DESTINATION STARTUP

Reglagene

One-Sentence Summary of What You Do: Reglagene pioneers safe and effective precision chemotherapy medicines that selectively kill cancer cells without the toxic side effects of existing agents.

Affiliated Institution: University of Arizona

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Angel Funding (including Self or Friends/Family), Venture Capital

Please describe your company and the problem you are trying to solve: Reglagene is a preclinical stage oncology therapeutics company developing new medicines that fight cancer safely. Despite advances in cancer's early detection and novel therapies, 62% of patients with Stage II-IV cancers still receive chemotherapy as frontline treatment, and 86% of those patients report side effects and toxicities.

Traditional chemotherapies, like temozolomide, work by indiscriminately inducing DNA damage in both healthy and cancer cells. The unwanted DNA damage that occurs in healthy cells results in the toxicity you frequently hear about when a person undergoes chemotherapy. By targeting unique structures that are highly overexpressed in cancer cell DNA, Reglagene's medicines selectively induce DNA damage in cancer cells while sparing healthy cells, resulting in much lower patient toxicity. We've coined this process 'Precision Chemotherapy' and see this platform technology expanding into other cancers. At Reglagene, we can disrupt the chemotherapeutics space by fixing the decades old problem of toxic cancer treatments.

What is/was your go-to-market strategy? Reglagene's first product targets Glioblastoma (GBM), the deadliest brain cancer. GBM claimed the lives of Senators John McCain and Ted Kennedy. Temozolomide, the GBM standard of care, was FDA approved in 1999. The average survival post-diagnosis is 12-18 months, with five-year survival less than 5%. New GBM treatments lag other cancers owing to the difficulty of creating medicines that cross the blood-brain-barrier (a filter that protects the brain from toxins). Reglagene's orally-administered development candidate for GBM freely passes into the brain, and for six hours maintains brain concentrations up to 25x greater than the efficacious dose in seven patient-derived models we
have tested. We have dosed animals at the human equivalent of 16 grams per day without toxicity (Imagine taking 80 Advil in a day for a similar quantity.) Currently, we are conducting studies to prepare an IND filing with the FDA.

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Over 20 pharmaceutical companies are tracking our progress. We have special interest from companies developing DNA Damage Response (DDR) Inhibitors for cancer treatment. DDR Inhibitors prevent DNA repair in cancer cells. These medicines rarely work as monotherapy and must be combined with other therapies. The obvious combination is with traditional chemotherapy. However, the toxicity from this combination is intolerable for patients, leading to clinical failure. In preclinical studies, Reglagene's lead compounds demonstrate greatly reduced toxicity relative to traditional chemotherapy and produce additive and, in some cases synergistic, effects with DDR Inhibitors. Our aim is for Reglagene's medicines to become the combination drug of choice for DDR Inhibitors.

How will/do you generate revenue? Reglagene will generate revenue through licensing its products to pharmaceutical partners. Most pharmaceutical companies have limited early-stage product development capability and rely on in-licensing or acquisition to fill development pipelines. The oncology space is by far the most active disease area for licensing deals. These deals typically are made between preclinical development and Phase II human clinical trials, provide an up-front payment, and are backloaded with development milestone payments and royalties on product sales. Reglagene's first product is within six months of entering the licensing window.

Reglagene's business objective is to exit by IPO. Cancer therapeutics companies exit frequently (one per week over the last five years) with 50% of the exits by IPO. Completion of a Phase I trial demonstrating safety and efficacy is the standard for transition to the public markets. IPO valuations >$1B are common at this stage.

Considering an M&A exit, frequently it is the filing of IPO documentation that precipitates offers from acquirers. Reglagene's business imperative is to behave like an IPO company, even if the eventual exit comes by M&A.

How will this showcase benefit your company or technology? Reglagene's objective for Destination Startup is to build relationships and awareness with prospective investors. If there is interest in engagement with Reglagene, we would schedule follow-on meetings to take deeper dives into Reglagene's product development activities and business plan.

Reglagene has announced a $10M Series A raise. We are actively courting prospective lead and follow-on investors. The round may still may be open at the time of Destination Startup in February.

In addition to our GBM product Reglagene is developing a product for Ewing Sarcoma (a rare and deadly pediatric cancer). Both programs will be driven through FDA IND filing on the strength of the Series A raise in anticipation of Phase I human clinical trials. Program acceleration has begun owing to a $1.5M Convertible Note that closed on August 31 and was raised in five-weeks' time. Data collection for the FDA filing for the GBM product has begun and we are choosing our Ewing Sarcoma product from the best five of the over 500 drug prototypes we have tested. We anticipate nomination of the Ewing Sarcoma development candidate by year end.

Talent acquisition is also a major part of the use of proceeds. Reglagene's transition from product discovery to product development demands new skill sets. We have identified candidates for critical roles such as Head of Preclinical Development, Pharmacology and Toxicology Director, Chemistry, Manufacturing, and Controls (CMC) Director, and Chief Medical Officer.

Who are the members of your team and why is this the right team to get the job done?
Reglagene's CEO, Richard Austin PhD, MBA, is a pharmaceutical R&D veteran with over 25 years of experience ranging from the laboratory bench to operations management at well-known pharmaceutical companies (GlaxoSmithKline and Sanofi). His expertise in early drug discovery and development and operations management makes him the ideal CEO for a startup biotech therapeutics company.

Reglagene's CSO, Laurence Hurley, PhD is a serial entrepreneur who has brought multiple medicines into human clinical trials. Over his fifty-year career, he has tweaked and improved his technology, and considers the technology brought forth at Reglagene the pinnacle of his career.

Reglagene's product development leaders Vijay Gokhale PhD, and Teri Suzuki, PhD have decades of experience in academics and the pharmaceutical industry, respectively. Dr. Gokhale has brought forth the intellectual property for many startup companies and Dr. Suzuki has led teams through preclinical development. Bios of Reglagene's management team can be found here: https://www.reglagene.com/management