

Perimeter Medical, with FDA approval of their Optical Coherence Tomography Imaging System for breast cancer, begins commercialization

Medical science continues to advance and amaze. In this case surgeons can now better see the “perimeter” (edge) of an area where cancer has been removed, all in real-time, thanks to advanced tomography and soon to be enhanced with artificial intelligence (AI). The company behind this innovation has recently gained USA FDA approval and is now commercializing their technology with an initial focus on breast cancer.

The company is Perimeter Medical Imaging AI, Inc. (TSXV: PINK) (“Perimeter”).

Two million women in the world were diagnosed with breast cancer in 2019, 317,000 of those in the USA. Breast cancer is the 2nd most common cancer in American women. The average risk of a woman in the U.S. developing breast cancer sometime in her life is about 13%, or a 1 in 8 chance. About 43,600 women in the U.S. are expected to die in 2021 from breast cancer. Clearly, that is 43,600 too many, not to even mention the global cases.

Two million reasons why we need better medical devices to diagnose and treat breast cancer

Breast Cancer is a global problem....

... and cancer left behind after surgery leads to re-operations.



2M women worldwide

were diagnosed with breast cancer in 2019¹, 317k in the U.S. in 2019²



Recurrence risk doubles when positive margins are not excised



\$16,000 cost increase per re-operation³



48% complication rates for re-operations³

Source: Perimeter Medical Imaging AI corporate presentation

Perimeter is an early stage medical device company based in Canada and USA with a focus on commercializing their Optical Coherence Tomography (OCT) Imaging System.

Perimeter recently announced that they have received USA FDA approval (FDA 510(k) Clearance) for their OCT Imaging System. The system is designed to examine tissue microstructures during surgical procedures by providing cross-sectional, real-time margin visualization. It achieves ultra-high-resolution, sub-surface image volumes of the margin (1-2 mm below the surface) of an excised tissue specimen. In addition, Perimeter is developing advanced artificial intelligence/machine learning image assessment tools intended to increase the efficiency of review. The project is called the ATLAS AI Project.

Currently, the revolutionary technology is targeting breast cancer, but the use case can be applicable to almost every cancer. 'Real-time' margin visualization assists surgeons and radiologists/pathologists with their decision making which can potentially help patient outcomes and reduces cancer costs. It is far better to get all the cancer at the margin than to have to return later with a bigger problem.

Perimeter CEO Jeremy Sobotta, stated: “This is an exciting and important milestone for Perimeter that enables us to bring our ‘commercial ready’ OCT Imaging System to the U.S. market.....Our Perimeter OCT Imaging System is the foundational building block that allows us to continue developing ‘next-gen’ improvements, such as the artificial intelligence tools currently in development under our ATLAS AI project.”

Latest news

- 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 14, Perimeter announced an important milestone in ATLAS AI project with standalone AI algorithm achieving key performance metrics.
- 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.

Perimeter’s commercialization strategy and potential revenues

Perimeter’s business model means they intend to make money from selling the Optical Coherence Tomography (OCT) Imaging

System and then a recurring revenue from its use. The chart below is only illustrative, but it gives an idea of the potential revenues that can be made **if** commercialization ramps up successfully.

The shorter term amount shown below, which could potentially one day relate to Perimeter, is a potential revenue of \$303 million pa. Longer term across all cancer segments globally there is a US\$3.7 billion addressable market.

Analysts' are forecasting Perimeter's revenue to rise from C\$1 million in 2021, to C\$3 million in 2022, and to C\$11 million in 2023. This shows the potential for revenue to scale rapidly, if successful.

