HEALIONICS Q2 2021

In Q2 of 2021, we continued enrolling patients in the follow-on human study of our revised *STARgraft* device, and were honored as a Top 50 MedTech Startup.

Financial Snapshot

6/30/21 Cash Balance: $4,227k
Income and Financing in Q2:
Grant funding received: $120k
Financing received: $1,245k *(Series A-1)*
Operating Expenses in Q2: $982k
Includes $319k one-time payment of salaries partially deferred by three key employees between 2013-2015.
Grant Funding Pool: $985k
Available to be drawn thru June 30, 2022.

Financing

As mentioned in last update, we raised a total of $4.7M in the Series A round that closed in April. Our current cash balance is projected to fund operations through the end of 2022.

PPP loan

The U.S. Small Business Administration recently confirmed that our $179k PPP loan is forgiven (meaning no repayment is required).

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.

As of June 30th, there were 13 active patients in the follow-on human study of our revised *STARgraft* device, with an average time since implant of 76 days (earliest ones at 134 days). Enrollment has been slower than expected with fewer patients presenting that meet our screening criteria (due in part to COVID), but we will start getting 6-month results on the earliest patients in August. We have seen no signs of the swelling issue observed with the earlier version of *STARgraft* used in our first human study. The incidence of device-related adverse events thus far has also been lower than that at a similar timepoint in the first human study.

COVID impact

All our employees are fully vaccinated and Washington state restrictions have been largely eliminated. Our clinical trial site in Paraguay continues to operate with strict protective measures and its staff are all vaccinated, though the vaccination rate among the general Paraguay population is still low.

STARport

The National Institutes of Health recently awarded us a 3rd year of support under our existing grant for the *STARport* dialysis port. (As a reminder, this device is intended to eliminate the pain, health risks and costs associated with use of dialysis needles and facilitate a shift toward home-based hemodialysis.)

Selected as a Top 50 MedTech Startup

Healionics has been selected as one of the "Top 50 MedTech Startups" in the 2021 MedTech Innovator Showcase competition. (Judging of the 1,100 applicants was performed by industry professionals.) As such, Healionics has received increased exposure to potential strategic partners and corporate/VC investors as a featured presenter at two recent conferences (MedTech Innovator Summit, and Wilson Sonsini Medical Device Conference) and will also be a featured presenter at the AdvaMed MedTech Conference in September.

iSTAR Medical

Healionics' spinout iSTAR recently announced FDA approval of an Investigational Device Exemption (IDE) to begin a pivotal trial of its *STAR* material-based MINIject glaucoma treatment device. After discussion with FDA, the company decided to pursue a Premarket Approval (PMA) path in order to obtain the broadest possible indications for use of its device. iSTAR's IDE study will enroll over 350 patients with primary open angle glaucoma at sites in the US, Canada and Europe, and will follow them for 2 years prior to PMA submission. Meanwhile, iSTAR expects to receive CE mark later this year, which will allow them to commence European sales of MINIject.

Best regards,
Mike

Mike Connolly
CEO
Healionics Corporation