

Healionics Q3 2022 Updates

In Q3 of 2022, we completed animal studies of *STARgraft-3* in preparation for a human study to begin in Q4. Our cash runway was extended by a one-time payment related to iSTAR's recent partnership agreement. Healionics was awarded another international patent and achieved recertification of its quality management system.

Financial Snapshot

9/30/22 Cash Balance: \$3,850k

Income in Q3:

Payment related to iSTAR-AbbVie partnership: \$1,374k

Interest income + iSTAR royalty payment: \$15k

Operating Expenses in Q3: \$576k

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.

In Q3, we completed sheep studies of *STARgraft-3V* and began analyzing results and conducting other required device testing in preparation to begin a human study later this year.

STARgraft-3V has an ePTFE core made by Vascutek that is no longer commercially available so, as previously noted, we must find a suitable replacement in order to commercialize our device. We bench-tested the available on-market ePTFE grafts as potential replacements, but found that none of these were suitable. Therefore, we began a collaboration with Merit Medical to produce a customized core. To meet our design requirements, we anticipate several prototype iterations and test cycles (working with Merit) will be needed to yield a satisfactory replacement core.

We may be able to generate enough human data with *STARgraft-3V* to submit for an initial 510(k) FDA clearance in late 2023. If not, we'll aim to submit in 2024 after completing preclinical and human studies of *STARgraft-3M* (version with the customized Merit core).

iSTAR Medical

As noted last quarter, our spinout company iSTAR concluded a strategic partnership with AbbVie. As part of this [agreement](#), AbbVie paid iSTAR shareholders \$60M in return for an option to acquire iSTAR after its U.S. pivotal human trial is completed (projected to occur in 2025). The agreement required shareholders to immediately invest 70% of that payment in iSTAR to help fund its pivotal trial, with the remaining 30% (\$18M) retained by shareholders to cover potential taxes related to the payment. Healionics' 7.6% ownership in iSTAR meant we were able to retain \$1.37M, and we believe our net operating loss (NOL) carryforward is large enough to cover the future tax obligation related to this payment.

Cash Runway

As a result of the above payment, our cash on hand is now projected to last through the end of 2023.

Intellectual Property

China issued a new patent covering an alternate potential construction for our vascular graft. Our patent portfolio now includes: 8 issued US, 16 issued international, and 9 pending in all countries.

Quality System Certification

Following an external audit, our quality management system was recertified for another 3 years under ISO 13485, the predominant international regulatory standard for medical device design and manufacturing. Healionics has maintained continuous certification under this standard since 2013.

Best regards,
Mike

Mike Connolly
CEO
Healionics [Corporation](#)