HEALIONICS Q1 2021 Update

In Q1 of 2021, we began a follow-on human study of our revised *STARgraft* device, and neared closing of a funding round to support completion of that study and FDA market clearance.

Financial Snapshot

3/31/20 Cash Balance: $3,844k
Income and Financing in Q1:
Grant funding received: $206k
Financing received: $1,499k (Series A-1)
Operating Expenses in Q1: $505k
Grant Funding Pool: $294k thru mid-'21
(Additional $1M anticipated upon renewal of existing grant in mid-2021.)

Follow-on Human Study of revised *STARgraft*

Our *STARgraft* vascular graft (artificial blood vessel) is intended to provide a safer and more reliable means to access the bloodstream for dialysis in patients with kidney failure.

We began a follow-on human study of our revised device (*STARgraft-2*) in February. The study will ultimately enroll a total of 25 patients and follow them for 12 months, observing the graft's resistance to both infection and occlusion. Seven patients have been implanted so far and follow-ups to date have shown good blood flow with no detectable signs of the swelling issue observed in our first human study.

Funding Round

Our Series A-1 funding round was oversubscribed, closing a total of $4.7 million. These funds will be used to support the above human study and obtain FDA market clearance for *STARgraft*. Many thanks to all who participated for your support.

Market

Another comparable transaction was recently announced in our market space. Humacyte, a pre-revenue company developing a synthetic blood vessel, is going public via SPAC merger with an $800 million pre-money valuation. (Their biologic device is not expected to receive FDA approval until 2023.)

Intellectual property

The China counterpart to US patent 10,842,916 (for potential use of *STAR* material to treat age-related macular degeneration) has been allowed. We now have a total of 21 patents issued or allowed worldwide, with 12 pending.

STARport

Our *STARport* dialysis port is intended to eliminate the pain, health risks and costs associated with use of dialysis needles and facilitate a shift toward home-based hemodialysis. During Q1, we continued life-cycle bench testing of a revised design. Once this testing is complete, we will begin another animal study of *STARport* (in preparation for an eventual first human study).

COVID impact

Our clinical trial site facility in Paraguay continues to operate with strict protective measures and the majority of the surgical staff are now vaccinated. Our Seattle employees have been continuing to do much of their work from home, with access to our facility as necessary for fabrication and testing. Most of them are now vaccinated and Washington state restrictions are gradually being eased.