

# CASE STUDY



## THERADAPTIVE AND REGENERATIVE MEDICINE

How working with Geneva set the foundation for  
technology transfer and clinical success

# THERADAPTIVE AND REGENERATIVE MEDICINE BACKGROUND



TECHNOLOGY TRANSFER  
CAPABILITIES



Geneva has worked with Theradaptive, Inc., a privately held biotechnology company focused on regenerative medicine technology, on getting their therapeutic platform into the clinic since 2017.

Theradaptive has developed a platform technology that enables the conversion of therapeutic proteins into variants that bind to implants very tightly, like paint. Using this technology, Theradaptive developed a protein called AMP2 that very potently induces bone regeneration and that binds to implants similar to a paint. AMP2 has demonstrated regeneration of bone across gaps larger than 2 inches long. The result: regenerative medicine to heal tissues like bone and cartilage in extremities to avoid amputation. The technology can also be applied to any recombinant protein, thus

enabling long-term, localized therapeutics for cancer treatment, vascular, dermal, or cartilage repair.

Theradaptive received federal phase II funding under the Defense Health Agency's Small Business Innovation Initiative Research Program and has a partnership on two DoD contracts valued at over \$5.2M to develop next-generation 3D-printed regenerative spinal fusion devices. The platform nature of the technology has generated strong interest with several strategic partners that complements Theradaptive's internal development programs. The company's founder is 20-year Army veteran and MIT alumnus retired LTC Luis Alvarez, PhD. LTC Alvarez developed the platform technology during active duty in the Army.

## GENEVA'S ROLE

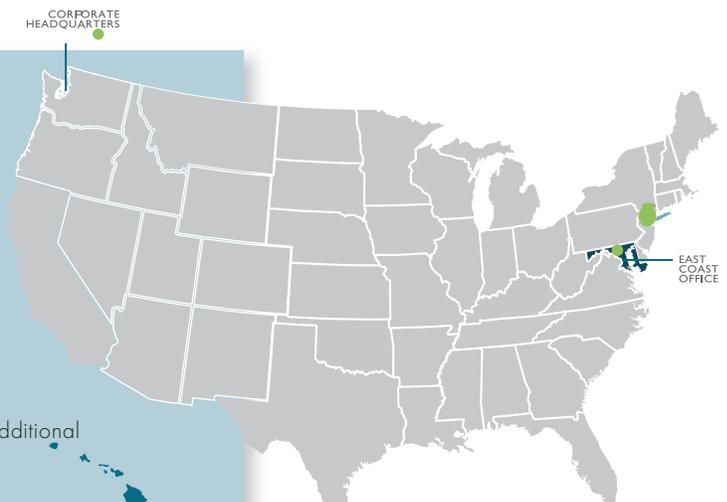
- Secured targeted funding under the **Department of Defense Joint Warfighter Medical Research Program**
- GLP-compliant preclinical development
- Spin out of technology to partners
- CMO scale up development
- Recruitment of highly trained research technical personnel
- Secured experienced FDA/regulatory consultants
- Intricate program management that ensured acceleration of regulatory timelines and risk-based reviews



## Geneva is honored to advance Regenerative Medicine at military treatment facilities including:

- National Cancer Institute
- Uniformed Services University
- Walter Reed National Military Medical Center
- Walter Reed Army Institute of Research

Geneva collaborates at 50+ performance sites worldwide in 195+ additional research programs



# THE ARMY'S INTEREST IN THERADAPTIVE'S TECHNOLOGY

## THE ROLE OF TECH TRANSFER IN THE MILITARY

The mission of Army medical research is to discover, develop, and deploy products that will maintain the readiness of our warfighters, protect them from disease, and improve battlefield survivability.

Many of these products are dual-use, with significant potential to serve the civilian market. Under the the U.S. Army Medical Research and Development Command, or USAMRDC, the Medical Technology Transfer (MTT) office finds the best pathways for technologies to successfully move toward commercialization. Through MTT licensing and partnerships, the Army supports advances in medical technologies and simultaneously stimulates business and economic development.



"It's going to redefine how physicians practice regenerative medicine."

Extremity Injury is a top-ranked priority focus area for both the Military Operational Readiness Research Program and the Combat Casualty Care Research Program.

