ENCODE
IDEAS

Perimeter Medical Imaging AI, Inc. (PINK.V)
INITIATION REPORT

October 21, 2020

FINANCIAL SUMMARY TABLE

Symbol	PINK.V
Exchange	TSX-V
Current Price	$2.02*
52 week High	$2.49
52 week Low	$0.21
O/S	38.68mm**
Market Cap	~$78.1mm*
Average Volume (3M)	~44k
Cash	~$11.2mm**

*as of 10/20/2020 **as of 6/30/2020
All Figures in Canadian Dollars

KEY CATALYST DATES

1Q 2021	OTIS Commerical Launch and First Sale
1Q 2021	ImgAssist Accuracy Data Results
2Q 2021	OTIS ImgAssist Pivotal Trial Study Initiation
4Q 2021	OTIS ImgAssist Pivotal Trial Data Relase

KEY DISCLOSURES

One or more of the Encode Ideas, L.P. partners own stock in the covered company; Encode Ideas, L.P. is currently engaged to provide research coverage and awareness to Perimeter. Encode Ideas, L.P. partners intend to continue transacting in the securities covered therein, and we may be long, short, or neutral thereafter.

HIGH CONVICTION INVESTMENT IDEA

We believe Perimeter's widefield OCT unit, OTIS, can be a solution to the reexcision "epidemic" in breast conservation surgery.

Perimeter Medical's Optical Tissue Imaging System, or OTIS, is an FDA 510(k) cleared optical coherence technology (OCT) that can rapidly image large tissue surfaces, such as an excised tumor, at 10-100x the resolution of ultrasound or MRI. OTIS can fit seamlessly within a surgical suite, allowing for intraoperative tumor tissue imaging, in order to determine if positive margins remain, and additional tissue should be removed. Initially, Perimeter will be focused on breast conservation surgery (BCS), also known as lumpectomy, where it is estimated that between 20-30% of women will require a repeat surgery due to positive margins (cancer left behind) being found via histology 2-5 days after the initial surgery. Currently, there are limited options for intraoperative tissue assessment, and those available are expensive, inconvenient, and cannot be scaled easily. OTIS has the potential to become part of the BCS standard-of-care, which we estimate to be an annual addressable market of $400mm in the U.S. BCS is the near-term commercial focus for Perimeter, but, once installed, we expect surgeons will utilize OTIS in other intraoperative settings. When considering the platform potential of OTIS across other intraoperative indications, the total annual addressable U.S. market grows to >$1b.

Base Case: Commercializing for BCS

Starting in 2021, Perimeter will launch OTIS with a 8-10 person commercial team. Initially they will be focused on high volume BCS hospitals, and within them, specifically targeting surgeons who already have experience reading patient images (ultrasound, MRI, etc.). We estimate that this approach will allow Perimeter to target 30% of the total addressable U.S. market. At a price of $150k per OTIS unit, with a $750 / treatment consumable (OTIS Tissue Immobilization System), even with this targeted approach, we believe Perimeter can build a meaningful commercial business with peak annual sales of $50mm by 2025.

Best Case: "Intelligently" Commercializing for BCS

In parallel with their 2021 OTIS launch, Perimeter will be completing the clinical development of its artificial intelligence (AI) plug-in for OTIS, ImgAssist AI. ImgAssist will highlight areas of interest (high probability of +ve margins) on a tumor image, simplifying the decision making process for a surgeon, and dramatically reducing the OTIS learning curve. Perimeter is currently running a 400-patient sample study with ImgAssist, to determine its accuracy vs histology. Perimeter will also be running a 600-patient randomized clinical trial (RCT) comparing BCS reoperation rates for OTIS with ImgAssist vs standard-of-care. These data, which are anticipated to be available in 4Q21, will then be used for an FDA De Novo 510(k) submission early-22, and potential commercial clearance for ImgAssist by 2H22. The data from the RCT combined with FDA-clearance of ImgAssist, should open OTIS adoption to the broader BCS market. In this scenario, with ImgAssist commercially available in 2022, we believe OTIS can become part of the BCS standard-of-care, with peak annual sales of $160mm by 2025.

Perimeter Medical Imaging AI: An Intelligent Investment

We believe Perimeter can re-rate over the coming years to the below expected prices based on our internal adoption curve assumptions for base and best case scenarios.

Base Case Implied Share Price	*$6.68*
Best Case Implied Share Price	*$13.50*

We believe there is a high probability that ImgAssist AI will be FDA-cleared and commercialized, and therefore ascribe a 70% probability to our best case scenario playing out. Probability adjusted, we get to a $11.45 implied stock price which would equate to a return of ~567% from today's level.

The Reexcision Epidemic

In a 2015 NEJM editorial, penned by the surgeon Dr. Hiram S. Cody III of Memorial Sloan Kettering Cancer Institute, the title "Reexcision--The Other Breast Cancer Epidemic" succinctly captures the problem Perimeter Medical seeks to address. The percentages vary from surgeon to surgeon, institution to institution, but the macro data suggest approximately 20-30% of women undergoing BCS will require a repeat surgery (reexcision) to address positive margins found by pathology after their initial surgery. Surgeons are acutely aware of the problem, but currently have limited tools to address this reexcision "epidemic". In our opinion, to address the reexcision problem and drive broad adoption, a new technology will likely need most of these key attributes;

- High accuracy (i.e. intraoperative data positively correlates with histology)
- Requires the technology to be able to discern surface and subsurface features
- Accurate for both invasive carcinoma and ductal carcinoma in-situ (DCIS)
- Rapid intraoperative results
- Total specimen imaging
- Total specimen preservation for histology (i.e. tissue sample is not altered during intraoperative assessment)
- Fits within existing surgical workflow
- Operating the technology does not require additional staffing or space
- Minimal learning curve / training required for utilization
- Cost effective

Existing intraoperative technologies or techniques do have some of these attributes, but haven't checked enough of the attribute boxes to drive meaningful adoption. Histopathology, which includes frozen sections and imprint cytology, has high accuracy for invasive carcinoma, but falls short in all the other attributes. Most notably these techniques are labor intensive and expensive, requiring a dedicated lab and pathologist in near vicinity to the operating theatre, making adoption at scale highly unlikely. Imaging technologies, such as ultrasound, MRI, and radiography, also have good accuracy for invasive carcinoma, are quicker generating results than histopathology, but struggle with accurately determining DCIS margins and subsurface features. We believe Perimeter's widefield OCT unit, OTIS, is the only technology that can successfully check all these attribute boxes, and therefore has the potential to be a solution to the reexcision "epidemic".

OTIS Attributes

In its current commercial form, OTIS, can address the vast majority of the attributes that should be required for early adoption. OTIS can deliver rapid, total-tissue imaging results of both surface and subsurface features within 5-10 minutes. The OTIS Tissue Immobilization System, a single-use consumable, assists in stabilizing the tissue specimen for imaging, and importantly preserves specimen integrity for future histology. The data generated thus far would indicate that OTIS has high accuracy to detect both invasive carcinoma, and importantly, the sometimes more challenging BCIS. A 2019 Mount Sinai study found that intraoperative tissue assessment by surgeons using OTIS were concordant with final pathology in 178/185 tissue samples for overall accuracy of 96.2% (main specimen + shave margins). Albeit from a single center study, these data would indicate that surgeons who are comfortable reading images from OTIS, can make tumor assessments real-time, that are highly correlated to histology. Finally OTIS can fit seamlessly into the existing surgical workflow, both for BCS, and in the future, for other surgical indications.

OTIS's attributes clearly position it as having standard-of-care potential for BCS. In our opinion, the final attribute needed, in order for OTIS to become standard-of-care, is its ease of use / learning curve. The surgical community is somewhat bifurcated in their interest, and comfort level, in image reading (ultrasound, MRI, etc). There is a growing group, albeit a minority, of avant-garde surgeons who are comfortable reading their patients' images. Although the OCT images generated by OTIS have 10x the resolution of ultrasound images, reading them is very similar, so the OTIS learning curve for these surgeons is minimal. Perimeter estimates that this group of avant-garde surgeons constitutes 30% of their target BCS market. For the remaining 70% of surgeons, they generally prefer to have interventional radiologists reading their images, and therefore would have a steeper learning curve towards adopting OTIS. This is where Perimeter envisions their ImgAssist AI component will dramatically expand their market. ImgAssist will highlight areas of interest, where, based on the thousands of images used to inform the AI, there is a high probability of a positive margin. The ImgAssist will simplify the image reading process, reducing the amount of training needed for surgeons to use OTIS, thereby opening up the technology to becoming standard-of-care for BCS.

Perimeter expects to sell OTIS for $150k/unit and its single use Tissue Immobilization System for $750/procedure. A 2017 JAMA Surgery publication found that the average cost for repeat BCS was $16,000. If 25% of women need repeat BCS, then the simple math would indicate that there is approximately $4k of repeat surgery cost per primary BCS. If using OTIS can lower re-operation rates from 25% to 10% then the per patient savings would be $2,400. Based on this math, a hospital doing 100 BCS/year buying an OTIS unit, could in theory see a return of its capital costs in less than a year. However, as we outlined above, in the initial stages of commercialization without ImgAssist, a hospital with an OTIS installed, may only have a few avant-garde surgeons using it. If we apply the 30% figure to the same 100 BCS/year hospital, it would take 2-years to see a return on its capital costs. These figures seem reasonable, and support OTIS's cost effectiveness in our opinion, especially considering that other intraoperative tissue assessment techniques have high logistical and human resource costs.

2021: OTIS Commercialization & ImgAssist AI Development

In 2021 we expect Perimeter to launch its commercial efforts in the U.S. with a team of approximately 8-10 people. Their initial focus will be targeting high volume BCS hospitals, where there is an avant-garde surgical champion, or two. Perimeter estimates that there are 500 high-volume (>100 BCS/year) hospitals in the U.S. During this first commercial phase, we envision a regular cadence of these leading U.S. breast cancer centers installing OTIS units. Although Perimeter will be generating revenue in 2021 off a small, but growing OTIS install-base, we caution investors from putting too much emphasis on the income statement during this initial commercialization phase. Rather, we feel emphasis should be on where OTIS is being installed, and who are the surgical champions / key opinion leaders (KOLs) driving OTIS adoption.

