In Q2 of 2023, we continued enrolling and following patients in the *STARgraft*-3V human study, commissioned an outside regulatory assessment of our readiness to file with FDA, met with key physicians and strategic companies, extended our international patent portfolio, completed an external audit of our quality system, and saw our spinout company reach a commercial milestone.

Financial Snapshot

6/30/2023 Cash Balance: $2,237k
Income in Q2:
Interest income + iSTAR royalty payment: $34k
Operating Expenses in Q2: $504k

STARgraft Update

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

We have enrolled 19 of a targeted 21 patients in our human study of *STARgraft*-3V (study description is at ClinicalTrials.gov). Median duration of implant is now over 4 months (first patient is over 7 months), with no device-related infections and good patency so far. We plan to complete enrollment and continue with periodic follow-up exams of patients before deciding whether to file a 510(k) late this year.

An outside assessment of our readiness for 510(k) was performed by Evera Regulatory Advisors. Their report has been particularly helpful in identifying the set of non-clinical test data we'll need for an eventual FDA submission.

Clinical / Industry Meetings

The promising early results of our current human study were presented at the Vascular Access Society of the Americas conference, where we also met with physician key opinion leaders and with several companies that could be potential acquirers down the road.

Intellectual Property

Japan approved our patent on a corrugated form of *STAR* biointerface that may be useful for a needle-free dialysis access port and other percutaneous (through-the-skin) devices, as well as an alternate potential construction of our vascular graft. (This patent is already granted in US, China, Australia, and South Korea.)

Quality System Certification

We completed a surveillance audit (with no discrepancies) to maintain certification of our quality management system under ISO 13485, the predominant international regulatory standard for medical device design and manufacturing. Healionics has maintained continuous certification under this standard since 2013.

iSTAR Medical

Our spinout company iSTAR reached a commercial milestone, having implanted over 1,000 patients with its *STAR* biomaterial-based MINIject glaucoma device. The company also presented updated clinical results at the World Glaucoma Congress.

Best regards,

Mike Connolly
CEO
Healionics Corporation