

Company Overview

Siva Therapeutics is developing **Targeted Hyperthermia™** cancer therapy (THT), a safe and effective procedure which generates therapeutic heat within solid tumors using **SivaRods™** gold nanorods and a **SivaLum™** infrared light device. Hyperthermia has multiple beneficial effects on tumors, and it is more selective than chemotherapy, less destructive than radiation, and without the risks of surgery. Siva has raised over \$2.8 million to date, more than \$2 million through grants and \$810,000 through angel investors, in addition to founder contributions. The company is currently raising \$2.5 million in financing, which will enable completion of large animal studies and filing for an Investigational Device Exemption (IDE) from the FDA in preparation for clinical studies.

Need in Rectal Cancer Treatment

Siva's initial clinical target is first-line treatment for early to mid-stage **rectal cancer**. While the 5-year survival for rectal cancer is relatively good (~65%), patient quality of life is poor, resulting in a large unmet need. There are widely available, excellent early-stage diagnostics for rectal cancer, and it tends to be localized through early Stage 3, making it ideal for interventional treatment. Targeted Hyperthermia treatment for rectal cancer will be a minimally invasive outpatient procedure that addresses an underserved patient segment.

Initial Market

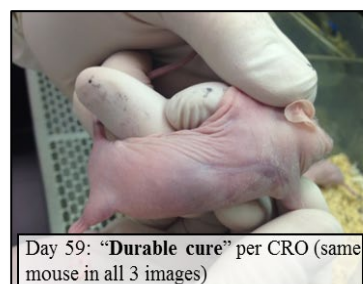
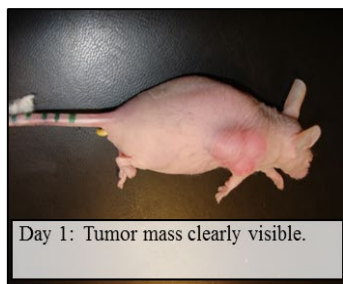
There are 44,000 new cases of **rectal cancer** in the US every year, resulting in 19,500 deaths. The US market is estimated to be **\$6.6 billion** with an 8% CAGR, and a **service obtainable market for THT estimated at \$2.1 billion**. Additional markets will follow.

Product Technology

THT is an **interventional oncology** approach which employs the systemic injection of polymer-coated gold nanorods (SivaRods) into the patient and illumination of the affected region with a patented near infrared light device (SivaLum). The SivaRods concentrate in tumors, absorb the infrared light, and convert it into therapeutic heat which emanates from **within** the tumor mass. Heat stimulates the immune system, shrinks tumors, and enhances drug efficacy.

Strong Preclinical Data

THT has very strong preclinical efficacy data, both as a monotherapy and in combination with a leading cancer drug. **THT stand-alone treatment is significantly more effective than the drug monotherapy**: all animals on drug alone were dead by 30 days after the study began. Combination treatment with both THT and drug (images below), yields outstanding results: 66% of the animals survived and thrived out to 95 days post-treatment, the end of the study, with no evidence of residual cancer. The preclinical safety profile is excellent.



Management Team

50 years of combined biotech/life science/med device experience; with 5 previous cash-flow positive companies with products to market; a surgical services company from startup to acquisition; 12x return for early investors; oncology lead molecule identified, partnered and in the clinic; and a drug discovery product line from concept to \$26MM P&L; acquisition for multiple of revenues.

- CEO: Len Pagliaro, PhD – ThermoFisher Scientific, BioImage A/S, Cerep Inc. (Eurofins)
- COO: Colin Shepherd, PhD, MBA – PhylloTech, AimsBio
- Cofounder & Counsel: Steve Kregstein, JD – ClearVision, Sound Surgical

Current Raise and Use of Funds

Siva is raising a \$2,500,000 financing round – Milestones:

1. Large animal studies
2. File for IDE and plan for de-novo pathway grant
3. Prepare for first in human studies