While keeping one-eye fixated on Perimeter's commercial developments in 2021, investors should fixate their other eye on the clinical and regulatory developments around ImgAssist AI. Early in the year, Perimeter should be reporting data from its Atlas AI Project, a two-stage clinical program supported by a US$7.4mm grant from the Cancer Prevention Research Institute of Texas. The first-stage of Atlas AI will use up to 400-patient tissue samples collected from MD Anderson, Baylor College of Medicine and UT Health San Antonio, to refine the ImgAssist algorithm and measure the accuracy of its margin assessments vs. standard histology. Although the company has not overtly stated what percentage accuracy would be considered positive from this first-stage, we feel ≥90% should be viewed favorably by investors, and warrant Perimeter transitioning to the second-stage (RCT-stage) of the Atlas AI Project. We anticipate data from the first-stage of the Atlas AI Project in 1Q21, afterwhich the company will apply for an Investigational Device Exemption (IDE) from FDA, in order to kick-off the RCT-stage of the Atlas AI project in 2Q21.

The RCT-stage of the Atlas AI Project will enroll 600 BCS patients and compare reoperation rates using OTIS with ImgAssist against the current BCS standard-of-care (i.e. no OTIS). These data are anticipated late-21, and if they show a meaningful improvement in reoperation rates with OTIS with ImgAssist versus the standard-of-care, Perimeter would then have the clinical data to pursue FDA-clearance for ImgAssist and really drive commercial adoption. We anticipate Perimeter will pursue a De Novo 510(k) clearance for ImgAssist AI, and that the company could have their submission into FDA by early-22. This would put ImgAssist AI on track for a potential mid-22 FDA clearance and launch.

Perimeter should have commercial, clinical and regulatory developments throughout 2021. We like the combination of early commercial traction with OTIS coupled with the blue-sky clinical and regulatory developments around ImgAssist AI. As we suggested above, we think investors should keep one eye on the commercial adoption of OTIS in 2021, and the other on the ImgAssist developments, which foreshadow where the company is headed.

Scenario Analysis

Our base case assumption for Perimeter is predicated on the commercialization of OTIS alone, without ImgAssist AI. Although we think there is a very low-probability that ImgAssist is declined by FDA, we could see a delay in its commercialization, if for example, FDA insisted Perimeter head down a pre-market approval (PMA) path instead of the De Novo 510(k) path we expect. Investors should be comforted that, even in the scenario of an ImgAssist delay, OTIS's appeal for the group of avant-garde surgeons, which constitutes 30% of the total addressable BCS market, remains fully intact. Most of the attributes we outlined earlier; speed, total-tissue imaging, fitting in the surgical workflow, sample preservation, are all independent of the AI. Even with this targeted approach, we believe Perimeter can build a strong commercial business with peak annual sales of $50mm by 2025. Furthermore, the platform potential of OTIS is also independent of the AI, so as more units are placed, more experimentation in new surgical settings should occur, which could represent additional upside to our base case assumptions.

In our best case assumption, with FDA clearance in 2022 for ImgAssist, Perimeter will have a technology (OTIS + ImgAssist) that allows them to tackle the entire BCS market. ImgAssist, by highlighting areas of interest on an image, will dramatically reduce the OTIS learning curve for surgeons. The evidence from the RCT will motivate hospitals and surgeons to adopt OTIS, and make it part of their standard-of-care for BCS. In this scenario we estimate peak commercial sales of $160mm by 2025.

Financial Considerations

In July 2020 Perimeter went public on the Toronto Venture Exchange (TSX-V) via an RTO with New World Resources. In addition to its TSX-V listing as PINK, Perimeter trades in the U.S. under the old New World OTC symbol, NWFFF, and in August also listed on the Frankfurt Exchange under the trading symbol 4PC, We expect the company to pursue a listing on a U.S. national exchange in 2021.

Perimeter's main shareholder is Toronto-based Roadmap Capital, a special-situations focused private equity firm, who controls approximately 16.7mm shares or 44% of the O/S. The shares controlled by Roadmap are subject to an 18-month hold period from the time of Perimeter's listing on the TSX-V. The principal of Roadmap, Hugh Cleland, is on the Perimeter board of directors.

Perimeter reported a cash balance of CA$11.2mm as of 06/30/20. Their cash balance does not include the US$7.4 CPRIT grant. We believe Perimeter's cash balance is sufficient to fund operations into 2022. We anticipate the company could raise additional capital in the 2H21 as part of a listing on a U.S. national exchange and to support the commercial ramp from the anticipated FDA-clearance of ImgAssist AI.

Executive Summary

I. Introduction

1.1 Cancer

As the world's second highest leading cause of death, cancer affects millions of people of all ages annually (World Health Organization, 2018). In 2018 alone, over 17 million new cancer cases were diagnosed with over 9 million cancer-related deaths, with both numbers expected to almost double by 2040 (World Health Organization, 2018). Among the most prevalent types of cancer are lung, breast, and stomach (World Health Organization, 2018).

Types of Cancer	Number of New Cases Worldwide in 2018
Lung	2.09 Million
Breast	2.09 Million
Stomach	1.03 Million
Prostate	1.28 Million
Colorectal	1.80 Million

Table 1
(World Health Organization, 2018)

1.2 Breast Cancer

Breast cancer, involving the metastasis of cell tumors in the breast, affects 1 in 8 women, with 3 percent of women facing fatal consequences eventually, according to the American Cancer Society, marking itself as the most common cancer in women (American Cancer Society, 2019). In 2020, over 276,000 cases of breast cancer were predicted to be diagnosed in women with over 42,000 deaths, making up 7.0% of cancer deaths in the US (National Cancer Institute). In 2019, almost 317,000 cases of breast cancer were actually diagnosed in women (American Cancer Society, 2019).

There are four main stages of breast cancer, according to the Surveillance, Epidemiology, and End Results (SEER) system: in situ, local (Stage I), regional (Stage II), and distant (Stage III) with each subsequent stage indicating an increase in the geographic spread of the tumor cells (American Cancer Society, 2019). Figure 1 displays the percent of cases diagnosed on average by stage. On a molecular level, different forms of breast cancer can be categorized by the existence of estrogen receptors (ER +/-), progesterone receptors (PR +/-), hormone receptor (positive when ER+ and PR+), and human epidermal growth factor receptor 2 (HER2 +/-), with the four main categories indicated in Figure 2 (American Cancer Society, 2019).

The highest risk factors for breast cancer are old age (65+), pathogenic genetic variations, and atypical hyperplasia with history of relatives with breast cancer diagnoses, weight, hormones, and reproductive history also playing a significant role among many other factors (American Cancer Society, 2019). Chemoprevention and preventive mastectomies can be undertaken to decrease the risk of contracting breast cancer beforehand, but these processes typically come with other health effects and cannot ultimately guarantee the complete elimination of any risk (American Cancer Society, 2019). As the stages of breast cancer progress, the survival rate for those diagnosed decreases significantly according to Figure 3.

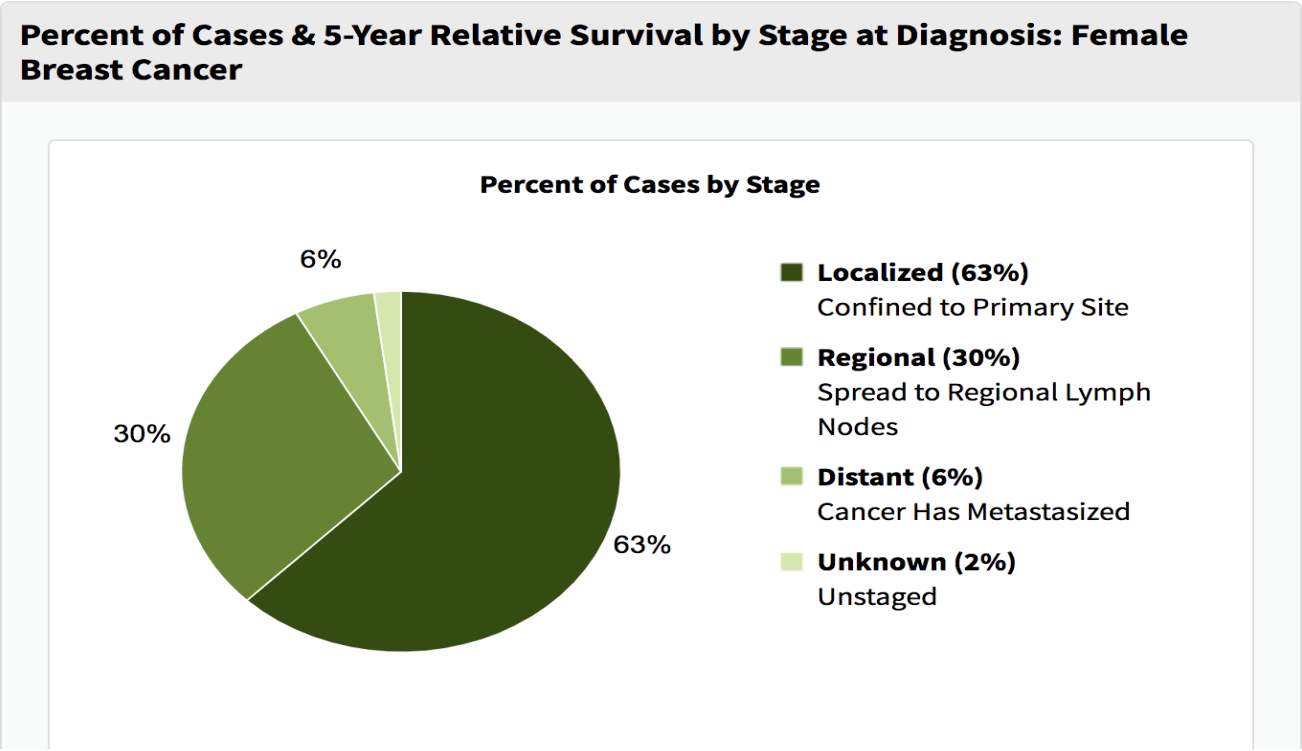


Figure 1
(National Cancer Institute)