Perimeter business model has the potential to reach 500 hospital early adopters thereby achieving a potential revenue of \$303M pa (first table below is in US\$,000)

Significant Initial Addressable Market Opportunity

Installed Base	100	250	500	1,000	3,000	5,000
Cumulative Capital Revenue ⁽²⁾	\$ 12,500	\$31,250	\$62,500	\$125,000	\$375,000	\$625,000
Annualized recurring revenue from installed base ⁽²⁾	\$ 11,250	\$28,125	\$56,250	\$112,500	\$337,500	\$562,500

Assumptions: 3 procedures per unit per week X 50 weeks X \$750 per consumable

Estimate of early adopter market: ~500 US hospitals performing more than 100 lumpectomies per year

New breast cancer diagnosis (US + Canada)	300,000
Breast conserving surgeries	200,000
Add selected international markets	103,500
Total initial addressable procedures	<u>303,500</u>
Total initial addressable market at \$1000/patient	
Includes: consumable, capital amortization, and service	\$ 303,500,000

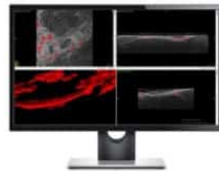
Initial Target Market

- Intraoperative breast cancer surgery
 - 500+ high-volume hospitals
 - 20-30% procedure share
- Other indications pre-AI



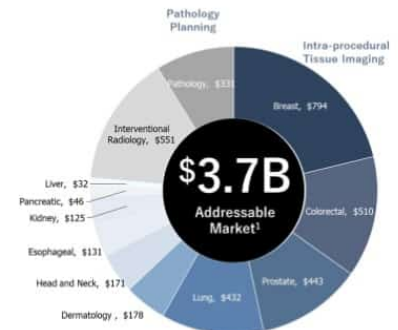
Breast Cancer AI Software

- Accelerates adoption within intraoperative breast cancer surgery
 - Enables democratizing adoption from remaining users



Total Addressable Market

- Geographic and treatment workflow expansion



Source: Perimeter Medical Imaging AI corporate presentation

Note: The above table figures are presented by Perimeter for illustrative purposes only and are not Perimeter projections.

Closing remarks

Given that breast cancer is estimated to account for 30% of all female cancer diagnoses this year the need for advanced medical technologies such as Perimeter's OCT Imaging System is enormous. Globally there are two million new cases of breast cancer diagnosed a year of which many typically would require surgery.

Perimeter's initial addressable market potential is \$303 million just in US, Canada and selected international markets, just based on breast cancer. If expanded to all cancers globally it rises to US\$3.7 billion.

Perimeter Medical Imaging AI Inc. is still at the beginning of their journey but the need and potential growth ahead are enormous. Perimeter currently trades on a market cap of C\$157 million.

Disclosure: The author is long Perimeter Medical Imaging AI Inc. (TSXV:PINK).

Warrant Exercise Builds Treasury for Perimeter's 2021 Commercialization Efforts

Last week, Perimeter Medical Imaging AI, Inc. (TSXV: PINK) announced that approximately 2.35 million warrants subject to an accelerated expiry were exercised, resulting in cash proceeds to the company of over C\$4.7 million.

Inclusive of the C\$4.7 million raised from the exercise of accelerated warrants noted above, Perimeter received over C\$7.28 million from the accelerated warrant exercise and can expect a further C\$0.68 million if the remaining warrants are exercised by March 8.

The company plans to use the proceeds in its commercialization and development plans to bring Perimeter's medical imaging solution to the market in 2021. Perimeter's direct clinical sales efforts include a limited market release of the platform this quarter with a broader commercial launch in the second quarter.

Perimeter's OTIS™ Platform

Perimeter is a medical technology company utilizing ultra-high-resolution, real-time, advanced imaging tools in cancer surgeries to improve patient outcomes and reduce costs in the healthcare system.

Perimeter's OTIS™ platform, cleared by the FDA as an imaging tool, is a system that provides surgeons, radiologists, and pathologists with ultra-high-resolution, sub-surface image volumes to allow clinicians to visualize microscopic tissue

structures during a clinical procedure.

