

OptoVibronex, LLC

Vibrational OCT to diagnose and treat skin cancer
with enhanced accuracy and far greater efficiency

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Near Infrared Light
(OCT 3D Imaging)

Traverse Audible Sound
(Stiffness)

VOCT Virtual Biopsy: Device and method
(Vibrational Optical Coherence Tomography)

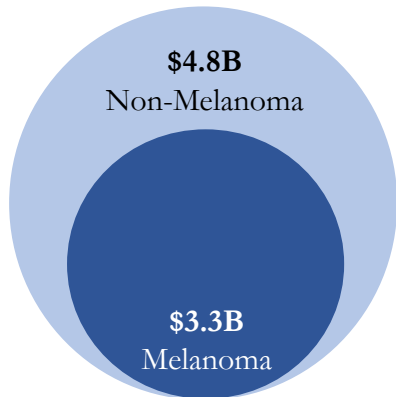
VOCT is a non-invasive, and more efficient way to diagnose and treat skin cancer.

- Our innovation combines OCT 3D imaging and transverse audible sound to **perform virtual biopsies of skin lesions**
 - **Reduces time** to screen skin lesions (from currently hours to 15 minutes)
 - **Reduces time** to obtain biopsy results (from currently hours or days to 15 minutes)
 - Is **non-invasive**
 - **Accurately defines skin lesion margins** in three dimensions
 - Measures tissue **stiffness** (an important property currently ignored)
 - **Minimizes the potential for incomplete removal** of malignant tumor
 - **Minimizes unnecessary scarring** and removal of healthy tissue

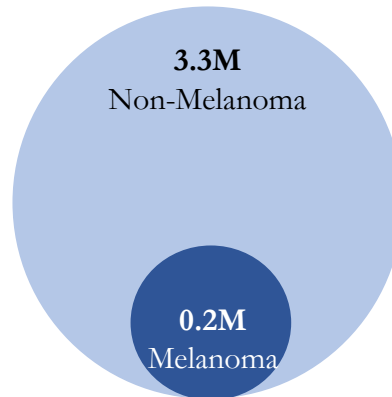
Unmet Market Need

- 3.5mm people diagnosed with skin cancer annually, of which 190,000 are diagnosed with melanoma
 - There is a **significantly greater demand for skin lesion diagnoses and treatment than there are dermatologists available**
 - There is a 41% increase in the risk of dying from melanoma if treatment is delayed*
 - Yet it can take 6-12 months to see a dermatologist about “problematic” lesions.
 - This is despite a 600% increase in Mohs surgeons over the past 10 years (21% CAGR)

\$8.1B
Annual cost of treatment
for all skin cancers



3.5M
People diagnosed with
skin cancer annually



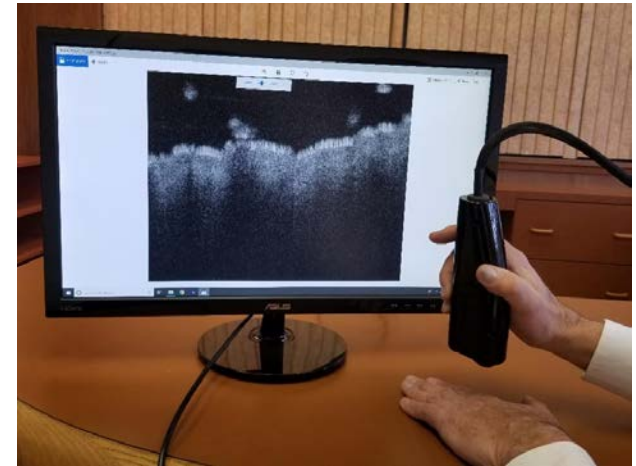
Problem is that current treatments:

- Take 1-72 hours for complete diagnosis and removal
- Lack accurate lesion margin definition, hence unnecessary surgical cuts
- Ignore tissue stiffness, key data/input for accurate diagnoses.
- Only 10,000 dermatologists in the US (for >7M biopsies).

The Innovation - Summary

- **Developed and tested commercial VOCT**
 - Showed characteristic differences between benign and malignant skin lesions
 - Non-invasive biopsy
 - Clear delineation of lesion margins
 - Surgeons can use existing codes to bill for each separate lesion

- Current standard of treatment:
 - Diagnosis:
 - Visual inspection initially
 - “Suspicious” lesions recommended for biopsy
 - Biopsy:
 - Small portion excised initially, and sent to laboratory
 - If cancerous, additional excisions with wider margins
 - Average number of cuts during Mohs surgeries is 3, but can be as high as 8; pathology tests for each excision can take more than 1 hour.



