Perimeter Medical Imaging AI Reports 2020 Financial Results and Provides Corporate Update

written by Raj Shah | May 1, 2021

April 30, 2021 (Source) – Perimeter Medical Imaging AI, Inc. (TSX-V:PINK)(OTC:PYNKF) (FSE:4PC) ("Perimeter" or the "Company"), a medical technology company driven to transform cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address high unmet medical needs, today reported financial results for the year ended December 31, 2020 and provided a corporate update.

Jeremy Sobotta, Perimeter's Chief Executive Officer stated, "In 2020, we achieved a number of key milestones, added to our leadership team, and created momentum that continues to build in 2021. The FDA's recent 510(k) clearance for Perimeter S-Series OCT allows us to bring our commercial-ready imaging platform to the U.S. market, and sales development activities are underway. Importantly, we have a strong balance sheet that allows us to execute against our clinical development and commercialization plans as we strive to enable physicians to create better patient outcomes with lower healthcare costs."

Mr. Sobotta added, "In addition, we have made significant progress with our 'next-gen' development work combining artificial intelligence tools with our OCT imaging system under the ATLAS AI project, which is funded, in part, by the Cancer Prevention and Research Institute of Texas. We believe the recent Breakthrough Device Designation from the FDA is further validation that Perimeter's technology could provide significant advantages over existing alternatives for intra-operative evaluation of margins and has the potential to be a

transformative, disruptive new technology that helps surgeons treat breast cancer. Looking ahead, we aim to initiate a randomized, multi-site, pivotal study this year to evaluate Perimeter OCT coupled with ImgAssist AI against the current standard of care and assess the impact on re-operation rates for patients undergoing breast conservation surgery."

Corporate Highlights

- In February 2020, Perimeter was awarded a $7.4 million grant by the Cancer Prevention and Research Institute of Texas ("CPRIT"), a leading state body that funds cancer research, to support the development of Perimeter's artificial intelligence software under the ATLAS AI project.
- In 2020, Perimeter announced the additions of Ian Mortimer, President and Chief Financial Officer of Xenon Pharmaceuticals Inc., and Aaron Davidson, CFO and Senior Vice President of Corporate Development of Profound Medical Inc. to its Board of Directors. The appointees bring key expertise in the areas of financial management, public company oversight, life sciences, and medical device technology development to the board.
- In September 2020, Perimeter added to its leadership team with the appointment of Steve Sapot as Chief Commercial Officer. A proven sales leader, Mr. Sapot led a capital sales team during his tenure at Faxitron that achieved an install base of thousands of new radiography systems in leading hospitals and breast cancer centers around the globe.
- Subsequent to year end, in March 2021, Perimeter completed the acceleration of certain share purchase warrants issued on June 29, 2020 and, since the Company's third quarter results ending September 30, 2020, has received a total of approximately $8.3 million in proceeds from the exercise

of approximately 4.3 million warrants.

Product and Clinical Development Updates

- On March 1, 2021, Perimeter announced that it had received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for version 2.1 of the Perimeter S-Series OCT, enabling Perimeter to bring its commercial-ready imaging platform to the U.S. market. Previously referred to as “OTIS,” Perimeter S-Series OCT is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization with image review manipulation software for identifying and annotating regions of interest.
- On March 30, 2021, Perimeter announced that Dr. Beth DuPree, a surgeon at Northern Arizona Healthcare Verde Valley Medical Center, initiated a clinical study, which will enroll up to 100 patients, that will evaluate the use of Perimeter S-Series OCT during breast conserving surgery, with the aim of demonstrating that surgeons can effectively use Perimeter S-Series OCT to aid their decisions if additional tissue needs to be excised.
- On April 15, 2021, Perimeter announced that the FDA granted a Breakthrough Device Designation for Perimeter OCT combined with ImgAssist AI – to be called Perimeter B-Series OCT. This designation allows for accelerated interactions with the FDA during product development and prioritized review of future regulatory submissions. In addition, a new Medicare policy program (Medicare Coverage of Innovative Technology, or MCIT) provides national Medicare coverage for up to four years for FDA-designated Breakthrough Devices upon market authorization, enabling more rapid utilization of new and innovative technologies for the Medicare population.

ATLAS AI Project

- In July 2020, Perimeter initiated the first phase of its ATLAS AI project which involved collecting images of breast tumors from patients at leading cancer centers in Texas – including Baylor College of Medicine, M.D. Anderson Cancer Center, and UT Health San Antonio – to both train and test its ImgAssist AI technology.
- On April 14, 2021, Perimeter provided an update on its ATLAS AI Project. Using more than 400 volumes of images of excised breast tissue collected in the first stage of the project, the standalone AI algorithm achieved a key performance metric of 0.94 AUC (area under the receiver operating characteristic curve). The data generated to date support the continued advancement of Perimeter's "ImgAssist" AI technology to the next stage of the ATLAS AI Project. Perimeter intends to conduct a randomized, multi-site, pivotal study to evaluate Perimeter OCT combined with ImgAssist AI against the current standard of care and assess the impact on re-operation rates for patients undergoing breast conservation surgery.