The Problem Being Solved

According to Dr. Alastair Thompson, MD, a surgical oncologist and professor at Baylor, *“One of the big problems in breast cancer surgery is that in about one in four women on whom we do a lumpectomy to remove cancer, we fail to get clear margins.”*

Therefore doctors are searching for an effective and user-friendly tool to help identify that the breast cancer has been removed from a woman’s breast.

Baylor is one of many institutions that is conducting a study with Perimeter’s medical imaging system for providing real-time, high-resolution images of the removed tissues to assist cancer surgeons in making better decisions during operations.

Hospitals see this type of system could lead to a large improvement in patient care and reduce the need for second surgeries.

Atlas AI Project – Artificial Intelligence (AI) / Machine Learning (ML) Tools

In addition, Perimeter is advancing its advanced AI/ML image assessment tools through clinical development through its Atlas AI project.

Backed by a \$7.4 million grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT), a leading state body that funds cancer research, the project will collect images of breast tumors from up to 400 patients for the purpose of training and testing Perimeter’s “ImgAssist” AI technology to increase the efficiency of image review.

AI and analytics are seen as a way to address the inefficiencies and challenges that current operating rooms are facing in identifying cancerous tissues. According to the

company, currently 1 in 4 patients who receive a lumpectomy has to come back for a second operation because the surgeon did not remove all of the cancer cells.

Focus on Breast Cancer but Applications Beyond

Cancer continues to grow amongst the population and puts a burden on the healthcare system. According to the World Cancer Research Fund, breast cancer is the most common cancer in women worldwide, representing about 25 percent of all cancers in women.

In 2021, Breastcancer.org estimates that over 330,000 new cases of breast cancer are expected to be diagnosed in the United States and over 43,000 women are expected to die from breast cancer.

While currently focusing on deployments targeting breast cancer centers, OTIS™ has applications beyond breast cancer and into the larger multi-billion-dollar cancer surgery market.

Final Thoughts

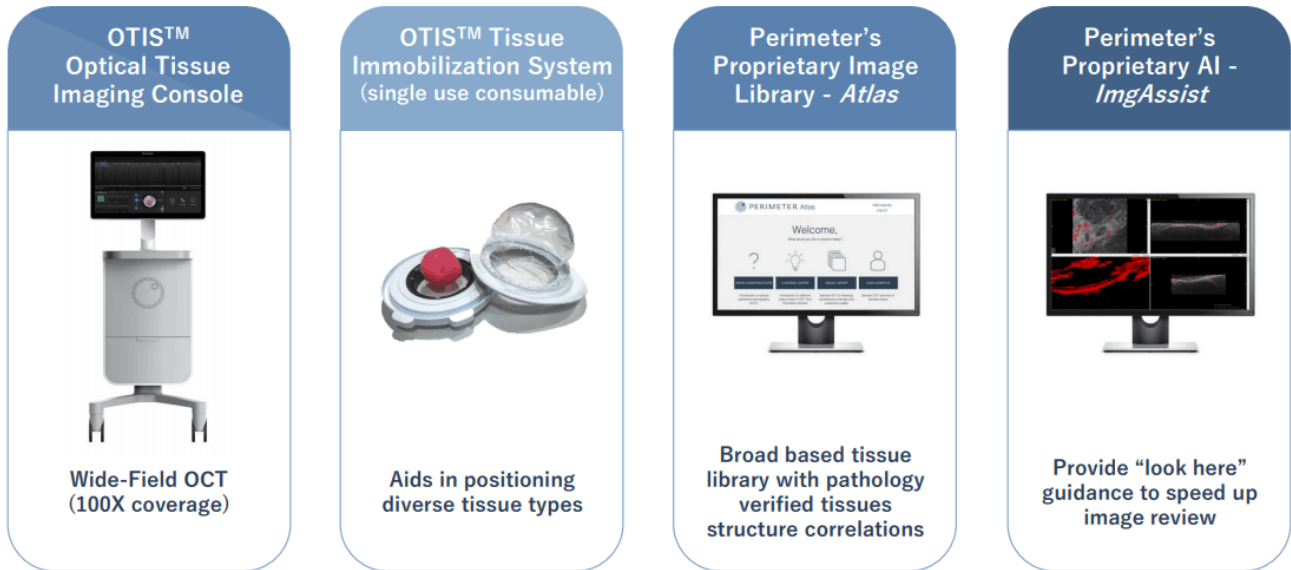
According to a recent industry report from Markets and Markets, the Surgical Imaging Market is projected to grow from US\$1.8 billion in 2020 and reach US\$2.4 billion by 2025, growing by 6.3% annually.

