

# STABLEYES

## Reimagining the handheld OCT

**M&T Senior Design Final Business Analysis**  
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### **Executive Summary**

Tabletop optical coherence tomography (T-OCT) is an infrared-based imaging technology used to acquire cross sectional images of the retina that are useful for diagnosing ocular and non-ocular diseases. In the past decade, handheld OCT (H-OCT) devices have been developed to enable OCT imaging for infants, children, and patients undergoing surgery, as these populations are typically uncooperative or cannot use the chin mount. Handheld OCT devices provide more mobility and resolution (nearly 3-fold increase) in collecting images, but this additional mobility results in instability and difficulty in acquiring images. Furthermore, the handheld OCT is heavy (~4 lb), and there is a sub-millimeter optimal imaging zone that physicians must maintain for imaging. In current practice, physicians hold three to four fingers between the OCT lens and the patient's eye, but this method leads to inconsistent results. When physicians cannot obtain a reliable image of the patient's retina on their first visit, patients must return for another exam or stay sedated longer to get the proper images.

We are developing the Stableyes system to address the need for improved H-OCT imaging. There are 2 main components to the Stableyes system: (1) the motorized imaging mount designed to be placed over the patient's head. The mount supports the weight of the H-OCT device and allows physicians to control the position of the device relative to the patient's head; (2) a software suite that enables physicians to assess the clarity of collected images and identify key physiological features (e.g., retinal nerve fiber layer) with our proprietary machine learning identification algorithm.

We intend to market the device to retinal specialists as an initial beachhead market, but eventually plan to expand to all ophthalmologists. Retinal specialists regularly use H-OCT in their practice and are typically based in academic hospitals; and, therefore, would be our early adopters. The optical coherence tomography market itself is currently valued at \$1.5MM with a CAGR of 15.34%. This high rate of growth is attributed to the rapid rise in cardiovascular and retinal disorders, a growing geriatric population, and the use of OCT in non-ophthalmologic settings.

### **Value Proposition**

Stableyes' value proposition is three-fold: (1) Stableyes will **improve ease-of-use** of the handheld OCT and allow for technicians, not just physicians, to utilize the device. (2) Stableyes will **reduce the likelihood of misdiagnosis** and repeat image collection. (3) Stableyes will **aid in diagnosis** of retinal images through the image analysis platform. Ultimately, this will result in **cost-savings** for hospital systems by enabling the use of technicians as opposed to physicians, reduced procedures, reduced patient visit times, and improved diagnosis.

## **Stakeholders**

The five main stakeholders we have identified are: physicians, hospitals, patients, insurers, and handheld OCT manufacturers. First, physicians are likely to adopt this technology if they have a handheld OCT or are planning on purchasing a handheld OCT. Stableyes allows for improved ease-of-use of the handheld OCT, higher quality and more reproducible images, and enables physicians to delegate imaging to technicians. Second, hospitals are likely to support the integration of this technology into ophthalmology departments as it will reduce repeat procedures due to misdiagnosis and improve diagnosis of retinal disorders. Ultimately, reducing the time of patient visits and improving diagnosis will result in better patient outcomes and higher patient churn for the hospital. Third, while they will not directly interact with Stableyes, patients will experience improved diagnosis and can receive treatment for their retinal disorders. Fourth, early diagnosis will be enabled by improved handheld OCT imaging. As such, early diagnosis will result in early treatment and reduced disease progression in an insurer's patient population. This will ultimately reduce costs associated with surgeries for late-stage or fully developed retinal disorders. Finally, handheld OCT manufacturers are likely to support the introduction of Stableyes into the retinal diagnosis workflow as it complements their device and can potentially aid in the increased adoption of handheld OCTs among physicians.

## **Market Opportunity and Expected Growth**

Of the broad physician market, there are three main customer segments that we have identified: retina specialists, general ophthalmologists, and non-eye related physicians (including general practitioners).

Our beachhead market is retinal specialists, of which there are approximately 3,300 in the US. Our target customer segment is retinal specialists who utilize research tools, like the handheld OCT, who are likely located in academic centers and hospitals around the country. Fortunately, the retina specialists are concentrated in academic centers like the Scheie Eye Institute at Penn Medicine, by nature of the specialty.

Our secondary segment will be general ophthalmologists, of which there are approximately 15,000 in the US. This set of physicians are typically located in private practices or hospital settings. As such, they likely have handheld OCT's, but are also likely to have the tabletop OCT in their practice. This is primarily because the handheld OCT is currently viewed as a research tool. However, with the use of Stableyes' diagnosis platform and the handheld OCT's improved resolution, we believe that this market is ready to adopt our technology in conjunction with the handheld OCT.

Finally, general practitioners as well as other specialists (cardiologists, dermatologists, etc.) are increasingly utilizing OCT in their practices for the diagnosis of cardiovascular disorders and dermatologic diseases. As such, this segment will serve as a late adopter target as there are certain market trends that need to evolve further before this segment will become viable for Stableyes to market to.

## **Competition**

There are 3 main groups of competitors to the Stableyes system. First, is the tabletop OCT systems developed by companies like Topcon. These systems have stability in their image collection and associated image analysis software, but they are not able to be used on surgical patients. The handheld OCT itself, without the Stableyes addition, is unable to take reproducible

images. And finally, ML/AI diagnostic software are limited to post-collection OCT images, have limited disease scope, and cost significant sums of money.

### **Cost of Production**

Our current cost of goods sold is approximately \$280. These costs are primarily associated with electronic components of our system, including the bipolar stepper motors. Once our design is finalized, we intend to explore reduced cost stepper motors that meet design specifications. This would theoretically bring the overall cost of production down to \$250. Furthermore, many of the other costly items (e.g., aluminum rods) would reduce in cost at scale. Therefore, we expect the final price to be in the range of \$225.

That being said, we anticipate that there will be a high cost associated with SG&A since medical device sales to physicians working at high volume academic hospitals will be significant. Therefore, our ideal monetization strategy is to either partner with or sell our device and IP to one of the primary H-OCT manufacturers such as Leica Microsystems or Alcon.

### **Revenue Model**

In the case in which we pursue direct sales of our product to physicians and hospital systems, we envision a revenue model in which we charge hospitals an upfront fee for the delivery and installation of the hardware (the imaging mount component of the system) and then charge the hospitals a recurring subscription fee for the use of the ML-enabled software suite. This is similar to the Peloton business model which enables sellers to attain additional value from their sale following the initial purchase.

The initial upfront cost of the device would be approximately \$5,000, assuming we can bundle the device into existing CPT codes. The subscription service component would amount to approximately \$25/month/device.

Ideally, however, we engage in either a one-time sale to a H-OCT manufacturer or engage in a partnership with H-OCT manufacturers that enables us to leverage the marketing network of these large medical device companies and bundle our system with H-OCT sales, though reducing the revenue per device that Stableyes would receive.