

# US Patent Issued on CPSI's *FrostBite*<sup>™</sup> Pancreas Cancer Cryoablation Catheter

**Latest patent covers an endoscopic-based cryocatheter (*FrostBite*<sup>™</sup>) designed to provide an advanced approach for targeting pancreatic and other gastroenterological based cancers.**

February 14, 2018

OWEGO, NY -- CPSI Biotech announced today the issuance of a patent (US Pat#: 9,877,767) by the US Patent Office covering a new endoscopic based ablation catheter designed for the minimally invasive treatment of pancreatic cancer. The needle tipped catheter, *FrostBite*<sup>™</sup>, is designed to be utilized in conjunction with endoscopic ultrasound technologies allowing for the visualization of pancreatic tumors, insertion of the *FrostBite*<sup>™</sup> needle tip through the stomach wall into the targeted tumor, then freezing the tumor in place, resulting in tumor destruction. Commenting on this development, Dr. John M. Baust (President, CPSI Biotech) stated "The issuance of this patent is timely and represents a significant milestone. *FrostBite*<sup>™</sup> has undergone substantial R&D efforts and is poised to move to the next stage of engineering and testing in support of commercialization."

CPSI has been actively working on the development of *FrostBite*<sup>™</sup> for several years. *FrostBite*<sup>™</sup> is designed to be used in conjunction with CPSI's patented cryoengine technologies to freeze (cryoablate) cancer in place within the body (*in situ*), thereby destroying the targeted tumor. This new device and approach has been developed to support the growing field of natural orifice transluminal endoscopic surgery (NOTES) in which "scarless" abdominal operations can be performed with an endoscope passed through the mouth, thereby enabling the introduction of surgical tools, such as *FrostBite*<sup>™</sup>, into the stomach to target various tissues via the stomach wall, avoiding the need for invasive external surgical procedures. In this manner, *FrostBite*<sup>™</sup> is designed to be introduced into the stomach via an endoscopic ultrasound (EUS) device and then the cryoneedle tip of the catheter passes directly through the stomach wall into a tumor in the pancreas. The use of EUS allows for the real-time visualization of the tumor and positioning of the ablation needle prior to cryoablative treatment.

In discussing the technology, Dr. Baust further commented "the objective of *FrostBite*<sup>™</sup> is to provide a powerful ablative tool to attack pancreatic cancer. Ultimately our goal is to reduce the need for other traditional highly invasive and toxic approaches such as chemotherapy, radiation or major surgery to treat this deadly disease." The potential impact of the technology is tremendous. Speaking about the technology, Dr. P. Jay Pasricha (Professor of Medicine and Neurosciences, Division of Gastroenterology, Johns Hopkins School of Medicine and consultant for CPSI) previously commented, "We are very encouraged by the potential of the *FrostBite*<sup>™</sup> EUS-cryocatheter platform. The ability to target and freeze tissues *in situ* under endoscopic ultrasound guidance will provide for a more precise and minimally invasive strategy to treat cancer including pancreatic, esophageal and other tumors. We are looking forward to continuing our work with CPSI to bring this technology to the clinic."

The initial R&D efforts behind *FrostBite*<sup>™</sup> were supported, in part, by a Phase I Small Business Innovation Research (SBIR) grant awarded to CPSI by the National Cancer Institute (NCI) of the National Institutes of Health (NIH). In September of 2017, CPSI was awarded a 2 year Phase II SBIR

grant by NCI focused on the continued development of the next generation *FrostBite*<sup>™</sup> cryoablation catheter, cryoengine and NOTES approach for the treatment of pancreatic cancer.

With the issuance of this patent and Phase II studies under way, CPSI is poised to embark down the commercialization path. To enable this, CPSI is partnering with GI Cryo, Inc., a med-tech start-up focused in the GI ablation therapy area; to commercialize *FrostBite*<sup>™</sup> and other related technologies. To this end, Baust commented “Based on our successes, we are actively working through GI Cryo to obtain the necessary investment to bring this potentially lifesaving technology platform to the market.” In speaking to the impact of this revolutionary technology, Baust stated “*FrostBite*<sup>™</sup> has a number of potential application areas. We envision that future iterations will allow for treatment of other cancers such as colorectal, stomach and esophageal cancer. It is our belief that the technological innovation and diversity of application areas positions *FrostBite*<sup>™</sup> as an enabling platform.” The potential impact of this technology in the GI space cannot be overstated given the very low (<5%) five year survival rate and estimated >300,000 deaths annually worldwide from pancreatic cancer. Estimates suggest that ~45% of these individuals could be treated with cryo, representing an annual market potential of >\$500 million for pancreatic cancer alone.

More information on *FrostBite*<sup>™</sup> or any of CPSI’s other technologies can be found on CPSI’s website at [www.CPSIBiotech.com](http://www.CPSIBiotech.com).

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 February 12, 2018. 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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