

## **Dune Medical Devices Announces Positive Interim Results From EU MarginProbe™ Study Presented at German Breast Cancer Society Meeting**

**Framingham, MA, July 09, 2010** – Dune Medical Devices, Inc. today announced that positive interim results from a European post-market study of the MarginProbe™ System, a technology to enable better detection and removal of cancerous tissue during breast-conserving surgery (BCS), were presented at the German Breast Cancer Society Meeting (DGS 2010) held in Hamburg, Germany from July 1-3, 2010. Data presented demonstrated that use of MarginProbe during initial surgery to treat ductal carcinoma in-situ (DCIS), contributes to a fifty-percent reduction in the need for additional surgery to remove residual cancer.

MarginProbe enables intraoperative, real-time detection of “positive margins”, or cancer found at the edges of excised breast tissue. Positive margins are an indicator that cancer remains in the breast, and with this information, surgeons can immediately remove it and potentially avoid a second operation. The study, which is currently being conducted at four breast cancer centers in Germany, assesses whether MarginProbe use during surgery for DCIS helps to avoid the need for further surgery to achieve “clear margins.”

“DCIS can be a diffuse disease, and reoperation is quite common. These data further demonstrate the benefit of MarginProbe in this setting,” said Marc Thill, MD, Head of the Gynecological Cancer Center at University Hospital, Schleswig-Holstein in Luebeck, Germany. “Given the wide body of data supporting a significant reduction in the number of second surgeries, it is quite conceivable that this technique could be established as the standard of care for invasive cancer as well as for DCIS in surgical therapy.”

“The ability to detect DCIS intraoperatively is significant since DCIS is considered a very challenging target,” said Bill Densel, who was named Dune’s Chief Executive Officer in April, 2010, after serving as Chief Business Officer since January, 2009. “These data support earlier published findings which reported MarginProbe’s capability to detect all types of malignancy found in the breast and to positively impact reoperation rates.”

In BCS, there exists tremendous need for an intraoperative technology to help surgeons achieve the removal of the complete tumor with a rim of healthy tissue, known as the margin, preferably in one surgical session. According to the medical literature, between 20 percent and 40 percent of BCS patients require a second surgery because clear margins were not achieved during the initial procedure. Earlier this year, Dune completed the MarginProbe pivotal trial to support U.S. market approval.

“Dune’s technology creates a novel platform that can probe into the internal structures and properties of human tissues and provide information in real-time,” said Densel. “In addition to pursuing MarginProbe approval in the U.S. and commercial roll out in target

markets, Dune will continue to advance ongoing development of additional applications for real-time cancer detection in both diagnostic and therapeutic procedures.”

### **About MarginProbe**

The MarginProbe procedure provides surgeons with real-time detection of cancer at the edges of the tissue removed during breast conservation surgery (BCS), which allows for the complete removal of the tumor from the breast. The MarginProbe system comprises a single-use probe and a portable console. During breast cancer surgery, the surgeon utilizes the probe to apply radio frequency signals to excised tissue specimens. The reflections of these signals are captured by the probe, compared to a pre-defined criteria, and characterized as positive or negative for cancer at the tissue margins. With simple operation and instantaneous results, the procedure easily integrates into existing surgical workflow.

In October 2008, *American Journal of Surgery* published results of a 300-patient, randomized, controlled clinical trial designed to study the benefit of MarginProbe in intraoperative margin assessment for BCS and the associated reduction in second surgeries. In the treatment group, surgeons applied the MarginProbe to excised tissue specimens and re-excised additional tissue according to the device's readings. The second surgery rate was significantly reduced by 56 percent with use of MarginProbe as compared to standard of care.

The MarginProbe™ System is commercially available in Europe and Israel. It is an investigational device in the United States.

### **About Dune Medical Devices**

Founded in 2002 by Dr. Dan Hashimshony, Dune Medical Devices envisions the application of its tissue characterization technology to a broad range of diagnostic and therapeutic procedures in order to improve performance and outcomes by providing physicians with a real-time assessment of target tissue properties.

Dune's initial focus has been surgical oncology, where it is engaged in the development and commercialization of intraoperative systems intended to identify cancerous tissues, thereby enabling immediate removal and cancer-free surgical results. The MarginProbe System for breast cancer surgery is Dune's first commercial product..

Dune Medical Devices is a privately-held company, financed by Apax Partners. It has offices in Framingham, MA, Israel, and Switzerland.

For more information, please visit [www.dunemedical.com](http://www.dunemedical.com).

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