



## **2012 Research Fund Update on Histotripsy**

With funding and support from Faith's Angels and other foundations and grant funding organizations, we have made significant strides to transform our novel therapeutic ultrasound technology termed Histotripsy into a bone fide clinical recourse for congenital heart disease and other cardiovascular conditions. Histotripsy is a technique discovered at the University of Michigan and is form of high intensity, focused ultrasound that has the ability to treat and remove targeted tissue deep in the body completely non-invasively (i.e. no scalpels, needles, incisions, etc.). Our goal has been to adapt this innovative technology for specific clinical interventions for children with congenital heart disease. Children born with hypoplastic left heart syndrome (HLHS) are literally born with "half a heart" and are dependent on mixing of de-oxygenated and oxygenated blood to prove appropriate oxygen delivery to the body for survival. Unfortunately, some infants with HLHS are born without a communication between heart chambers to allow for this mixing and hence cannot support the body's metabolic demands. If a communication is not created emergently, these infants will die. Unfortunately, current technologies to create these communications are suboptimal, technically challenging, invasive, and have inherent complications including death. Histotripsy may be an alternative approach for these infants, being able to create lifesaving intra-cardiac communications non-invasively, quickly, and with less complications and challenges.

Over the past year, our research efforts have led to the design and current construction of an optimized and customized histotripsy therapeutic transducer tailored for human neonatal patients with HLHS. We have also built an integrated ultrasound imaging and therapy system prototype for our clinical device. In addition, we have continued live, in vivo, animal experiments to further delineate the safety and efficacy of Histotripsy to create intra-cardiac communications that may be lifesaving in some infants with HLHS. We plan to replicate many of these experiments in an animal model with the new customized transducer and integrated therapy system prior to applying for approval for an inaugural clinical trial from the Food and Drug Administration (FDA).

In addition, over the past year we have been characterizing the effect of Histotripsy therapy on the circulation blood volume, an important safety issue as we continue to push towards clinical applications. We are able to control the effect on the circulating blood cells by modulating our delivered ultrasound energy and by effectively "thinning" the blood with systemic heparinization. In addition, we've begun to characterize some of the biological responses elicited by Histotripsy's therapy that may reveal even more clinical applications for this therapy. These data are currently being incorporated into a manuscript and are an essential part of an application to the National Institutes of Health for continued funding for a project concentrating

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Faith's Angels Inc. is a 501c3 nonprofit organization.

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on the dissolving of blood clots (deep venous thrombosis), which is a major problem in hospitalized adults but also in children with congenital heart disease requiring cardiac surgery.

In all, the past year has been very productive and we have made continuing strides to advance Histotripsy technology closer and closer to clinical application. With continued support from Faith's Angels and other organizations we hope our goals and dreams of optimizing Histotripsy therapy to help children with congenital heart disease will be realized in the near future.

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