Value proposition of VOCT,

relative to current standard of care

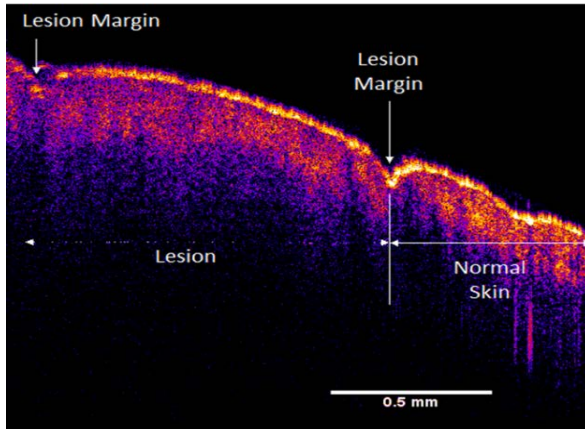
○ Accurate virtual biopsy without the need of lab work (**reducing overall healthcare costs**)

○ No need to perform excisions in multiple stages: **saves time for dermatologists and patients.**

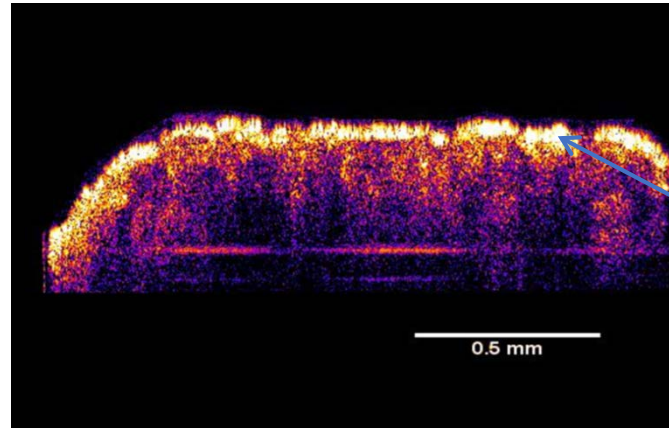
○ Accurate lesion margins **reduces unnecessary excisions and unnecessary healthy skin removal**

The Innovation – Details & Summary Data (Slide 1 of 3)

Normal Skin VOCT

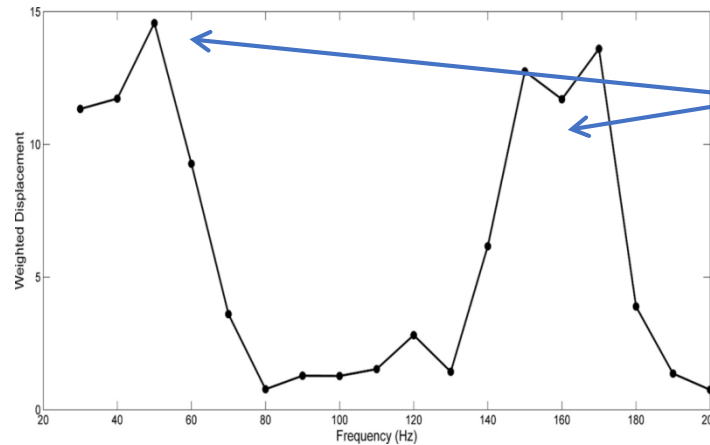
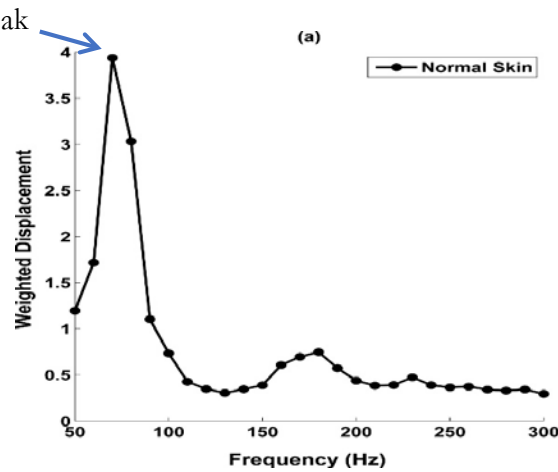


Squamous Cell Carcinoma VOCT



Note the difference in proliferation of surface Squamous Cells on the SCC VOCT image versus the normal normal skin VOCT image