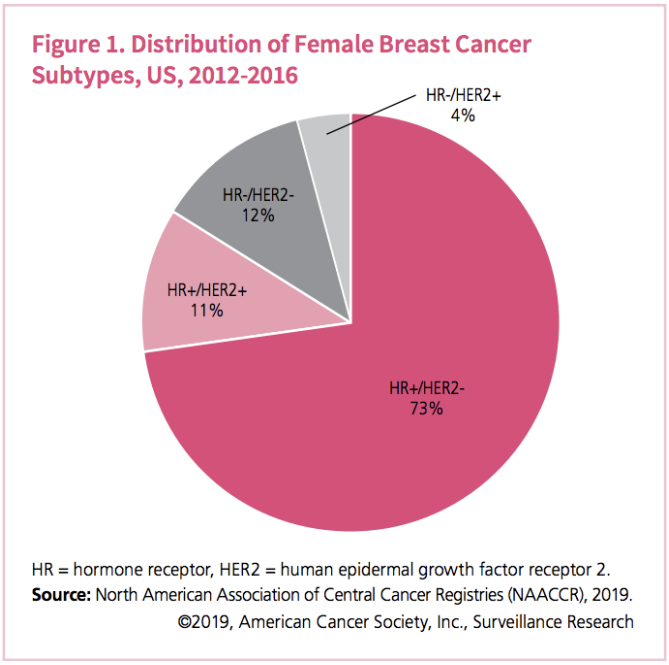
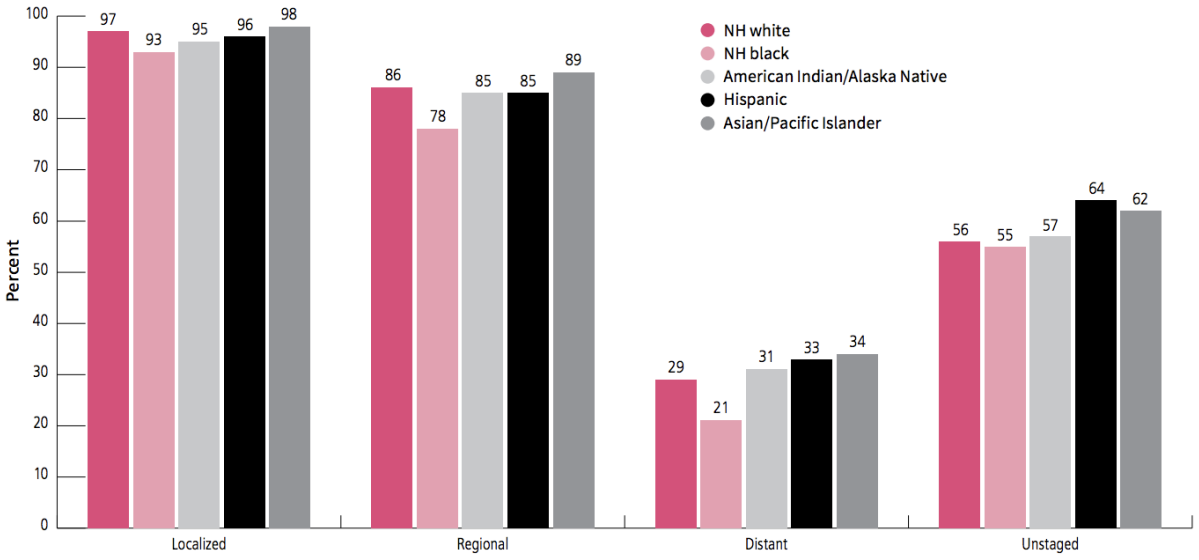


Figure 2
(American Cancer Society, 2019)

Figure 11. Five-year Breast Cancer-specific Survival Rates (%) by Stage at Diagnosis and Race/Ethnicity, US, 2009-2015



Survival rates are based on patients diagnosed during 2009-2015 and followed through 2016.
Source: SEER Program, 18 SEER registries, National Cancer Institute, 2019.

Figure 3
(American Cancer Society, 2019)

1.3 Breast Cancer Diagnosis and Treatments

Early screening, diagnosis, and treatment is necessary in order to treat breast cancer in a timely manner to avoid tumor escalations as depicted in Figure 3 (National Cancer Institute, 2020). Current methods of diagnoses include mammograms, clinical breast exams, ultrasounds, MRIs, and biopsies (National Cancer Institute, 2020). Out of the 1.6 million breast biopsies conducted in the US annually, almost 1 in 4 yield inaccurate results, a rate of accuracy in screening that leaves room for improvement (Elmore et al, 2015).

Once the existence of an invasive tumor is confirmed, several methods for treatment exist: hormone therapies, chemotherapy, radiation therapy, immunotherapy, and surgery (the most common) among others (National Cancer Institute, 2020). Within surgery, several avenues exist ranging from lumpectomies (breast-conserving surgery or BCS) to full mastectomies (American Cancer Society, 2019). Full mastectomies involve the complete removal of the breasts; lumpectomies involve a partial removal (American Cancer Society, 2019).

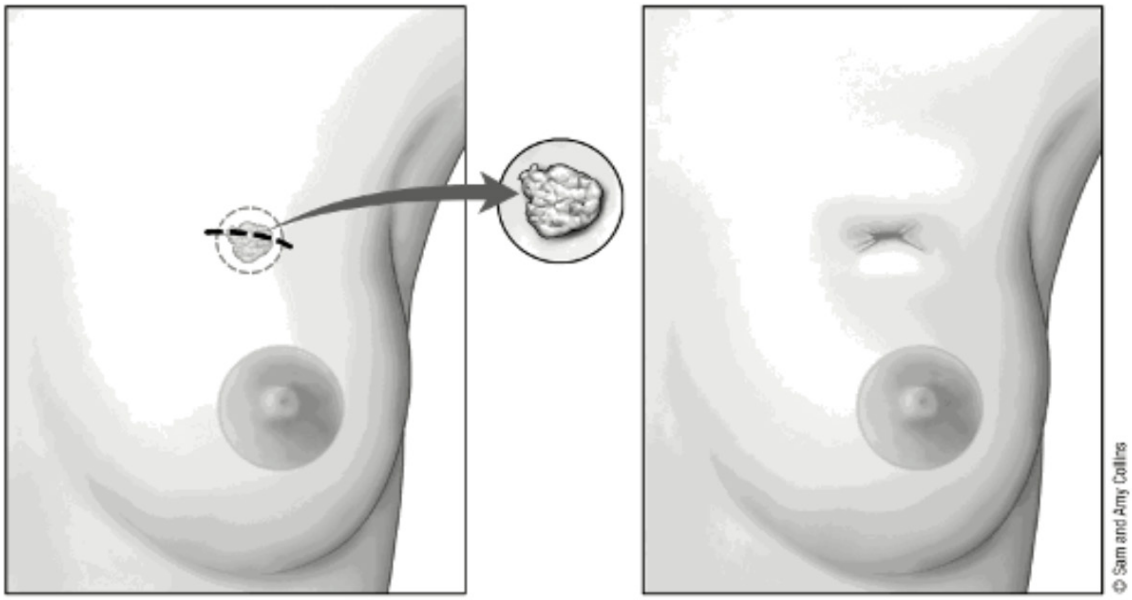


Figure 4
(American Cancer Society, 2019)

As depicted in Figure 4, lumpectomies involve the careful extraction of cancerous tissue and tumors and some surrounding "healthy" tissue (Cancer Research UK, 2017). After the procedure, a tissue sample is sent to pathologists to identify the extent of the tumor – the distance of the cancer cells from the edge of the tissue sample defines a margin of interest (Nowikiewicz et al, 2019). If the cancer cells fall within the margin (positive), reexcision may be necessary; if the cancer cells do not fall within the margin (negative), risk of recurrence is considered to be lower (Cabioglu et al, 2007). These margins vary year by year as new studies come to light. Due to the extended timeline (5-7 days) necessary for a pathologist to examine the tissues and report back on the margin, surgeons cannot take action to identify the true extent of the tumor during surgery through other means and must rely on histological reports post-surgery, increasing the rates of reexcision (Perimeter Medical Imaging, 2019).

1.4 Therapy Risks

With the current standard of care, breast cancer patients who are surgically treated remain at risk (Fisher et al, 2018). Since the mid-1900s, the process of lumpectomies and mastectomies have evolved in the discipline of oncoplastic surgery to try and balance conserving breast cancer tissue and the general appearance of the breast while also eradicating harmful and diseased tissues, a discipline that is still evolving (Freeman et al, 2018). According to a study on breast-conserving treatments, around 20-30% of breast cancer patients post-surgery still have cancerous cells (positive margins) in the vicinity of the surgery location in the breast, cells that have twice the likelihood of leading to a resurgence in tumor growth and the need for multiple operations, as shown in Table 2 (Houvenaeghel et al, 2019).

Lumpectomies have a shorter recovery time and have less of an overall effect on the body than mastectomies, leading to BCS being a popular treatment option, but lumpectomies decrease in value relative to mastectomies depending on reexcision rate: around 20% of those who choose a lumpectomy or breast-conserving surgery have to undergo a reexcision (Houvenaeghel et al, 2019). This rate of reexcision can vary drastically depending on the surgeon: in one conducted study with around 5000 physicians conducting BCS, the reexcision rates individually ranged from 0 to 91.7% (Kaczmarski et al, 2019). Due to several factors affecting the reexcision rate of individual surgeons including experience, the specific patient, and treatment options, it is difficult to identify an exact reexcision rate per institution as it is not currently an established metric for evaluation (Kaczmarski et al, 2019). This has widespread effects: patients often have to take up additional financial burdens, undertake the risk of surgery again, and may suffer prolonged physical consequences, both healthwise and cosmetically (Perimeter Medical Imaging, 2019). Some patients may even choose to have a mastectomy the second time to avoid any further

risks, which on average could increase 2-year by $26,276; patients who undergo BCS again have an average cost increase of $11,621 for the same period (Metcalfe et al, 2017).