Summary 2020 Financial Results

All of the amounts are expressed in Canadian dollars unless otherwise indicated and are presented in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS") applicable to the preparation of interim financial statements, including International Accounting Standard ("IAS") 34, Interim Financial Reporting.

Operating expenses for the year ended 2020 were $10,159,444 compared to $8,708,853 during the previous year.

For the year ended December 31, 2020, the net loss was

$7,885,966 compared to $10,342,686 in the prior year.

For the year ended December 31, 2020, cash used in operating activities was $8,262,987.

As at December 31, 2020, cash and cash equivalents were $10,025,122 and investments were $1,674,750.

As of December 31, 2020, the Company received US$1,220,666 of the US$7,446,844 available from the CPRIT grant to fund activities related to the first year of its ATLAS AI Project.

For detailed financial results, please see Perimeter's filings at www.sedar.com and on the company's website at https://ir.perimetermed.com/.

About Perimeter Medical Imaging AI, Inc.

Perimeter Medical Imaging AI (TSX-V:PINK)(OTC:PYNKF)(FSE:4PC) is a Toronto-based medical technology company with U.S. headquarters in Dallas, Texas that is driven to transform cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address areas of high unmet medical need. Cleared by the U.S. FDA, the Perimeter S-Series Optical Coherence Tomography (OCT) Imaging System provides clinicians with cross-sectional, real-time margin visualization (1-2 mm below the surface) of an excised tissue specimen. Giving physicians the ability to visualize microscopic tissue structures "real time" in the operating room has the potential to result in better long-term outcomes for patients and lower costs to the healthcare system. Perimeter is also advancing the development of its proprietary, next-gen "ImgAssist" artificial intelligence technology under its ATLAS AI project, which is made possible, in part, by a $7.4 million grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT). Perimeter has been granted a Breakthrough Device Designation for the

Perimeter B-Series OCT coupled with ImgAssist AI, and has plans to initiate a randomized, multi-site, pivotal study to evaluate it against the current standard of care and assess the impact on re-operation rates for patients undergoing breast conservation surgery. The company's ticker symbol "PINK" is a reference to the pink ribbons used during Breast Cancer Awareness Month, underscoring the company's dedication to helping surgeons, radiologists, and pathologists use Perimeter's imaging technology and AI in the fight against breast cancer, which is estimated to account for 30% of all female cancer diagnoses this year.

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Forward-Looking Statements

This news release contains statements that may constitute "forward-looking information" within the meaning of applicable Canadian securities legislation. In this news release, words such as "may", "would", "could", "will", "likely", "believe", "expect", "anticipate", "intend", "plan", "estimate" and similar words and the negative form thereof are used to identify forward-looking statements. Forward-looking information may relate to management's future outlook and anticipated events or results, and may include statements or information regarding the future financial position, business strategy and strategic goals, competitive conditions, research and development activities, projected costs and capital expenditures, research and clinical testing outcomes, taxes and plans and objectives of, or involving, Perimeter. Without limitation, information regarding future sales and marketing activities, Perimeter's technology platform, including Perimeter S-Series OCT, Perimeter

B-Series OCT, Perimeter ImgAssist (the “Products”), sales, placements and utilization rates, reimbursement for the various procedures, future revenues arising from the sales of the Company’s Products, future potential partnerships, research and development activities, the Company’s plans to seek further regulatory clearances for additional indications, as well as the Company’s plans for development of the Products is forward-looking information. Forward-looking statements should not be read as guarantees of future performance or results, and will not necessarily be accurate indications of whether, or the times at or by which, such future performance will be achieved. No assurance can be given that any events anticipated by the forward-looking information will transpire or occur. Forward-looking information is based on information available at the time and/or management’s good-faith belief with respect to future events and are subject to known or unknown risks, uncertainties, assumptions and other unpredictable factors, many of which are beyond Perimeter’s control. Such forward-looking statements reflect Perimeter’s current view with respect to future events, but are inherently subject to significant medical, scientific, business, economic, competitive, political, and social uncertainties and contingencies. In making forward-looking statements, Perimeter may make various material assumptions, including but not limited to (i) the accuracy of Perimeter’s financial projections; (ii) obtaining positive results from trials; (iii) obtaining necessary regulatory approvals; and (iv) general business, market and economic conditions. Further risks, uncertainties and assumptions include, but are not limited to, those applicable to Perimeter and described in Perimeter’s most recent Management Discussion and Analysis which is available on Perimeter’s SEDAR profile at www.sedar.com, and could cause actual events or results to differ materially from those projected in any forward-looking statements. In particular, we note the risk that our technology

may not achieve the anticipated benefits in terms of surgical outcomes. Perimeter does not intend, nor does Perimeter undertake any obligation, to update or revise any forward-looking information contained in this news release to reflect subsequent information, events, or circumstances or otherwise, except if required by applicable laws.