Resonant Frequency



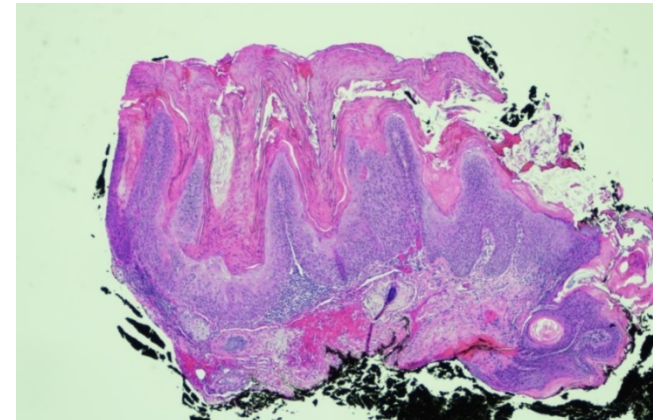
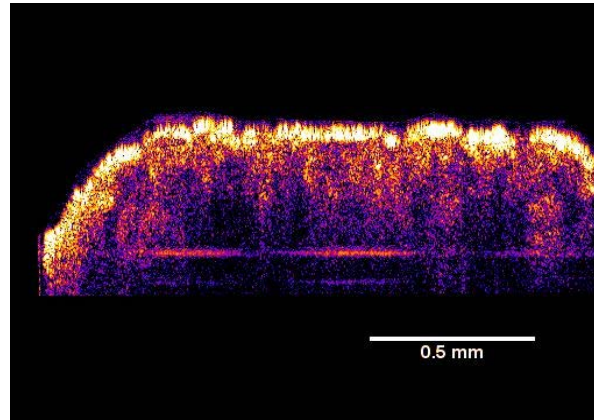
Note this SCC is characterized by a large cellular peak and a broad collagenous peak.

The Innovation – Details & Summary Data *(Slide 2 of 3)*

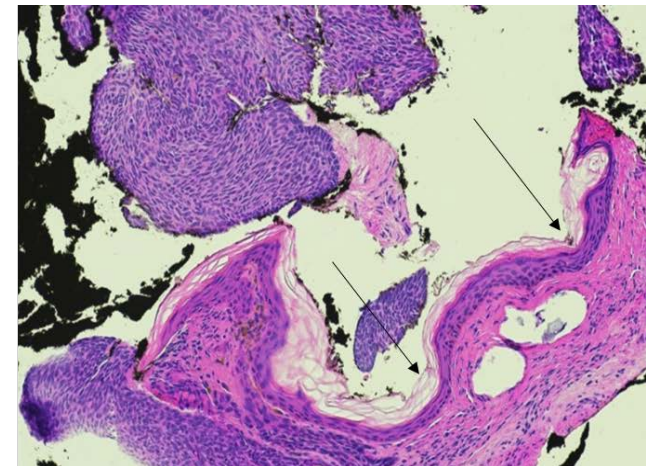
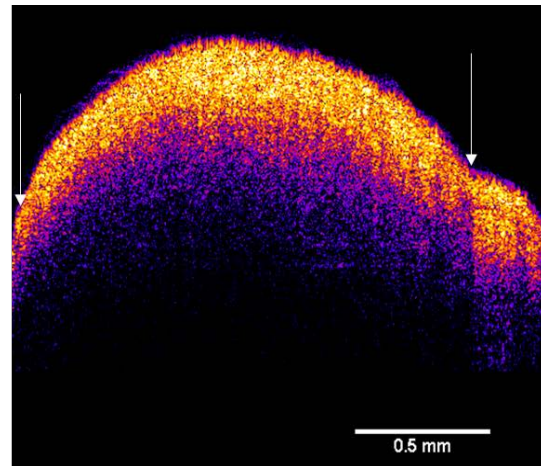
VOCT Image