On average, patient costs for reexcisions add an additional $16,072 in costs (Metcalfe et al, 2017). From the clinical side, high reexcision rates reflect poorly on the standard of care provided. Reducing said reexcision rate is extremely important for both patients and institutions as reducing the reexcision rate by even a marginal amount can save hundreds of thousands of dollars in operating costs for hospitals: for patients, the vastly variable reexcision rate can be the difference between choosing breast-conserving surgery over other forms of treatment or choosing one surgeon over another (Elmore et al, 2019). While measures such as changing the guidelines for positive vs. negative margins and attempting to introduce intraoperative pathological assessments into the clinical process have been considered and attempted, none have been particularly effective in bringing the reexcision rate down to the ideal 0% (Elmore et al, 2019).

Authors	Total BCS	Re-operation	
		Nb	%
Fisher 2002-2005	2586	503	19.45
2006-2009	3073	584	19
van Leeuwen			
2002-2005	9868	2974	30.14
2006-2009	11662	3445	29.54
2010-2013	12928	3599	27.84
Our data 1995-2004	3407	1117	32.78
2005-2010	2511	788	31.38
> 2010	4844	1263	26.07
Morrow 2005-2007	1100	374	34
Jeevan 2012	55297	11032	20
Laghans 2010-2013	4118	725	17.6
Landercasper 2013	6725	1451	21.6
Morrow 2013-2015	2509	543	22
Phipott 2013-2015	562	110	19.6
Findlay-Shirras 2009-2012	2494	556	22.3
Hughes 2010-2012	581	146	25.13
Wilke 2004-2010	241597	74517	30.8
HeelanGladden 2010-2016	863	99	11.5
Shuk-Kay Tang 2016	2858	492	17.2
TOTAL			
≤ 2005	15861	4594	28.96
2005-2010	259943	79708	30.66
≥ 2010	93779	20016	21.34

Table 2 (Houvenaeghel et al, 2018)

II. Product

2.1 Overview of Perimeter's Product

Perimeter Medical Imaging is pioneering a new imaging platform to optimize imaging in real time for clinicians. Perimeter's OTIS™ 2.0 platform consists of four main components: the OTIS™ Optical Tissue Imaging Console, the OTIS™ Tissue Immobilization System, the OTIS™ Imaging Atlas, and AI Tissue Assessment Algorithms that are in development.

2.2 OTIS™ Optical Tissue Imaging Console

The OTIS™ Optical Tissue Imaging Console (OTIS Imaging Console, shown in Figure 5) is a wide-field optical coherence tomography (OCT) system developed by Perimeter Medical Imaging. OCT technology has previously been used in fields such as optometry and ophthalmology for high resolution imaging of the eye in real time but has recently begun to expand into other disciplines such as cardiology and dermatology (Perimeter Medical Imaging, 2020). In the field of ophthalmology, OCT technology was originally used for retinal imaging, and its uses in microscopic disease imaging have spread to cancer imaging and cardiovascular system assessment. OCT imaging has strong similarities in modality to ultrasound B mode imaging, with the exception that OCT relies on near infrared light waves rather than sound waves (Fujimoto et al, 2000). OCT imaging relies on recording the time delay of the reflected light waves as they bounce off the object to be imagined and scatter back through space (Fujimoto et al, 2000). The relative echoed time delays and the intensity of the backscattered waves as the object is scanned in the transverse direction are used to map the surface and establish the position and details of the microstructure of the object in a two-dimensional data set, as shown in Figure 6 below (Fujimoto et al, 2000).

Figure 5
(Perimeter Medical Imaging, 2020)

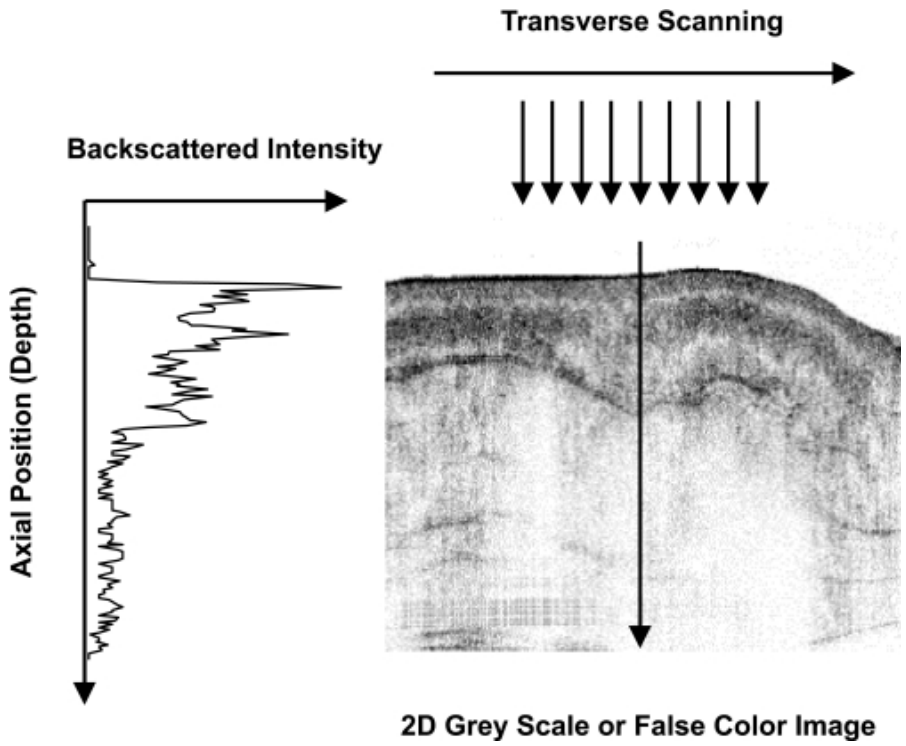


Figure 6
(Fujimoto et al, 2000)

OCT imaging has limited image depth compared to ultrasound imaging and magnetic resonance imaging (Fujimoto et al, 2000). However, OCT imaging provides a higher imaging resolution due to higher frequency waves than either ultrasound or magnetic resonance imaging: OCT images have a resolution that is 100 times greater than magnetic resonance images and 10 times greater than ultrasound images, which is necessary for identifying microscopic disease structure (Perimeter Medical Imaging, 2020).

Perimeter's OTIS Imaging Console offers high image resolution scanning typical of OCT technology combined with full specimen scanning capabilities at 6.5-15 micron resolution that allows for observing the surfaces of surgical specimens to around two millimeters deep. Perimeter's OTIS Imaging Console also offers a novel broader field of view in scanning, as previous traditional OCT applications have had a more limited scope of scanning on the scale of a few square centimeters – the development of this "wide-field" approach by Perimeter allows for scanning of more complex tissues and surfaces that can provide intraoperative information during procedures.

2.3 OTIS™ Tissue Immobilization System

The OTIS™ Tissue Immobilization System (Tissue Immobilization System, shown in Figure 7), is a single-use consumable device composed mainly of a plastic container and attached plastic bag, used for positioning a tissue specimen during scanning and developed by Perimeter Medical Imaging.

Movement during a tissue scan can result in compromised image resolution and overall quality: the Tissue Immobilization System rectifies this issue by attaching the plastic container component to the excised tissue specimen on the OTIS Imaging Console. When the tissue is positioned as desired by the user, the user can then activate a vacuum within the immobilization system, where the plastic bag on top of the system compresses and loses air, creating a vacuum that holds the tissue in place while scanning is completed.

Figure 7
(Perimeter Medical Imaging, 2020)

2.4 OTIS™ Imaging Console and Tissue Immobilization System Application

The OTIS Imaging Console and Tissue Immobilization System can scan excised tissues in real time during a surgical procedure and return a volume of images in as little as 2 minutes, depending on the scan density and the exact volume of images desired. During a surgery, users can remove a tissue specimen from the patient and place it on top of a glass window on the OTIS Imaging Console to be scanned. The Tissue Immobilization System would then be attached to the specimen before creating a vacuum and immobilizing the tissue to create optimal imaging conditions for the specimen at the angle and resolution required. Once the specimen is fixed in place, the user can highlight the area to be scanned using the Imaging Console and set the scan density: higher scan density optimizes quality through an increased volume of images over a longer period of time while lower scan density is faster but with a lesser volume of specimen images. Once the scan is finished, the user can scroll through the volume of images produced.

While standard procedures for imaging excised tissues take 2-7 days to send to a lab in order to receive a histopathology report, the OTIS platform can produce the necessary images in as little as 2 minutes (Perimeter Medical Imaging, 2019). In a traditional surgery, a radiologist would have to analyze the images to provide feedback to the surgeon: with the OTIS platform, surgeons can be trained to analyze the images and specific disease structures themselves, reducing the immediate need for a radiologist to provide intraoperative image analysis. The images provided by the OTIS platform are without color but contain details necessary for microscopic disease identification, as shown in Figures 8, 9, and 10 below.

