

US Patent Issued on CPSI's Engineered Tissue Model Platform

Latest Patent Covers the Design and Use of a Tissue Engineered Model System (ASSIST™) which Provides for a lab-based In Vivo like 3-D Tissue Alternative to Animal Testing

January 25, 2016

OWEGO, NY -- CPSI Biotech announced today the issuance of a patent by the US Patent Office covering the design and method of use of a new tissue engineered model (TEM) for utilization in research and development activities. Referred to as the ASSIST™ system, TEM is designed as a laboratory-based *in vivo* like 3-dimensional tissue substitute for animal testing. ASSIST™ can be formulated to contain any number of human, animal or other cell types which can be cultured to form a robust 3-D tissue structure.

The patent (US Pat#: 9,213,025) covers design and use of the advanced ASSIST™ TEM system which offers promise for utilization in the discovery sciences as well as the product development and testing arenas. CPSI has successfully utilized the ASSIST™ system with various cell lines to produce research based living 3-D tissue models of pancreatic, prostate and kidney cancer tumors, as well as cardiac and esophageal tissues. These TEMs have been used for medical device testing, drug discovery and thermal ablation studies by the CPSI research team including performance testing of the SCN cryoablation platform. This latest patent, issued in December 2015, follows the issuance of a series of patents focused on the SCN cryoablation system in 2015. CPSI also holds several other issued and pending patents on a variety of other cryoablation devices (probes, catheters) and methods of use, as well as several in the life science arena.

“With continued movement away from the use of animals in R&D efforts, this next generation tissue engineered model is designed to serve as a simple, cost effective laboratory based tool providing an alternative to animal studies” said Dr. J.M. Baust, President and Lead Scientist, CPSI Biotech. Baust added “Our hope is that ASSIST™ will provide a path forward addressing not only the ethical concerns with animal studies, especially early stage studies, but also help reduce the cost and timeline associated with product development. To this end, we have utilized ASSIST™ in a number of settings to test and optimize new probes, study drug interactions, cell and tissue response to cryoablation, etc. Using ASSIST™, these studies were conducted at a fraction of the cost of animal studies and allowed real-time feedback and data collection on device performance, enabling accelerated integration and testing of device design changes.”

This latest patent cover claims to system design and methods of use of the ASSIST™ system. “The unique design of ASSIST™ as a lab-based 3-D tissue model allows researchers to conduct studies on large customized tumors or tissues within the confines of the research laboratory without the need for animals and the associated review panel approval, surgical suites, housing, cost and ethical burden associated with their use. We have utilized ASSIST™ TEMs to test and optimize a number of new probes and catheters designed to ablate target tissues including various cancers, as well as cardiac arrhythmias.” said Dr. Baust. Baust added, “ASSIST™ TEMs

are compatible with many research and assay techniques thereby allowing for more complex and inclusive studies to be conducted in a 3-D setting which is often not feasible using standard cell culture or animal models. We truly believe that ASSIST™ represents an enabling bridge technology to help accelerate R&D activities.”

When asked about the potential impact of ASSIST™, Dr. Kristi Snyder (Director of Operations & Research Scientist, CPSI Biotech) responded, “The ASSIST™ technology has the potential to revolutionize how we approach R&D activities in life science and bioengineering. As an active researcher and animal welfare advocate, I see firsthand the issues with animal testing and the lack of adequate alternatives for researchers. The development of ASSIST™ has changed how we approach study design. Prior to ASSIST™, our work was restricted to cell culture based activities and on rare occasions ventured into collaborations with lead researchers and clinicians where in vivo testing was utilized. This was due to a combination of factors, including personal ethical challenges, overall cost and product development stage, among others. In this regard, ASSIST™ TEMs have been a game changer as my team can now test new device performance, study the cell and molecular response of cancer to freezing and heat treatments (cryoablation and hyperthermia ablation, respectively), work to optimize protocols and identify advanced combinatorial strategies to destroy cancer without the need for animal studies. Based on our initial successes, it is my hope that ASSIST™ will emerge as a mainstream alternative to early and mid-stage animal studies. With further development and a little luck, may eventually provide a path for the elimination of animal studies altogether in some cases.”

This new patent continues to broaden CPSI’s technology portfolio, providing for an improved position supporting CPSI’s business development initiatives in a number of areas including development of new devices for the treatment of the cardiac arrhythmia and gastrointestinal based cancers, whose overall markets approached ~\$5 billion and ~\$3.5 billion, respectively, in 2015. This is in addition to the billions of dollars spent annually on basic cell culture and animal research for which ASSIST™ could service. Baust ended by adding “with the growing push to reduce and eventually eliminate the use of animals in research, it is our hope that ASSIST™ will offer new options to the millions of researchers and product development and testing engineers worldwide.” CPSI is currently pursuing the acquisition of financing to support final development, testing and obtaining regulatory approval in support of commercialization of ASSIST™ as well as several of CPSI’s other cryoablation medical devices.

About CPSI Biotech - CPSI Biotech, a private, integrative bio/medtech greenhouse company, develops and designs life science research products and cryo-medical devices for applications in cancer, cardiovascular disease treatments and cell therapy bioprocessing. Ongoing R&D and business development activities continue to produce innovative technologies, devices and intellectual property for commercialization, licensing or sales in support of diverse clinical and research applications. By leveraging the innovation, flexibility and R&D strengths of CPSI in combination with the development, commercialization, manufacturing and clinical expertise of partnering organizations, rapid and efficient product development is attainable.

Disclosure Notice: The information contained in this release is as of January 20, 2016. CPSI assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments. CPSI’s technologies do not have regulatory clearance for commercial sale and are currently intended for “Research Use Only”.

With the exception of the historical information contained in this release, this release contains materials and statements related to future business, financial performance, future events and/or developments involving CPSI which constitute forward-looking statements. The matters described herein contain forward-looking statements that involve risk and uncertainties that may individually or mutually impact the matters herein described, including but not limited to, CPSI's ability to develop and market new products, to retain and attract key employees, to obtain regulatory clearances and approvals for its products, to effectively react to other risks and uncertainties, such as fluctuation of quarterly financial results, contract and grants acquisition, reliance on third party manufacturers and suppliers, litigation or other proceedings, economic, competitive, governmental impacts, whether pending patents will be granted or defensible, validity of intellectual property and patents, the ability to license patents, the ability to commercialize developmental products, competition from existing and new products and procedures and CPSI's ability to raise the capital that is required to accomplish the foregoing.

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