One of the major factors driving the growth of this market includes the increasing demand for minimally invasive procedures that Perimeter's platform addresses.

With the commercial launch of the product scheduled for this year, Perimeter has the potential to benefit from this growing market.

Perimeter's Medical Device Platform

Disruptive technology comprised of four key components



SOURCE:

Perimeter Medical Imaging AI is potentially disrupting post cancer surgery imaging with a goal to help save lives, costs, and time

Any technology that can help us beat cancer is most welcome. One company is developing a revolutionary way for surgeons to better assess if they have removed all the cancer, all while still in the operating room. This same company was recently recognized as one of the "10 most promising companies" at the Texas Life Science Forum.

The company is Perimeter Medical Imaging AI, Inc. (TSXV: PINK) ('Perimeter'). The AI in their name refers to the fact that they use Artificial Intelligence (AI) in addition to their imaging technology. A combination of imaging and AI helps surgeons identify if cancer is still present post-tumor removal surgery by examining the 'perimeter' of the excised area, hence the company name.

Perimeter's goal as a medical technology company is to transform cancer surgery with advanced, real-time, ultra-high-resolution imaging tools to address areas of high unmet medical need. Perimeter's OTIS™ platform is an FDA-cleared point-of-care imaging system that provides clinicians with real-time, ultra-high-resolution, sub-surface image volumes of the margin (1-2 mm below the surface) of an excised tissue specimen.

Perimeter's OTIS™ (Optical Tissue Imaging System) is FDA cleared point-of-care imaging system for use in real time clinical procedures



1. OTIS Optical Tissue Imaging Console

- Ultra-high resolution sub surface imaging in real time
- Automated capture
- Inter-disciplinary use
- Non-destructive to tissue
- Non-toxic (no injectable agents)
- Fits into current clinical workflow



Source

Cancer left behind after surgery is a significant problem

As we all know cancer surgery does not always get all the cancer. For example, breast lumpectomy surgeries currently face 25% re-operation rates. This is not ideal for the patient and it is not ideal for the health care system. Re-operating costs are, on average, \$16,000 to cover the additional hospital cost per patient, which when added up, amounts to an additional \$560 million annual cost to the U.S. healthcare system.

The best solution for all parties is to be able to do point-of-care real time imaging using Perimeter's Optical Tissue Imaging System (OTIS) taking only 10 minutes to do. By contrast the current standard way is to send off a post-

operative histology tissue sample for assessment, which takes 2 to 7 days. Now that's a potential disruption right there.

Perimeter's commercialization strategy

Perimeter currently uses their OTIS device in limited markets but have plans to expand, with an initial focus in the US on post surgery breast cancer imaging. According to Perimeter (and WHO projections) the total addressable market across all areas for Perimeter is US\$3.7 billion.

U.S. Commercial Market Entry

Commercialization Strategy

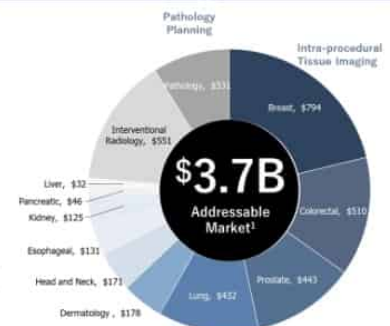
- **Build a body of clinical evidence to support commercial launch**
 - Initiated 20 patient Action Study
 - Clinical development of ImgAssist AI (ATLAS AI Project) under CPRIT grant
 - **Currently underway: 400 patient study** at leading cancer centers to collect images of breast tumors in order to train AI
 - **Next steps: Randomized, multi-site pivotal study** in ~600 patients to test AI against current standard of care / assess the impact on re-operation rates for patients undergoing breast conservation surgery
- **Direct clinical sales efforts**
 - Market development activities (Q4:20)
 - Limited market release (Q1:21)
 - Broader commercial launch (Q2:21)