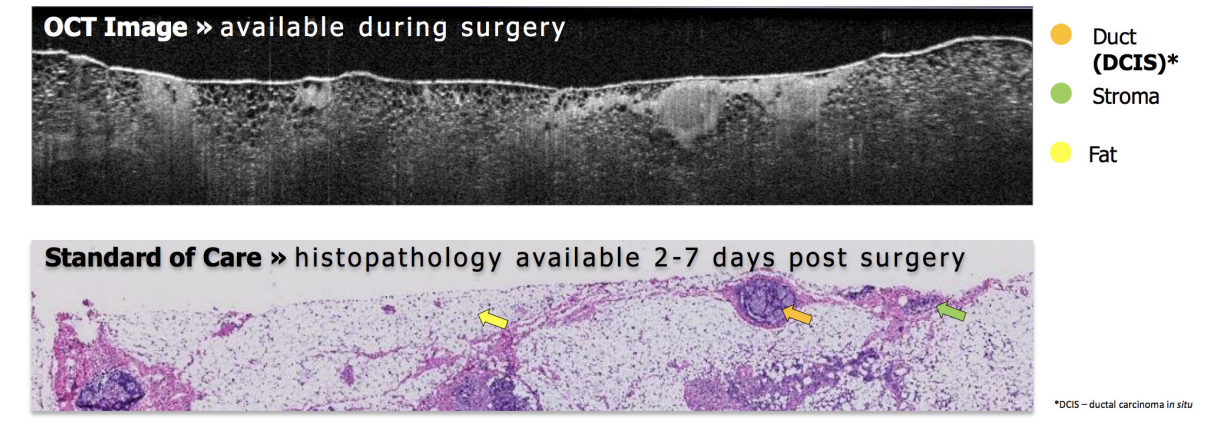


Figure 8 (Perimeter Medical Imaging, 2019)

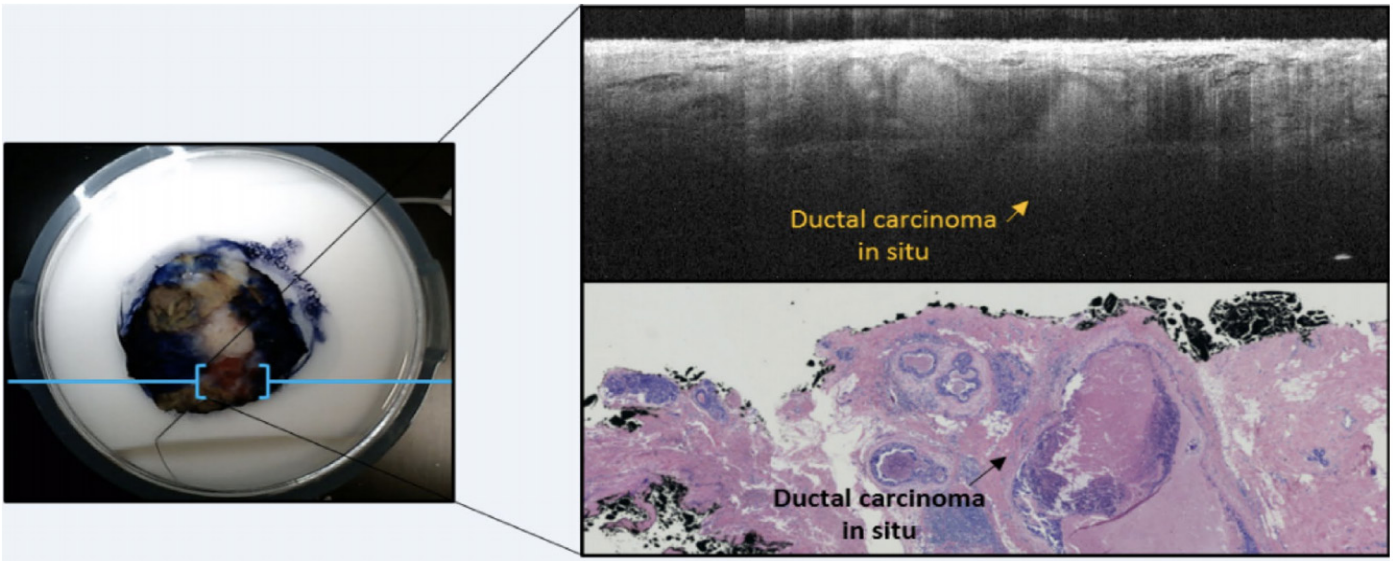


Figure 9
(Schmidt et al, 2019)

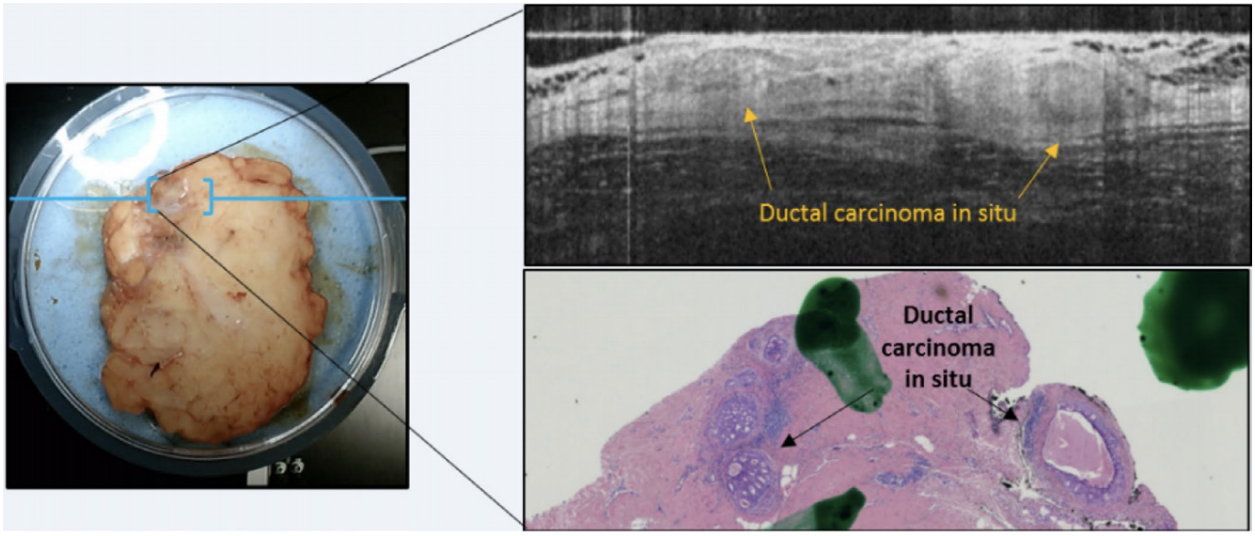


Figure 10
(Schmidt et al, 2019)

2.5 OTIS™ Imaging Atlas

To further facilitate image analysis during surgery, Perimeter Medical Imaging is also putting together a proprietary Imaging Atlas (shown in Figure 11). The Imaging Atlas contains a continually growing volume of images of normal and abnormal breast cancer tissue specimens along with a learning application and case examples: this atlas can be used to compare a user's scans to similar images, both wide-field OCT and histopathology, during surgery to identify areas of interest and to train a reader to identify microscopic disease structures using image-based learning.

Figure 11
(Perimeter Medical Imaging, 2020)

2.6 AI Tissue Assessment Algorithms

To further enhance the OTIS™ Imaging Atlas, Perimeter is developing machine learning algorithms (ImgAssist AI technology) for use in OCT scanning (Figure 12). These machine learning algorithms are being developed to be able to identify features of interest in OTIS-produced images (shown in Figure 13 and 14 below in red). Studies regarding the algorithms are still ongoing with data anticipated in the future that will allow the algorithms to be approved for use, but the tool is intended to serve as a supportive software component to aid physicians in their image analysis efforts.

Figure 12
(Perimeter Medical Imaging, 2020)

ImgAssist AI relies on feeding a growing dataset of images with clearly defined and identifiable cancer signatures into the algorithm so that a strong correlation develops through which the OTIS platform can identify new cases. The number of images used to train the algorithms strongly correlates to the accuracy of the machine learning

algorithm when used in practice. When a user scans a tissue specimen using the OTIS Imaging Console, areas of interest are highlighted in blue, allowing the user to scroll through and select images to look at it in greater detail (where areas of interest are then highlighted in red as seen below). Higher sensitivity in the algorithm correlates with lower specificity and vice versa.

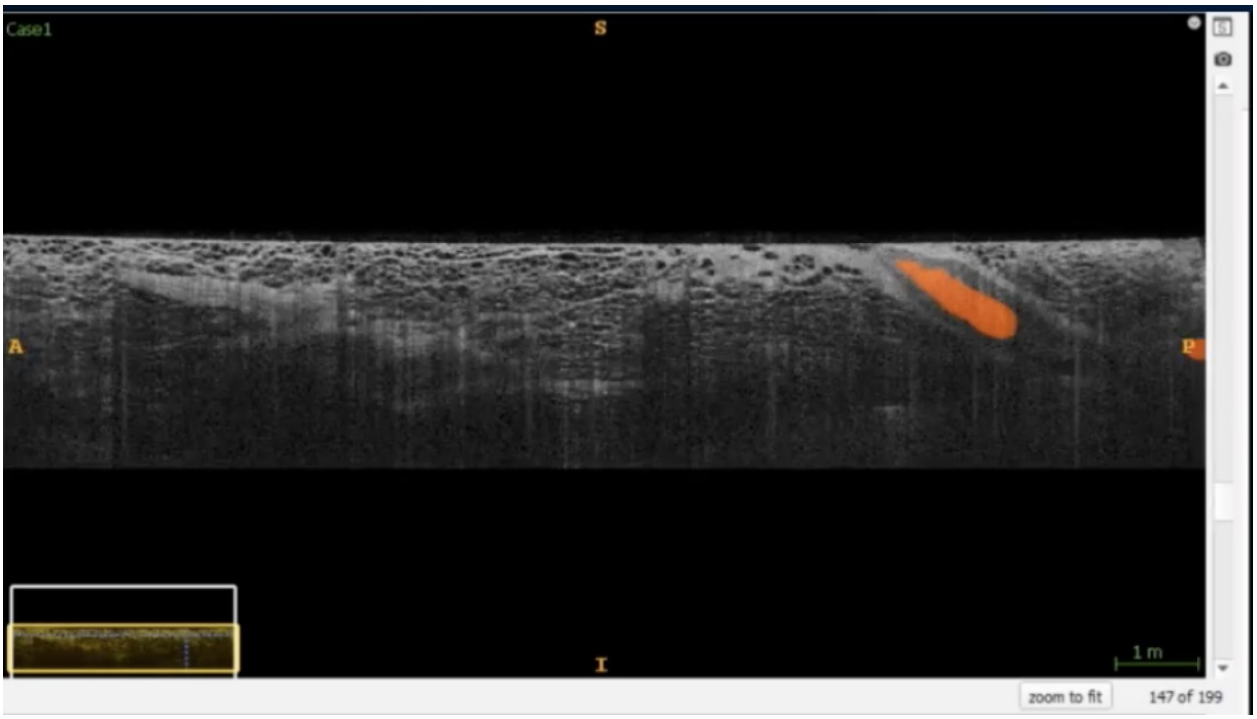


Figure 13
(Perimeter Medical Imaging, 2020)

