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NinePoint Medical Receives FDA 510(k) Clearance for Nvision VLE Imaging System

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NinePoint Medical, Inc. an emerging leader in the development of medical devices for in vivo pathology, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Nvision VLE Imaging System, a next-generation, high-resolution optical imaging technology. The Nvision VLE Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure by providing two-dimensional, cross sectional, real-time depth visualization. The Nvision VLE Imaging System is the first volumetric optical coherence tomography (OCT) device cleared by the FDA for endoscopic imaging that uses a circumferential scanning technique and an automatic pullback to generate cross sectional and longitudinal images simultaneously in real-time.

NinePoint Medical's proprietary Nvision VLE Imaging System is designed to enable physicians and pathologists, for the first time, to view high-resolution, volumetric images of organs and tissues in real-time. Clinicians can then analyze and immediately act on these images, thus providing patients with streamlined care and a significantly shortened timeline between detection, diagnosis and treatment of disease. The Nvision VLE Imaging System:

- Is the only technology that can generate a volumetric image of the target organ in real-time that can be viewed simultaneously in cross section and longitudinally.
- Utilizes a high-resolution display and proprietary software to provide an image that can be reviewed by a physician to identify areas of suspicion such as inflammatory, metaplastic or dysplastic changes, or possible cancers.
- Can image beneath the mucosal surface at less than 10 micron resolution up to a tissue depth of 3mm, unlike white light endoscopy, which can only image surface detail. This also compares favorably to confocal microscopy, which only has up to 250-500 microns depth of penetration capability.
- Offers a full field, circumferential view, compared with confocal microscopy, which only offers a 0.5x0.5mm segment of tissue.
- Can image circumferentially or helically up to 6cm in length in less than 100 seconds.

“The Nvision VLE Imaging System can provide high-resolution images of potentially diseased tissue, which are deeper than can be imaged with endoscopy alone,” said Charles Carignan, M.D., president and chief executive officer of NinePoint Medical. “We believe this will improve upon the existing standard of care, which currently relies on endoscopic technology and random biopsy protocols due to an inability to see deep into tissue where disease may exist. Our initial focus is on providing physicians with higher-resolution cross sectional and longitudinal images of diseased tissue in the epithelium of various organs, which impacts millions of adults in the United States. We will be



conducting clinical trials of the Nvision VLE Imaging System in 2012 and will be scaling up our manufacturing capabilities to support a commercial launch in 2013. In addition, we are focused on developing additional features of our system to bring even more value to physicians and patients. We believe our technology can improve patient outcomes, shorten the timeframes associated with diagnostic and treatment procedures and significantly reduce health care system costs.”

In 2010, NinePoint Medical entered into an intellectual property licensing agreement with Massachusetts General Hospital (MGH) supporting the development of the Nvision VLE Imaging System, NinePoint’s proprietary, next-generation, high-resolution optical imaging technology. Under the agreement, NinePoint obtained certain exclusive rights in multiple fields to 188 patents and patent applications owned by MGH.

“FDA 510(k) clearance of the Nvision VLE Imaging System represents a significant milestone for NinePoint Medical,” said Cindy Domecus, acting vice president of regulatory affairs of NinePoint Medical. “This is the first volumetric OCT device cleared for endoscopic imaging, and we believe the high-resolution images will provide additional, important detail to physicians who are diagnosing disease that is often not visible on the surface. We look forward to developing the Nvision VLE Imaging System into a tool to improve patient care across a broad spectrum of disease states.”

About NinePoint Medical, Inc.

NinePoint Medical, Inc. is a transformational medical device company developing innovative, real-time, in vivo pathology devices focused on dramatically improving patient care. Through its proprietary Nvision VLE Imaging System, NinePoint intends to bridge the gap between the diagnosis and treatment of disease. The Nvision VLE Imaging System will enable physicians and pathologists, for the first time, to view real-time, high-resolution, volumetric images of organs and tissues up to 3mm deep at less than 10 micron resolution. Initially, NinePoint is focusing on devices that enable real-time, endoscopic screening and surveillance of diseases of the mucosa of various tissues that are often precancerous. Eventually, the company intends to develop medical devices that provide physicians with immediately actionable information and that will allow them to diagnose and treat patients during the same procedure. This convergence of access, diagnosis and treatment during one procedure is expected to improve patient experiences and outcomes, improve the efficiency of care and provide important savings to the health care system. Headquartered in Cambridge, Mass., NinePoint is backed by Third Rock Ventures and Prospect Venture Partners. For more information, please visit www.ninepointmedical.com.