In Q3 of 2021, we continued enrolling new patients and monitoring existing patients in the human study of our revised *STARgraft* device.

Financial Snapshot

9/30/21 Cash Balance: $3,840k
Income and Financing in Q3:
Grant funding received: $140k
Operating Expenses in Q3: $529k
Grant Funding Pool: $1,118k *available to be drawn*

Human Study of revised device (*STARgraft-2)*

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've enrolled 20 total patients in the human study of *STARgraft-2*, with the earliest ones now at 8 months post-implant. We've seen no signs of the swelling issue observed with the *STARgraft* version used in our first human study, but did see a significant number of other adverse events during Q3. We've identified the root cause of those events to be changes made in our protocol for pre-implant device preparation. We've corrected that protocol and are continuing to implant new patients. We've implanted 7 patients using this corrected protocol and have seen excellent functional performance in all of them to date.

New OEM core *(STARgraft-3)* and Timeline impact

In parallel with the current human trial, we are in process of qualifying a new ePTFE (expanded Teflon) core, because our prior OEM vendor exited the business. We plan an animal study of *STARgraft-3* (the device incorporating this new core) to validate its in-vivo performance, but had not previously planned to perform another human trial with it. However, the recent adverse events with *STARgraft-2* increase the likelihood that FDA will require such a trial. If so, our 510(k) submission will likely be delayed to the first half of 2023. We will schedule a pre-submission meeting with FDA once the *STARgraft-3* design is finalized and we've obtained further data from the current human trial (using the revised protocol).

Quality system

ISO 13485 is the predominant international regulatory standard for quality management systems related to the design and manufacture of medical devices. Healionics has maintained continuous certification to this standard since 2013, and successfully completed its annual independent surveillance audit in August.

COVID impact

All of our employees are vaccinated and our Seattle facility remains fully operational. Our clinical trial site in Paraguay continues to operate with strict protective measures and its staff are all vaccinated.

Comparable transaction

Another transaction in our market space was recently completed. Humacyte is a pre-revenue company conducting human trials of its human-cell derived vascular graft, with FDA approval projected in 2023. The company went public in August via SPAC merger, with a current market cap of $1 billion.

iSTAR Medical update

In August, Healionics' spinout company iSTAR began enrolling patients in the US pivotal trial for its *STAR* material-based MINIject glaucoma treatment device. Data from this two-year trial will be used to submit for PMA approval by the FDA.

Best regards,
Mike
Mike Connolly
CEO
Healionics Corporation