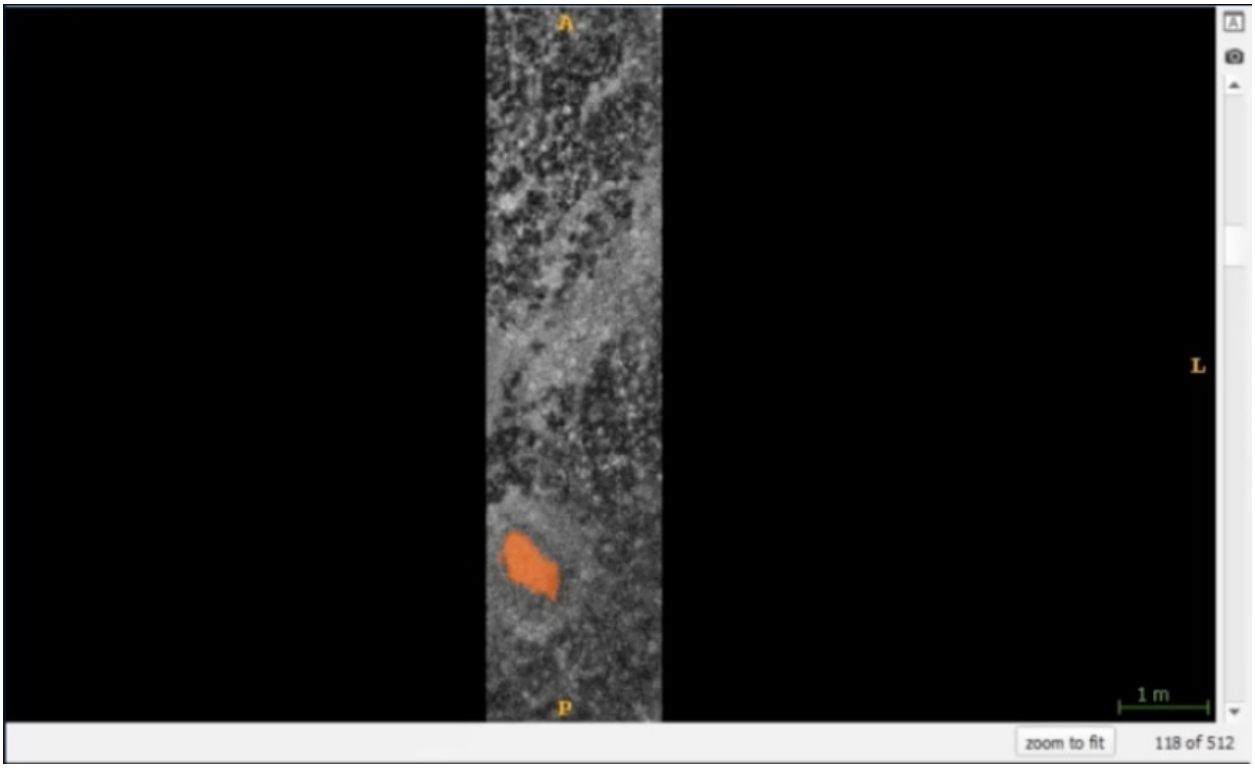


Figure 14
(Perimeter Medical Imaging, 2020)

III. Discussion

3.1 Clinical Studies

Perimeter has tested its platform in various published studies and a new pivotal program, Atlas AI Project, was started in 2020, across multiple locations, to test and train its ImgAssist AI technology. Over the course of the past studies, the platform has generated over a thousand volumes of OCT images while scanning over 400 tissue specimens, dominantly breast cancer samples (Perimeter Medical Imaging, 2020). In a study published in Academic Radiology in November 2017, the OTIS Imaging Console was used to determine whether breast cancer physicians could learn to identify diseased areas of a breast cancer tissue excision during BCS using OCT images, using traditional lab-based histology as the standard of comparison (Ha et al, 2017). Breast cancer samples from Columbia University Medical Center (CUMC) and Pathologists Diagnostic Services (PDS) in North Carolina were used in the OCT scans (Ha et al, 2017). The study was conducted using the guidelines summarized in the flowchart

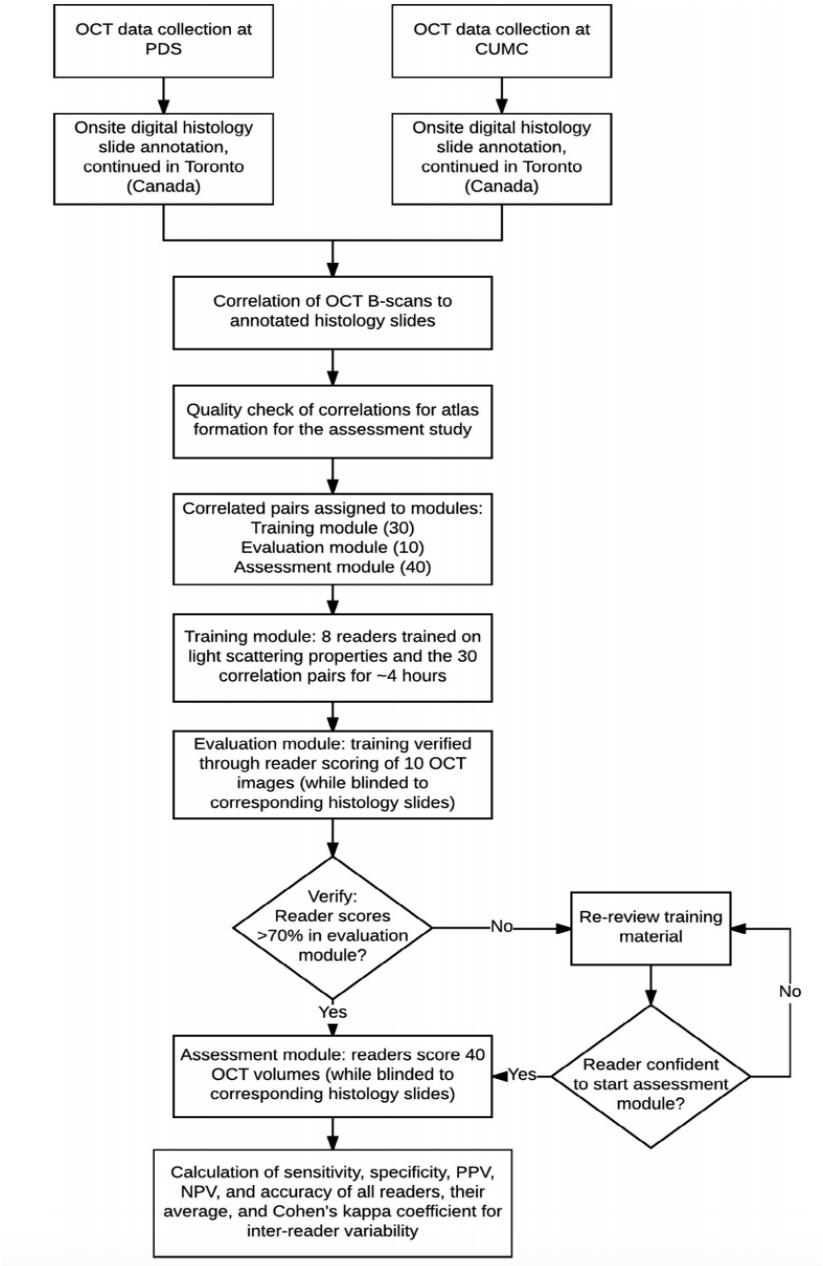


Figure 15
(Ha et al, 2017)

The results of the study asserted that physicians could be trained in around 3.4 hours to use OCT images to identify microscopic disease structure during BCS with an accuracy rate of 88%, with room to improve (Ha et al, 2017). The specific data from the study has been summarized in the two tables below (Table 3 and 4).

TABLE 3. Average Assessment Results for Distinguishing Non-suspicious From Suspicious Breast Tissue for Readers From Different Disciplines

Reader Discipline	Sensitivity	Specificity	PPV	NPV	Accuracy
Radiology	85%	93%	0.89	0.91	0.94
Pathology	79%	90%	0.85	0.87	0.84
Surgery	76%	84%	0.77	0.85	0.82
The 7 clinician readers	81%	89%	0.84	0.88	0.88
All 8 readers	80%	87%	0.82	0.87	0.87

NPV, negative predictive value; PPV, positive predictive value.

Table 3
(Ha et al, 2017)

TABLE 2. Statistical Analysis of the Results for Distinguishing Non-suspicious From Suspicious Breast Tissue

Reader	Time	Sensitivity	95% CI	Specificity	95% CI	PPV	NPV	Accuracy
R#1	90 min	81%	0.62–1.00	92%	0.81–1.00	0.87	0.88	0.89
R#2	94 min	81%	0.62–1.00	96%	0.88–1.00	0.93	0.88	0.97
R#3	87 min	94%	0.82–1.00	92%	0.81–1.00	0.88	0.96	0.96
P#1	189 min	94%	0.82–1.00	83%	0.68–0.98	0.79	0.95	0.89
P#2	150 min	63%	0.39–0.86	96%	0.88–1.00	0.91	0.79	0.80
S#1	180 min	88%	0.71–1.00	75%	0.58–0.92	0.70	0.90	0.81
S#2	90 min	63%	0.39–0.86	92%	0.81–1.00	0.83	0.79	0.84
NC	137 min	75%	0.54–0.96	71%	0.53–0.89	0.63	0.81	0.82

CI, confidence interval; NC, non-clinician; NPV, negative predictive value; P1–P2, pathologist 1–2; PPV, positive predictive value; R1–R3, radiologist 1–3; S1–S2, surgeon 1–2.

