

OPTIMUM

Therapeutics, LLC

Contact: Trini Wientjes, J.D.
Location: Columbus, OH
Email: twientjes@optimumtx.com
Tel: (614) 688-5885
Website: www.optimumtx.com



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
 National Institutes of Health



National Institutes of Health Commercialization Assistance Program
 (NIH-CAP)

Company Profile

Industry Sector: Oncology Therapeutics and Drug Delivery

Company Overview:

- Core team of pharmaceutical scientists with thought leaders in translational research
- Focus on R&D of oncologic products for treatment of solid tumors, from discovery through early proof-of-principle clinical evaluations
- Goal is to deliver the right drug to the right target at the right amount and at the right time, and avoid the wrong targets
- Achieve goal by integration of three platform technologies: (a) tumor-selective and tumor-penetrating nano/microparticles to deliver effective drug concentrations, (b) noncytotoxic chemo/radiosensitizers with unique targets, and (c) predictive computational models of biological processes ranging from intracellular signaling to clinical trials
- Projects funded by nine SBIR and RO1 grants from the NCI, collaborative agreements with pharmaceutical companies, private investors
- Networks of collaborating academic scientists and thought leaders

Target Markets of Optimum products:

- Cancers amenable to loco-regional treatments: bladder cavity, peritoneal cavity (pancreatic, ovarian, colorectal)
- Cancers amenable to systemic treatments: lung, breast

Key Value Drivers

Technology*: Tumor penetrating chemo-loaded microparticles (TP-Micro1)

Competitive Advantage:

- In US, 230,000+ new cases of cancers derived from organs in peritoneal cavity per year. Cavity is also site of metastasis in 50-70% of all cancers
- No FDA-approved product for intraperitoneal treatment of peritoneal cancers, in spite of well documented effectiveness of intraperitoneal treatment in patients (16+ months longer survival)
- Current practice is off-label use of intravenous products, not suited to the unique properties of peritoneal cavity (rapid drainage) and not able to penetrate bulky tumors
- TP-Micro1 addresses above unmet needs
 - Lead product in our proprietary first-in-class, multi-component, multi-functional, tumor-targeting and tumor-penetrating delivery system designed for treating peritoneal cancer
 - Can be used alone as therapeutics or to improve delivery of other therapeutics (new agents or life cycle management of off-patent or repurposed drugs)
 - Demonstrated superior efficacy, safety, toxicity, and PK/PD profiles over the standard-of-care in mice bearing pancreatic and ovarian tumors
 - Currently in GMP, phase I protocol in place

Plan & Strategy: Drive development through early clinical evaluations; have capability & access to resources to complete early clinical development. Seek co-development partners or licensees.

*Technology funded by the NCI and being commercialized under the NIH-CAP

Management

Leadership:

Jessie Au*, Pharm.D., Ph.D., - Chief Scientific Officer and Acting CEO

- Expert in preclinical-to-clinical translational research

Ze Lu, Ph.D. - Senior Research Scientist

- Polymer chemist, Laboratory management

Trini Wientjes, J.D. - Director of Operations

- In-house counsel, Operational management

Scientific Advisory Board:

Steven Bramer, Ph.D. - President, First-Stop Consulting, LLC

- FDA regulatory affairs

Guill Wientjes, Ph.D. - Professor of Pharmacy, The Ohio State University

- Modeling PK/PD, Clinical trial design

Plus additional advisors from legal, business, scientific, and regulatory fields

*Distinguished University Professor, The Ohio State University

Product Pipeline www.optimumtx.com/research

Product	R&D	In vivo preclinical	IND	Phase 1 Clinical Study	Phase 2 Clinical Study	Phase 3 Clinical Study
Peritoneal Cancer						
TP-Micro1 (paclitaxel-loaded)	→	→	→			
TP-Micro2	→	→				
TP-Micro3	→					
Bladder Cancer						
MMC (generic)	→	→	→	→	→	→
Instant release paclitaxel nanoparticles (proprietary)	→	→	→			
Noncytotoxic chemosensitizer						
Suramin (NC-1)	→	→	→	→	→	→
NC-2	→	→	→			
NC-3	→	→	→			