Healionics Q1 2023 Update

In Q1 of 2023, we continued enrolling patients in the human study of *STARgraft*-3V, assessed preliminary results, and extended our patent protection on this device in Europe.

Financial Snapshot

3/31/2023 Cash Balance: $2,700k
Income in Q1:
Interest income + iSTAR royalty payment: $33k
Operating Expenses in Q1: $609k

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 now enrolled 15 of 21 planned patients in our human study of *STARgraft*-3V (study description can be found at ClinicalTrials.gov). Median duration of implant is 80 days with the first patients now at 4.5 months. Performance looks good to date with high patency, no device-related infections, and no sign of the issues observed in earlier generation devices. We are continuing to enroll patients and perform follow-up exams, and will consider filing an FDA 510(k) late this year if data continue to look good.

We continue to work with Merit Medical to develop and bench test a customized replacement ePTFE core for *STARgraft* (as discussed in our Q3 '22 update).

Intellectual Property

The European Patent Office allowed a patent on *STARgraft*'s structure that extends its protection through 2035. (This patent is already issued in Japan and India).

South Korea allowed a patent on the 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 issued in US, China, and Australia.)

Our patent portfolio now includes 8 issued US, 18 issued/allowed international, and 7 pending in all countries.

iSTAR Medical

Our spinout company iSTAR is continuing its commercial roll-out in Europe and enrolling patients in its U.S. clinical trial. They also launched a new international clinical trial to study the use of their MINIject glaucoma device in conjunction with cataract surgery.

Best regards,
Mike

Mike Connolly
CEO