Theradaptive's current work grew out of a previously funded Peer Reviewed Orthopedic Research Program (PRORP) career development grant and leverages early DoD investment

Research Program (PRORP) career development grant and leverages early DoD investment in basic science received by Geneva to support the continuation of Dr. Alvarez's early work.

The Theradaptive team is translating these findings into products that will have military benefit and will realize a large return on DoD investment in an area that is not well represented by other research efforts. Treating segmental defects remains one of the top challenges facing military medicine and some of the costliest injuries to treat.

Musculoskeletal injuries comprised approximately 70% of all combat wounds in recent conflicts, with a significant fraction of these involving open complex fractures of long bones. These types of fractures generally exceed the critical size defect limit and do not heal well, often forcing the patient to decide between limb salvage with reduced function, or amputation.

Similarly, lower back pain due to degenerative disc disease is one of the top reasons for medical separation from service during peacetime. The definitive treatment for degenerative disc disease is fusion surgery which requires the generation of bone between vertebrae.



## THERADAPTIVE'S IMPACT ON HEALTHCARE

Theradaptive is going after previously out-of-reach clinical indications in vascular, soft tissue, and orthopedic repair as well as targeted chemotherapeutics. The company has developed therapeutics for the following indications:

- Spinal Fusion
- Long Bone Repair
- Dental & Facial Bone Repair
- Osteochondral Repair

This technology will not only benefit wounded warriors but will also address a significant unmet need in the general public. "We will be able to treat not only trauma, but also aging-associated diseases like lower back pain, said Alvarez. "It's going to redefine how physicians practice regenerative medicine."



Photo: The Theradaptive team



# GETTING INTO THE CLINIC



## GENEVA'S TECH TRANSFER CAPABILITIES

Geneva is adept at navigating the intricacies of government acquisitions and the military medical research environment, including negotiating Intellectual Property (IP) terms and Cooperative Research and Development Agreements (CRADAs). Geneva's experts engage with research teams to develop and implement plans for:

- Product development
- Manufacturing
- Clinical translation
- Regulatory support
- Product launch
- Commercialization strategies



Theradaptive is shaping the future of regenerative medicine with a new platform to deliver therapeutics that promote targeted native tissue repair. Their lead therapeutic, AMP2, is applied to an orthopedic implant to regenerate damaged bone, therefore significantly helping to speed up the injury process. For servicemembers with combat trauma this can mean the difference between amputation and limb preservation.

Geneva set the foundation for the development of this technology by fast-tracking the R&D development and regulatory milestones. Geneva Program Manager Linzie Wagner said, "Partnering with Theradaptive to accelerate their technology's development to various platforms was an important step for them. Geneva was able to leverage its expertise in DoD advanced technology development and identify turnkey applications and opportunities to thrust this product forward, bringing it one step further to first in human and ultimately the Warfighter."

The technology has demonstrated superiority over standard of

care in all preclinical studies conducted to date, including studies at the Cleveland Clinic and Mayo Clinic, where scientists were able to correct a bone defect about 5 centimeter (2 inch) bone defect.

In 2020, Theradaptive opened an R&D facility in Frederick, Maryland, expanding capabilities in therapeutic manufacturing, implant design, and additive manufacturing of medical implants. The company is establishing cGMP manufacturing capabilities to produce therapeutics able to enter clinical trials in late 2022.

Theradaptive was also able to leverage funds provided by DoD contracts to further preclinical development. The company was the recipient of the 2018 and 2019 Maryland Stem Cell Research Fund Commercialization Grant and was named a finalist for the 2018 First Coast Innovation Challenge. The company was also selected for contract award under the Advanced Regenerative Manufacturing Institute (ARMI) BioFabUSA program.

## Collaborate With Us

Geneva is a 501(c)3 non-profit organization that advances military medicine through innovative scientific research, exceptional program management, and a dedication to U.S. service members and veterans, their families, and the global community.

Geneva is proud to have over 25 years of experience in delivering full-spectrum scientific, technical, and program management expertise in the areas of federal contracts, federal grants, and industry-sponsored clinical trials.

For business development opportunities, please contact us at [bd@genevausa.org](mailto:bd@genevausa.org).





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