

Company Overview

We make novel devices to Improve Assisted Reproductive Technology (ART) spanning Human and Veterinary medicine. We have 3 solutions for ART. We created the world's 1st patented bovine intra-vaginal embryo culture device. We have POC. A semen separation device that improves sperm motility for artificial insemination (AI) and in vitro fertilization (IVF). Lastly, a micro-humidified embryo culture dish to improve human IVF in dry incubators.

Problem or Market Opportunity

The TAM for bovine and human reproduction if over \$80B. The SAM for genetics and assisted reproductive technology is \$10B and the SOM for disposable devices is over \$1.1B. As a device manufacturer, we have a broad base. We have industry connections for bovine: Dairy Farmers of America (investment and accelerator),Tyson Ventures (Demo-Day company with top 3 beef processor, 3200 ranches, process 150k head per week), AgLaunch 365. We were one of the final four out of 90 companies in the Farm Bureau Ag Innovation Competition, January,2024. We are getting known! In the human space, we were approached by one of the largest human IVF companies to develop the dish, and we are testing a novel device and generating IP with key industry partners we will advance our GTM strategy.

Technical & Competitive Advantage

Bovine IVF: Patents in US, EU, Brazil, the major regions of the world doing bovine IVF. We are the 1st to ever make a blastocyst with an IVC device. This will be the 4th form of ART in cattle. We know the 'secret sauce.' Semen separation device: Provisional patent submitted 4/24. Easier to use that other types of devices and less expensive. Working with 3rd party to produce devices that will be scalable in volume. Humidified culture dish: All marketed devices to not work. We are testing a novel prototype May, 2024 in California. The device will be agnostic to the choice of culture dishes used. The lab can use the dishes they like!

Regulatory Strategy & Intellectual Property

Animal Devices do not requite FDA approval. Significant IP already generated. We will generate revenue with animal before human. We are using Pearl pathways for IRB of the human semen separator. Provisional patent submitted. For the semen separator and the culture dish, we will take the FDA 510(k) pathway. Predicate devices are identified.

Key Milestones

Q/YYYY	Objective	Milestone Description			
Q2 2024	Bovine IVC	1st to create a blastocyst embryo in an IVC device and we have transferred to recipient a week ago. If pregnant, this will be the 1st.			
Q2 2024	Semen Separator	Prototype tests showed dramatic improvement in sperm sample parameters with human and bovine sample: Final device design in development. Provisional patent submitted.			
Q2 2024	Micro-humidified culture chamber	Micro-humidified culture chamber. This has been a lot of trial and error over the past 2 years. Provisional patent submitted. The newest design is being tested in California.			

Capitalization History

Year	Grant or Equity Type	Description	Amount
2021	Capital Raise	Self-Funded, Family and Friends	\$100K
2022	Capital Raise	Self, Friends and Family, Purdue Research Foundation, Dairy Farmers of America: (\$120k) and AgLaunch 365 (\$100K)	\$220K
2023	Grants & Funding	Elevate Nexus Regional & State Winner: (\$180K), Flywheel Fund: (\$20K), AgLaunch Famers Fund: (\$47K). Friends & Family: (\$30K), INTAP Grant - USDA grant writer: (\$3.7K)	\$280,700
2024	Funding to date	USDA Phase 1 Grant: (\$175K), Indiana Match Grant: (\$50K), INTAP Grant (\$15K)	\$240K

Current Round, Terms, and Use of Proceeds

The grant funds that we have already received will pay for significant amount of the device production for the cow device. New finding will be for human capital to build out the team. Funding will cover more development and testing of the semen separator and culture dish and help with the implementation of the GTM strategy.

Key Team Members and Advisors

Jim Donahue, MD, MBA | CEO

Human Fertility Doctor and Embryologist. Ran successful human IVF practice 27 years. Numerous innovations in reproductive medicine. Understands with the doctor and the embryologist needs.

Michael Whitt, PhD | Co-Founder

Biomedical Engineering Professor at California Ploytechnic. 25 years prior startup medical device founder. Everything we do is biomedical engineering.

Dave Dixon, DVM | Co-Founder

Bovine Reproductive Medicine Specialist, 20 years. Everything we do must work for Dave, as Veterinarians will be our primary customers for the cow devices.