In Q1 of 2024, Healionics reached a key milestone in our *STARgraft* clinical study, began preparing an application for U.S. regulatory approval, and closed our Series A-3 financing round.

Financial Snapshot

3/31/2024 Cash Balance: $6,000k
Income in Q1:
Interest income + iSTAR royalty payment: $80k
Operating Expenses in Q1: $596k

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.

Our ongoing human study continues to show excellent results. We reached the study's primary endpoint of six-month implant duration for all active patients, and most patients have now also reached the one-year secondary endpoint (median duration of active implant is 13.5 months). The 12 patients implanted with our current version of *STARgraft* have 100% Primary Unassisted Patency through the first 6-month and 12-month post-implant periods (meaning there have been zero occlusions, infections, or other device complications requiring intervention). Only one device has occluded thus far, occurring at 14.5 months post-implant. Our 6-month Primary Unassisted Patency (the Primary Outcome Measure for our study) compares favorably to that of on-market ePTFE graft historical controls (100% for *STARgraft* vs. 69% for controls). We are continuing to monitor longer-term graft performance with periodic patient follow-up exams.

We have completed most of the third-party chemical, biocompatibility, and mechanical testing required for FDA 510(k) clearance, and are in process of drafting a 510(k) application for the current version of *STARgraft*.

Meanwhile, we continue to work with OEM suppliers to refine and test a customized replacement ePTFE core for *STARgraft* (required due to market exit of the OEM core used in our current human study, as noted in prior updates). We launched a pilot animal study this month comparing the new *STARgraft* devices (incorporating the new customized replacement core) to the current version of *STARgraft*, aiming to verify equivalent performance.

Presentation at a Major Clinical Conference

Our submitted abstract, titled *Clinical Outcomes for a New AV Graft Designed to Resist Occlusion and Infection* was selected for a distinguished podium presentation at the Vascular Access Society of Americas in May.

Financing Round

Our series A-3 equity round closed with a total of $5.5M raised. We appreciate the strong support by existing shareholders as well as the many new investors that joined this round.

Intellectual Property

India's patent office issued our patent on a corrugated form of *STAR* biointerface important for future iterations of *STARgraft* as well as a needle-free dialysis access port and other percutaneous (through-the-skin) devices. This invention has now been patented in 4 key Asian countries, as well as the US and Europe. Overall, we have a total of 36 patents issued or pending: 8 issued U.S., 24 issued or allowed internationally, and 4 pending in all countries.

Best regards,

Mike Connolly
CEO
Healionics Corporation