

# OPTIMUM

Therapeutics, LLC

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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](http://www.optimumtx.com/research)

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

