DESTINATION STARTUP

SiVEC Biotechnologies

One-Sentence Summary of What You Do: SiVEC Biotechnologies is developing a breakthrough delivery platform for nucleic acid drugs and gene-editing tools using non-pathogenic, non-immunogenic bacteria for stable and specific delivery to mucosal tissues without host genomic integration.

Affiliated Institution: Colorado State University

Have you formed a company yet? Yes

Funding/Financing: Grant Funding, Direct/Indirect University Support, Other

Please describe your company and the problem you are trying to solve: Safe, robust, targeted delivery is essential for nucleic acid drugs and gene-editing therapies, yet delivery remains the primary obstacle to realizing their potential in human medicine. SiVEC Biotechnologies has a platform technology that can overcome these delivery hurdles. SiVEC Biotechnologies is developing a breakthrough delivery platform for nucleic acids and gene- editing tools using non-pathogenic, non-immunogenic bacteria for specific tissue delivery without host- genomic integration. We recently concluded proof-of- oncept efficacy studies under an NIH SBIR Phase I award and successfully met all Milestones by demonstrating: (1) bacteria are non-immunogenic and safe for repeat dosing and (2) successful tissue localization and biodistribution to the eyes, nose, lungs, muscle (IM), vagina, and oral cavity. This delivery platform has the potential to enhance the development of wide range of therapeutic pipelines: genetic disorders, cancer, degenerative diseases, and infectious diseases.

Our lead indication for this platform is a next generation antiviral for influenza, SiVEC- IAV™, for fast-acting, cost-effective, universal protection against seasonal and pandemic flu. In preclinical efficacy studies, SiVEC-IAV provided significant antiviral protection against H1N1 in a murine model of influenza. There are several provisional and non- provisional patents that protect the IP surrounding the platform technology, including PCTUS1825961, which encompasses SiVEC- IAV™ influenza A antiviral for humans. We are confident in a pending NIH SBIR Phase II award ($3M) which will allow us to initiate IND- enabling studies for SiVEC- IAV™. We are seeking an investment to allow us to complete preclinical testing, advance our antiviral program for human clinical development and build- out marketable applications for the delivery platform.

What is/was your go-to-market strategy? The global nucleic acid drug delivery market was worth $39.4 billion in 2018 and is expected to reach $131 billion by 2023. There is a significant opportunity for SiVEC to enter this growing market given the advantages of our delivery platform. Leveraging the versatility of our delivery platform, our lead indication is a next- generation antiviral therapy, SiVEC-IAV, for the rapid treatment and prevention of flu. In the US, the annual direct cost of flu- related

hospitalizations and outpatient visits is $5.5 billion, based on 11 million medical visits at an estimated cost of $500 for a single dose of flu antiviral medication. For the global market, the annual direct cost for hospitalizations and outpatient visits is estimated at $10.4 billion. The SiVEC delivery platform could enhance the development of a wide range of existing therapeutic pipelines that need a safe and robust delivery application. This niche represents tremendous potential as a marketable technology to address a vast number of therapeutic needs. Using a targeted, direct approach to reach companies who are leaders in the areas of nucleic acid- based drugs, gene-therapy, RNAi, or influenza therapies, we plan to qualify our leads through direct contact, to establish whether there is an interest in the type of products that could be developed with the SiVEC platform technology. We will generate customer interest through multiple channels to maximize exposure for SiVEC's technology and negotiate Development & Licensing deals within the Business Development function of the partner, charged with scouting new products for in-licensing or acquisition.

How will/do you generate revenue? SiVEC Biotechnologies holds expertise and IP to develop the SiVEC platform technology for a wide range of therapeutic pipelines in humans and animals. This delivery platform can be used to deliver any nucleic acid drug (siRNA, shRNA, mRNA, miRNA, aptamer, antisense oligos, DNA) or gene editing tool (CRISPR/Cas9, ZFNs) to any mucosal epithelial tissue. Depending on the therapeutic program and nucleic acid delivery need, a variety of business arrangements could be considered. However, because SiVEC Biotechnologies has a pool of IP, our ideal business strategy is to out-license the delivery platform, adding value to the licensee's portfolio by providing tissue specific delivery of a key nucleic acid or gene-editing tool for a particular therapeutic indication. Our out-licensing model provides value through recurring revenues. Alternatively, the delivery platform could be acquired for a particular therapeutic indication, providing a large revenue stream via different carve out options. Both models would support a rapid ROI to our investors. We seek a partner with expertise in the biologics, vaccine, or antiviral market to advance the SiVEC- IAV antiviral program into GMP production and human clinical development. While the development pathway for IND-iling is established, our ideal partner would oversee regulatory, manufacturing, and commercialization activities. Our partner would acquire or take a world- wide exclusive license for development and commercialization of SiVEC- IAV for prophylaxis and treatment of influenza in healthy and high- risk patients.

How will this showcase benefit your company or technology? SiVEC Biotechnologies has raised $500,000 in non- dilutive funds and we are confident in securing an additional $3M with an NIH SBIR Phase II grant award. We are currently seeking outside investment capital to help complete pre-clinical testing for SiVEC-IAV, advance the antiviral program into human clinical development, and build- out other marketable delivery applications for the SiVEC platform technology (CRISPR/Cas9 therapy, RNAi-drugs, mRNA delivery). Attending this showcase could help to attractively position SiVEC for early co- development partnerships with pharmaceutical partners; these partnerships, along with nondilutive funding and ongoing efforts to secure investor support, are a critical step for our long-term goal of establishing out- licensing agreements. Additionally, this showcase is an outstanding opportunity for the SiVEC team to network with other Colorado startups. Finally, SiVEC

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is actively growing and seeks to bring on an individual with business development skills to help complement our team and lead our company towards a multitude of successful business exits.

Who are the members of your team and why is this the right team to get the job done?

- Lyndsey Linke, PhD, ME (CEO, co-founder) — Dr. Linke has over 12 years of scientific experience related to the R&D of novel therapeutics, antivirals, and diagnostic tests. Dr. Linke is first named inventor on two pending patents and one provisional patent related to this delivery platform; has a PhD in Epidemiology and a Master of Engineering in Biomedical Engineering from CSU.
- Darcy Mora, MS (VP of Operations, co- ounder) — Ms. Mora has over 10 years of experience with infectious disease and vaccine R&D and most recently worked for the US Department of Agriculture as a biological scientist. Mora received her Master of Science in Veterinary Epidemiology and a Bachelor of Science in Biochemistry from CSU.
- Danny Goovaerts, DVM, MS — Mr. Goovaerts was formerly the director of R&D at Merck; he advises on manufacturing facility design, R&D strategy, regulatory considerations for different countries, business strategy, and more.
- John Wyckoff, PhD (Immunology and CMC) — Mr. Wyckoff is the current Director of BioMARC, a CDMO for human and animal biologics, and advises on many topics that are important to SiVEC's commercialization efforts, including manufacturing and regulatory considerations.
- Janet Englund, MD (clinical optimization) — Ms. Englund is a Board-Certified Physician with over 30 years' experience in respiratory diseases, with a focus on influenza.
- Terry Opgenorth, PhD, MS (Antiviral research, pharmaceutical research & development) —Mr. Opgenorth is the Vice President and Executive Director of Launchpad at CSU Ventures.
- Heidi Nelson-Keherly, PhD (Preclinical optimization & regulatory affairs) — Ms. Nelson-Keherly advises on our drug programs through to IND submission.