Obtaining Funding for Novel Projects

AN INTERVIEW WITH MARK S. HUMAYUN, MD, PHD

The Argus II Retinal Prosthesis System (Second Sight Medical Products Inc.) received approval from the US Food and Drug Administration (FDA) for the treatment of late-stage retinitis pigmentosa (RP) in February.

The Argus II is intended to provide electrical stimulation of the retina to induce visual perception in blind individuals with RP. The FDA approval came following more than 20 years of work in the field; 2 clinical trials; more than $100 million in public investment by the National Eye Institute, the Department of Energy, and the National Science Foundation; and an additional $100 million in private investments, a news release from the company said.

In this first installment of Translational Research, Michael J. Koss, MD, speaks with Mark S. Humayun, MD, PhD, about the challenges of receiving funding for this groundbreaking technology. The goal of this new column is to dig into the issues revolving around innovative research that are often not addressed in print. We welcome any ideas that you have for topics that you would like to see addressed. Dr. Koss may be reached at michael.koss@me.com; or you may contact Rachel M. Renshaw, Editor-in-Chief, with suggestions at rrenshaw@bmctoday.com.

Michael J. Koss, MD, FEBO: *The recent FDA approval of the Argus II retinal prosthesis represents a major milestone in your personal and professional career. Can you please tell us about the beginning of the whole project in terms of funding—was that easy to acquire?*

Mark S. Humayun, MD: Most long-term funding takes time and a lot of perseverance to secure. In this particular project, we had little to no funding for the first 5 years—not even $10 000—and this was largely because the idea was really quite innovative and unproven. The more risky a project, the harder it is to get the money early. The take-away here is the need to persevere.

Perseverance requires thick skin and the ability and willingness to seek funding from many different organizations depending on the nature of the project. For example, our first funding came from the Whitaker Biomedical Engineering Foundation, and I believe that we were successful because we were proposing electronic circuit development, which is an engineering project. After we received that funding we were able to develop the circuit for the prosthesis. This was followed by funding from the NEI, and then we got more substantive funding from organizations such as the National Science Foundation and Department of Energy.

Dr. Koss: *How important is it to have a good track record when it comes to obtaining grants? In other words, is it easier to qualify for funding if you have been successful in the past?*

Dr. Humayun: One grant often can lead to another—success builds on itself. The academic litmus test is to obtain grants from either the National Institutes of Health or the National Science Foundation, but really what leads to subsequent funding is what you were able to achieve with those early grants. Were you able to meet the timelines and objectives? Did you address the questions and further progress the science around your project? Showing ability in these areas is what helps the most for future projects.

Dr. Koss: *When the retinal prosthesis was ready to be presented to industry and you were seeking co-funding from them, what was the overall reaction?*

Dr. Humayun: Obtaining industry funding for very early projects in which there are many aspects that remain unresolved is challenging, so it was initially difficult to get industry to buy in. In general, it is easier to get funding from industry for projects that are much further along than we were with the prosthesis. Having said that, Second Sight Medical Products was formed almost 15 years ago. Alfred E. Mann, who founded the company in 1997, had a vision and, along with other initial investors, he realized that the road to a product would be long—

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-Mark S. Humayun, MD

over a decade or even longer—but he also realized that it was important to fund this work.

Dr. Koss: *Now that you have received FDA approval, will obtaining additional grant money for an approved product be easier than when you first initiated the project?*

Dr. Humayun: Well, that's an interesting question. Early in the project it was difficult to get funding because the idea was unproven. But after a product is approved, it is difficult to get funding for a different reason—people think the project is complete and the company should take it from there. However, the reality is that a research effort in academia and/or a company needs funding throughout. Even now, for the retinal prosthesis, there are a number of fundamental challenges that we need to overcome, such as how to improve the resolution, provide color vision, and make the implant smaller, among many other improvements.

If we don't continue to improve the technology, we will only be able to help a certain subset of patients, and that is not our complete vision. For example, if we can obtain more funding for research, we might be able to make the prosthesis suitable for patients with late- or end-stage age-related macular degeneration, which would increase the number of patients we could help tenfold over just those with RP. ■

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Michael Koss, MD, FEBO, is currently a visiting researcher with the Doheny Eye Institute, where he is primarily investigating the potential of a human embryonic stem cell transplantation for the therapy of dry age-related macular degeneration. He may be reached at michael.koss@me.com.