Table 4
(Ha et al, 2017)

In another study published in the Breast Journal in 2019, the viability of using OCT imaging to determine surgical margins during BCS was tested (Schmidt et al, 2019). Fifty patients were examined with the relevant demographics summarized in the table below (Table 5) (Schmidt et al, 2019).

	Number	Percent
Patients	50	
Mean age	61	
Tissue samples	185	
Histology		
IDC	33	66
ILC	2	4
Pure DCIS	14	28
Sarcoma	1	2
Single surgery	43	88
Margin re-excision	7	12
Convert to mastectomy	0	0
Cases with routine cavity shaves	38	76
Cases with directed shaves	10	20
Cases with shaves scanned using OCT	34	76
Tumor size		
T0	10	20
T1	35	70
T2	5	10
Node status		
N0	5	10
N1	44	88
N2	1	2
Hormone receptor positive	42	84
Her2 positive	4	8
Triple negative	5	10

Table 5
(Schmidt et al, 2019)

The results of the study indicated that OCT image analysis by a trained user accurately matched up to traditional gold standard postoperative lab-based pathology in 178 out of 185 tested cases for an accuracy rate of 96.2% (Schmidt et al, 2019). The results of the study are summarized in the table below (Table 6).

	Main lump + all shavesN = 50 and N^1 = 185	DCIS only Main lump + all shavesN = 14 and N^1 = 52	Additional shavesN = 50 and N^1 = 135	Re-excisions[a]N = 7 and N^1 = 19	Main lump onlyN = 50 and N^1 = 50
OCT accuracy	96.2% (178/185)	92.3% (48/52)	99.2% (134/135)	94.7% (18/19)	86.0% (43/50)

Abbreviations: N, number of patients; N^1, number of tissue samples; OCT, Optical coherence tomography; WF-OCT, wide-field optical coherence tomography.
[a]OCT concordance based on initial BCS.

Table 6
(Schmidt et al, 2019)

In an upcoming study, supported by funding from the Cancer Prevention and Research Institute of Texas, Perimeter Medical Imaging will be evaluating the ImgAssist AI algorithms to obtain FDA approval and testing them against the current standard of care by training the model with new datasets. Data and results are expected from these studies in the future.

3.2 Industry: Cost and Market Size

Perimeter's OTIS 1.0 (pre-commercial) and OTIS 2.0 platforms have received FDA clearance in 2016 and 2019 respectively (Perimeter Medical Imaging, 2020).

When launched, the expected average selling price for the product is $150,000, the expected average selling price for the consumable is $750, and the average cost of services is 10% of the capital price (Perimeter Medical Imaging, 2020). Perimeter plans to initially target a market of 500 high-volume lumpectomy-performing hospitals and centers, with the expectation that each institution performs 100 or more lumpectomies per year.

Currently, the OTIS platform has a Category III CPT code. Reimbursement for the device will be dependent on the outcomes of clinical studies that are set to take place in 2021 based on the performance of the AI portion of the platform, which will provide information to move to Category I and bring the device from the investigational phase to mainstream commercialization.

3.3 Intellectual Property

The OTIS platform has been issued 4 patents with 9 others pending (Perimeter Medical Imaging, 2020). Perimeter owns patents for the wide-field OCT scanning technology along with subsequent image generation and for the single-use consumable tissue immobilization system. While the specific patents for the algorithms have not been issued, clearance for the patented platform will encompass the device, consumable, and Perimeter's software in-development.

3.4 Future Considerations

Beyond the OTIS platform's use in breast cancer surgical imaging, Perimeter has plans to expand the use of OCT imaging to other tissue types, including thyroid, colon, and head & neck specimens. Sample OCT images are provided below (Perimeter Medical Imaging, 2019).

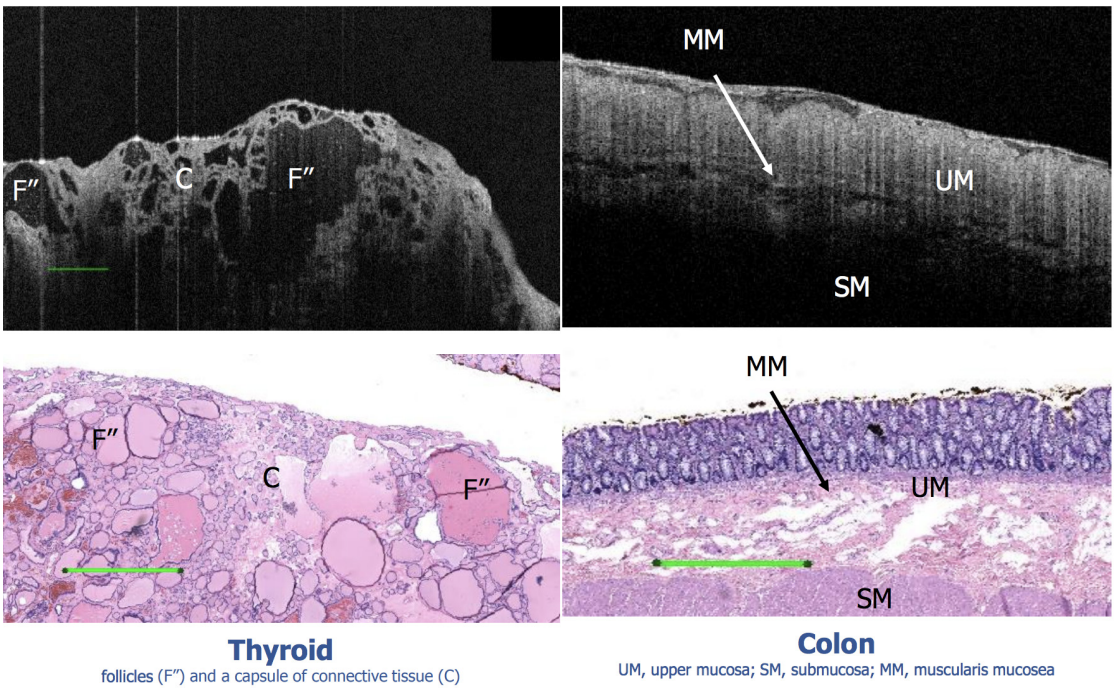
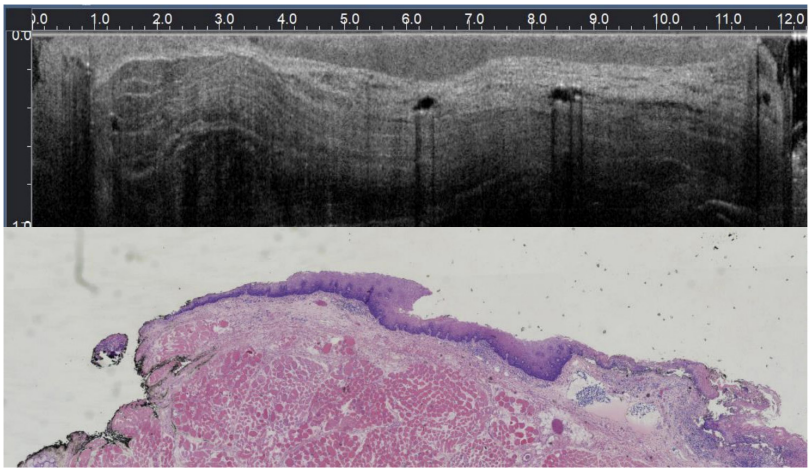


Figure 16
(Perimeter Medical Imaging, 2019)



Head and Neck Tonsillectomy (posterior/inferior)

Figure 17
(Perimeter Medical Imaging, 2019)

IV. Conclusions

Perimeter Medical Imaging, a medical technology company, is focused on developing OCT technology for use in real time during a surgery. The company's proprietary OTIS™ platform is targeted at optimizing OCT scanning for use in identifying microscopic disease structures in tissue specimens during surgery, with a current focus on breast cancer.

The platform consists of four parts: the OTIS™ Optical Tissue Imaging Console, the OTIS™ Tissue Immobilization System, the OTIS™ Imaging Atlas, and ImgAssist AI machine learning algorithms being developed by Perimeter Medical Imaging currently. The OTIS Imaging Console and OTIS Tissue Immobilization System allows images to be taken of breast cancer tissue samples during surgery for clinicians to examine in real time, increasing accurate identification of the area of potentially harmful breast cancer tissue in a patient and therefore decreasing the possibility of a reexcision. The OTIS Imaging Atlas helps train clinicians to identify areas of interest in tissue images during surgeries and provides a growing reference guide. The ImgAssist AI technology being developed is a tool that can identify areas of interest in new OCT images for easier identification by clinicians by relying on machine learning models based on a growing volume of cancer tissue images that Perimeter is building.

V. References

American Cancer Society. Breast Cancer Facts and Figures 2019-2020. Atlanta: American Cancer Society, Inc.; 2019.

