throw nor too heavy to lift. If I do not pick it up, it does not move. ■

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*For more on this topic, visit http://bmctoday.net/crstoday/pdfs/0212_supp.pdf to read "What Does it Take to Be an Innovator?" by J. Andy Corley.*

*Donald Schwartz, MD, is a clinical professor at the University of Southern California Doheny Eye Institute at Keck School of Medicine and an associate clinical professor at the University of California Irvine. Dr. Schwartz may be reached at (562) 427-5409; dschwartz@longbeacheyecare.com.*

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