Marketing Strategy

- **Target innovators and early adopters**
 - Ultrasound heavy surgeons
 - Oncoplastic surgeons
 - Regular cavity shave surgeons/frozen section

Potential Markets

- While outside the scope of Perimeter's current investment plan, OTIS™ has applications beyond breast cancer...



Source

To get a feel for the initial 'revenue potential' just from targeting US breast cancer lumpectomy cases only, Perimeter prepared the slide below. It shows based on a mid case scenario of 500 hospitals doing 3 imaging procedures per week at \$750 each, perimeter's potential revenue could reach \$56.3 million pa of recurring revenue. This is just theoretical at this stage, but shows the potential revenues from just one type of post cancer surgery (post breast cancer lumpectomy). In time Perimeter would aim to expand to many types of cancer post surgery imaging.

Perimeter's 'target potential' revenue only from breast lumpectomy post-surgery imaging

Installed Base	100 Hospitals	250 Hospitals	500 Hospitals	1,000 Hospitals
<i>3 Procedures Per Week</i>	3	3	3	3
<i>50 Weeks</i>	50	50	50	50
Annual Number of Procedures	15,000	37,500	75,000	150,000
<i>\$750 Per Consumable (ASP)</i>	\$750	\$750	\$750	\$750
Annualized Recurring Revenue from Installed Base (\$M)	\$11.3	\$28.1	\$56.3	\$112.5

Source

Perimeter's Q3 2020 financial results were reported [here](#).

Closing remarks

Perimeter Medical Imaging AI is potentially disrupting post cancer surgery imaging with a goal to help save lives, costs, and time. Perimeter's OTIS™ is already FDA cleared; however there is still some further next stage product development ongoing in the area of training the computer (AI training), as well as further studies. Perimeter is targeting a limited market release in Q1 2021 and a broader commercial launch in Q2 2021.

Perimeter's board and management team are extremely experienced and highly credentialed. The company is rapidly gaining recognition and now has a market cap of C\$87 million after only listing on the TSX-V in mid 2020. It is certainly looking like 2021 will be a breakthrough year for Perimeter Medical Imaging AI. Stay tuned.

Disclosure: The author is long Perimeter Medical Imaging AI, Inc. (TSXV: PINK)

AI for the next generation of medical imaging provides “a Google Maps for surgeons”

“A Google Maps for surgeons” is how Perimeter Medical Imaging AI Inc. (TSXV: PINK) President and CFO Jeremy Sobotta described the AI software currently being developed by the company to complement its FDA-cleared medical imaging system at a recent investment conference.

Perimeter is a medical technology company working to transform cancer surgery by creating ultra-high-resolution, real-time, advanced imaging tools to address unmet medical needs. The imaging tools have already been developed and are approved in ophthalmology and cardiology (optical coherence tomography or OCT). Perimeter is using this imaging technology (OTIS or Optical Tissue Imaging Console) to assess the tissues surrounding the known cancerous target area to determine whether more tissue should be removed during the ongoing surgery.

The imaging technology has the ability to rapidly image large and complex surfaces. It is capable of imaging up to a 10×10 centimeter surface area at resolutions ten to 100 times that of traditional imaging systems (and also has a system that enables the orientation and imaging of any size, shape and/or density of specimen). Of note, the company’s device is commercial, is FDA-cleared and will be launched into the early adopter market later in 2020/early 2021.