American Cancer Society. Treatment of Breast Cancer Stages I-III [Internet]. American Cancer Society. American Cancer Society; 2019 [cited 2020Sep1]. Available from: https://www.cancer.org/cancer/breast-cancer/treatment/treatment-of-breast-cancer-by-stage/treatment-of-breast-cancer-stages-i-iii.html

American Cancer Society. Limitations of Mammograms: How Often are Mammograms Wrong? [Internet]. American Cancer Society. American Cancer Society; 2019 [cited 2020Sep1]. Available from: https://www.cancer.org/cancer/breast-cancer/screening-tests-and-early-detection/mammograms/limitations-of-mammograms.html

American Cancer Society. Breast-conserving Surgery (Lumpectomy): BCS Breast Surgery [Internet]. American Cancer Society. American Cancer Society; 2019 [cited 2020Sep2]. Available from: https://www.cancer.org/cancer/breast-cancer/treatment/surgery-for-breast-cancer/breast-conserving-surgery-lumpectomy.html

Cabioglu N, Hunt KK, Sahin AA, Kuerer HM, Babiera GV, Singletary SE, Whitman GJ, Ross MI, Ames FC, Feig BW, Buchholz TA, Meric-Bernstam F. Role for Intraoperative Margin Assessment in Patients Undergoing Breast-Conserving Surgery. Annals of Surgical Oncology. 2007Jan28;14(4):1458–71.

Cancer Research UK. Breast cancer [Internet]. Types of breast cancer surgery | Cancer Research UK. Cancer Research UK; 2017 [cited 2020Sep1]. Available from: https://www.cancerresearchuk.org/about-cancer/breast-cancer/treatment/surgery/types-surgery

Elmore JG, Longton GM, Carney PA, Geller BM, Onega T, Tosteson ANA, Nelson HD, Pepe MS, Allison KH, Schnitt SJ, O'Malley FP, Weaver DL. Diagnostic Concordance Among Pathologists Interpreting Breast Biopsy Specimens. JAMA [Internet]. 2015Mar17 [cited 2020Sep1];313(11):1122–32. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4516388/#:~:text=In%this%study%of%US,invasive%breast%cancer,%and%a

Elmore LC, Margenthaler JA. A tale of two operations: re-excision as a quality measure. Gland Surgery [Internet]. 2019December [cited: 2020Oct1];8(6):593-595. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6989898/

Fisher S, Yasui Y, Dabbs K, Winget M. Re-excision and survival following breast conserving surgery in early stage breast cancer patients: a population-based study. BMC Health Services Research [Internet]. 2018 [cited 2020Sep1];18(1). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5806481/

Freeman M, Gopman J, and Salzberg C.; Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6006018/

Fujimoto JG, Pitris C, Boppart SA, Brezinski ME. Optical Coherence Tomography: An Emerging Technology for Biomedical Imaging and Optical Biopsy. Neoplasia [Internet]. 2000Jan [cited 2020Sep1];2(1-2):9–25. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1531864/

Ha RC, Friedlander LK, Hibshoosh HC, Hendon CL, Feldman Sundefined, Ahn Sundefined, Schmidt Hundefined, Akens Mundefined, Fitzmaurice MAundefined, Wilson Bundefined, Mango Vundefined. Optical Coherence Tomography: A Novel Imaging Method for Post-lumpectomy Breast Margin Assessment-A Multi-reader Study [Internet]. Academic Radiology. Elsevier; 2017 [cited 2020Sep2]. Available from: https://www.sciencedirect.com/science/article/abs/pii/S1076633217304117

Houvenaeghel G, Lambaudie E, Bannier M, Ribeiro SR, Barrou J, Heinemann M, Buttarelli M, Cohen M. Re-Operation and Mastectomy Rates after Breast Conservative Surgery for Positive or Close Margins: A Review. Clinics in Surgery- Surgical Oncology [Internet]. 2018 [cited 2020Sep1];3:2149. Available from: http://www.clinicsinsurgery.com/full-text/cis-v3-id2149.php

Houvenaeghel G, Lambaudie E, Bannier M, Rua S, Barrou J, Heinemann M, Buttarelli M, Piana JT, Cohen M. Positive or close margins: reoperation rate and second conservative resection or total mastectomy? Cancer Management and Research [Internet]. 2019 [cited 2020Sep1];11:2507–16. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6445211/

Kaczmarski K, Wang P, Gilmore R, Overton HN, Euhus DM, Jacobs LK, Habibi M, Camp M, Weiss MJ, Makary MA. Surgeon Re-Excision Rates after Breast-Conserving Surgery: A Measure of Low-Value Care. Journal of the American College of Surgeons. [Internet]. 2019April1 [cited 2020Oct1];228(4):504-512. Available from: https://www.journalacs.org/article/S1072-7515(19)30080-8/abstract#:~:text=The%20overall%20re%2Dexcision%20rate,91.7%25%20(median%2018.2%25

Metcalfe LN, Zysk AM, Yemul KS, Jacobs LK, Oker EE, Underwood HR, Thompson AM. Beyond the Margins—Economic Costs and Complications Associated With Repeated Breast-Conserving Surgeries. JAMA Surgery [Internet]. 2017Aug2 [cited 2020Sep1];152(11):1084–6. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5831419/

National Cancer Institute. Cancer of the Breast (Female) - Cancer Stat Facts [Internet]. SEER. National Cancer Institute; [cited 2020Sep1]. Available from: https://seer.cancer.gov/statfacts/html/breast.html

National Cancer Institute. Breast Cancer Treatment (Adult) (PDQ®)–Patient Version [Internet]. National Cancer Institute. National Institutes of Health; 2020 [cited 2020Sep1]. Available from: https://www.cancer.gov/types/breast/patient/breast-treatment-pdq#_148

Nowikiewicz T, Śrutek E, Głowacka-Mrotek I, Tarkowska M, Żyromska A, Zegarski W. Clinical outcomes of an intraoperative surgical margin assessment using the fresh frozen section method in patients with invasive breast cancer undergoing breast-conserving surgery – a single center analysis. Scientific Reports [Internet]. 2019 [cited 2020Sep1];9(1). Available from: https://www.nature.com/articles/s41598-019-49951-y

Perimeter Medical Imaging. Perimeter Clinical Overview: Q1 2019. Toronto, ON: Perimeter Medical Imaging; 2019.

Perimeter Medical Imaging. Perimeter Corporate Overview: Q2 2020. Toronto, ON: Perimeter Medical Imaging; 2020.

Perimeter Medical Imaging AI. [Internet]. Perimeter Medical Imaging AI. [cited 2020Sep2]. Available from: https://www.perimetermed.com/

Schmidt H, Connolly C, Jaffer S, Oza T, Weltz CR, Port ER, Corben A. Evaluation of surgically excised breast tissue microstructure using wide‐field optical coherence tomography. The Breast Journal [Internet]. 2019Oct14 [cited 2020Sep1];26(5):917–23. Available from: https://onlinelibrary.wiley.com/doi/abs/10.1111/tbj.13663

World Health Organization. Cancer [Internet]. World Health Organization. World Health Organization; 2018 [cited 2020Sep1]. Available from: https://www.who.int/news-room/fact-sheets/detail/cancer

DISCLOSURE

Never invest in any stock featured herein unless you can afford to lose your entire investment.

Neither Encode Ideas LP, nor its employees and affiliates are registered as investment advisors or broker/dealers in any jurisdiction whatsoever. The information contained herein is based on sources that Encode Ideas LP believes to be reliable but is not guaranteed by us as being accurate and does not purport to be a complete statement or summary of the available data. Readers should always do their own due diligence and consult a financial professional. Encode Ideas LP encourages readers and investors to supplement the information in this report with independent research and other professional advice. All information on the featured company is provided by the company profiled, or is available from public sources and Encode Ideas LP makes no representations, warranties or guarantees as to the accuracy or completeness of the disclosure by the profiled company. Any opinions expressed in this report are statements of judgment as of the date of publication and are subject to change without further notice, and may not necessarily be reprinted in future publications or elsewhere.

None of the materials or advertisements herein constitute offers or solicitations to purchase or sell securities of the company profiled herein and any decision to invest in any such company or other financial decisions should not be made based upon the information provide herein. Instead, Encode Ideas LP strongly urges you conduct a complete and independent investigation of the respective companies and consideration of all pertinent risks. Encode Ideas LP does not offer such advice or analysis, and Encode Ideas LP further urges you to consult your own independent tax, business, financial and investment advisors. Investing in micro-cap and growth securities is highly speculative and carries and extremely high degree of risk. It is possible that an investor's investment may be lost or impaired due to the speculative nature of the company profiled. Encode Ideas LP. its operators, owners, employees, and affiliates may have interests or positions in equity securities of the companies profiled on this website, some or all of which may have been acquired prior to the dissemination of this report, and may increase or decrease these positions at any time.

This report may contain forward-looking statements, which involve risks and uncertainties. Accordingly, no assurance can be given that the actual events and results will not be materially different than the anticipated results described in the forward-looking statement. There are a number of important factors that could cause actual results to differ materially from those expressed in any forward-looking statements made by Encode Ideas LP about the company profiled. These factors include that company's success in their business and operations; the activities of new or existing competitors, the ability to attract and retain employees and strategic partners, the ability to leverage intangible assets, the ability to complete new projects at planned costs and on planned schedules and adoption of the Internet as a medium of commerce, communications and learning. If applicable, investors are also directed to consider other risks and uncertainties discussed in documents filed by the profiled company with the Securities and Exchange Commission. Encode Ideas LP undertakes no obligation to publicly release the result of any revisions to these forward-looking statements, which may be made to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

In no event shall Encode Ideas LP, its operators, owners, employees, and affiliates be liable (jointly or severally) for any special, incidental, indirect or consequential damages of any kind, or any damages whatsoever resulting from loss of use, data or profits, whether or not advised of the possibility of damage, and on any theory of liability, arising out of or in connection with this report. If any applicable authority holds any portion of this section to be unenforceable, then liability will be limited to the fullest possible extent permitted by applicable law.

One or more of the Encode Ideas, LP general partners is long shares of PINK.V. Encode Ideas, LP is engaged with Perimeter Medical Imaging AI, Inc. to provide research coverage and awarness. Please visit our website for full disclosure.

Following publication of any report or update note, Encode Ideas, LP intends to continue transacting in the securities covered therein, and we may be long, short, or neutral thereafter regardless of our initial recommendation. Encode Ideas, LP general partners, consultants,and / or any affiliates may not transact in the security covered therein in the two market days following publication.