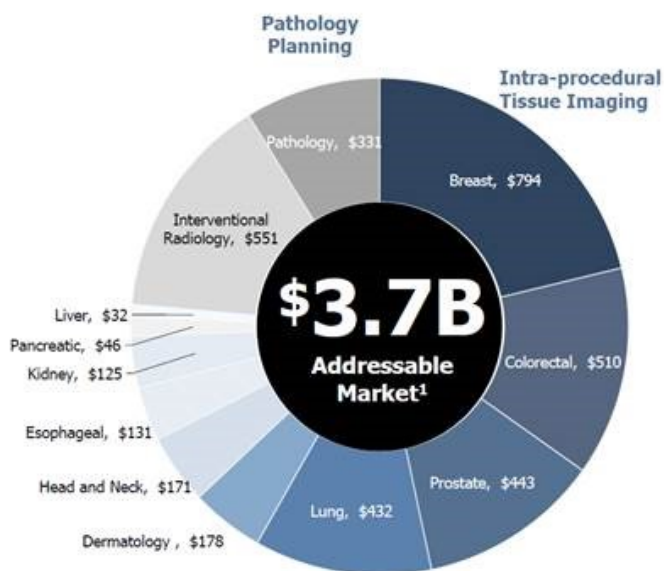
As previously announced, Perimeter Medical Imaging received a \$7.4 million Cancer Prevention and Research Institute of Texas

(CPRIT) grant to further develop the ATLAS AI Project. The funding granted by CPRIT will support technology development that is currently underway with the first part being data collection to further train and test the AI algorithm. Part two will be undertaken in early 2021 to confirm the safety and efficacy of the technology/process that aims to decrease the re-operation rates for breast cancer patients. Future deployment of the AI technology will be complementary to OTIS, once it has been FDA-approved.

As described in the September 16, 2020 online presentation, the company has engaged with world-renowned cancer centers in Canada, the US and Europe and has attracted an exceptional scientific advisory board. Members include medical professionals affiliated with the Harvard Medical School, the Mayo Clinic Cancer Centre, and the Ontario Cancer Institute in addition to others, which is an exceptional validation of this company's early-stage technology. Management is deeply experienced in the medical-technology industry, and the board of directors has a wealth of expertise in clinical experience, surgical workflows, and medical device commercialization.

The company went public at the end of June 2020 through a reverse takeover transaction and concurrent financing, and has access to approximately \$30 million of capital, so near-term development is well-funded as the company looks to sell up to half a billion dollars of installations into an undersupplied market.

Perimeter's technology is addressing an unmet need in a \$3.7 billion addressable market segment, according to the World Health Organization. It should be noted that this technology is not just restricted to breast cancer surgery, but is potentially applicable to a wide variety of other cancer and other treatments as shown below:



Addressable Market By Region

USA total addressable mkt: \$552 M

Biopsy: \$69 M
 Intra procedural: \$441 M
 Pathology: \$41 M

Europe total addressable mkt: \$1.0 B

Biopsy: \$132 M
 Intra procedural: \$839 M
 Pathology: \$79 M

ROW total addressable mkt: \$2.1 B

Biopsy: \$349 M
 Intra procedural: \$1.5 B
 Pathology: \$210 M

¹ WHO Projections for 2020.
 - Clinical Applications: Lung, Breast, Prostate, Colorectal, Liver, Head and Neck, Esophageal, Pancreatic, Dermatology and Kidney
 - Average cost per case for Intra-operative = \$500USD; Biopsy = \$50USD; Pathology= \$30USD
² Biopsy US Rates provided by MDXHealth.com

Source: Perimeter Medical Imaging AI

Finally, an estimated one in four women require repeat breast cancer surgery due to cancerous tissue remaining after the initial surgery. Perimeter’s use of existing technology and a machine learning/artificial intelligence combination is designed to significantly lessen this statistic. While it is too early to declare that this one technology is the “holy grail”, it does bring us one step closer to the statement that “cancer can be beaten”.