Histopathology

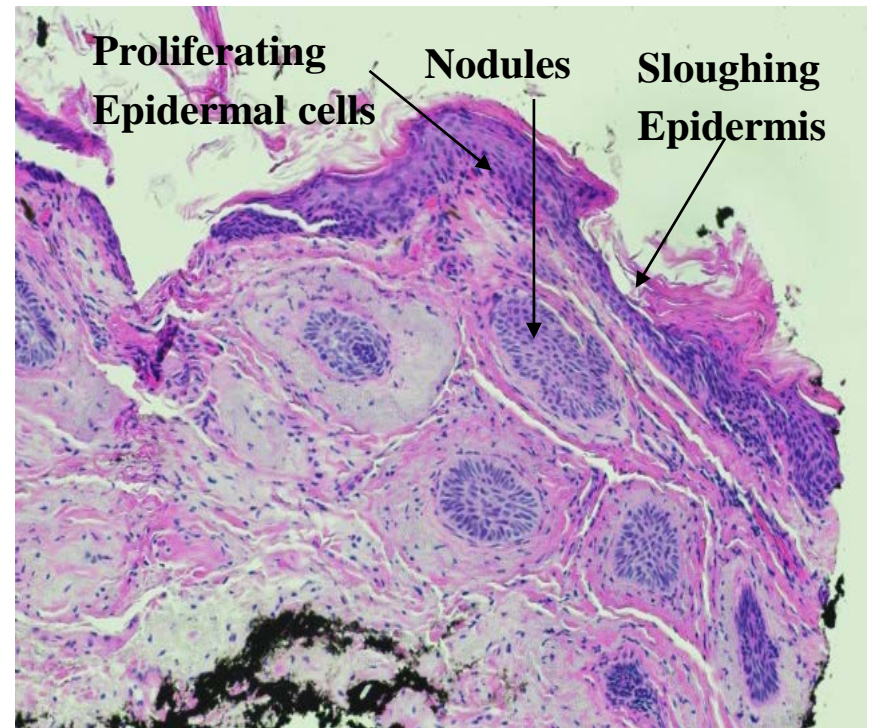
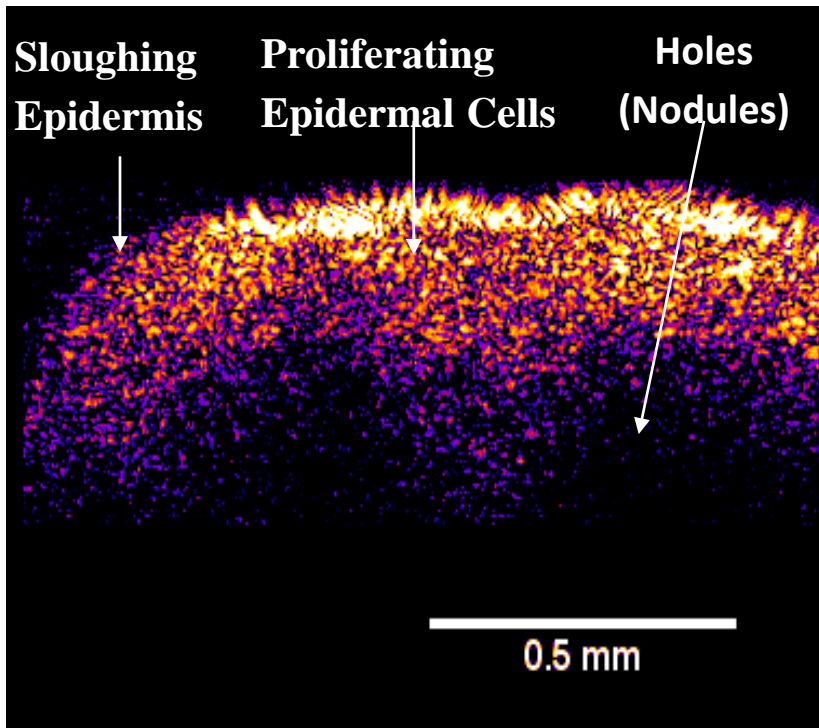
Squamous
Cell
Carcinoma



Basal Cell
Carcinoma



VOCT Image (left) and Histopathology (right) of Actinic Keratosis



Current Stage of Technology

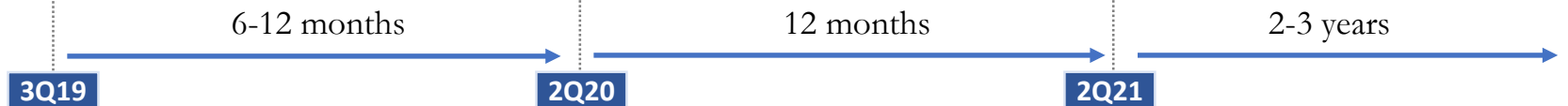
- IP owned by Rutgers University
 - **EXCLUSIVE LICENSE** already obtained by OptoVibronex, LLC
- Nationalized PCT patents
 - **PATENT ISSUED** in the US (15/776,287) and Europe (16866811.9)
- We have a **WORKING PROTOTYPES** that gathers all data and performs all necessary analyses
 - This prototype will serve as the basis for the **first FDA510(k) clearance**
- We **VALIDATED MARKET NEED** for our device and methods, via our team's participation in the Regional I-Corps program (Rutgers and MD Anderson Cancer Center)
- We **PUBLISHED SEVERAL HIGH PROFILE ARTICLES** related to VOCT:
 - Comparative “virtual biopsies” of normal skin and skin lesions using vibrational optical coherence tomography – *Skin Research and Technology*. 2019;00:1-7. <https://doi.org/10.1111/srt.12712>. Silver FH, Shah RG, Richard M, Benedetto D
 - Use of Vibrational Optical Coherence Tomography in Dermatology. *Archives of Dermatology and Skin Care*. 2018; 1(2): 03-08. Frederick H. Silver, Lisa L. Silver.
 - Use of Vibrational Optical Coherence Tomography to Image and Characterize a Squamous Cell Carcinoma. *Journal of Dermatological Research and Therapy* 5:067. doi. org/10.23937/2469-5750/1510067. Silver FH, Shah RG, Richard M, Benedetto D (2019)
- We have been **approached by potential partners** in Canada and the US
 - To jointly develop VOCT
 - Both as funding sources and business development

Development Timeline & Funding Requirements

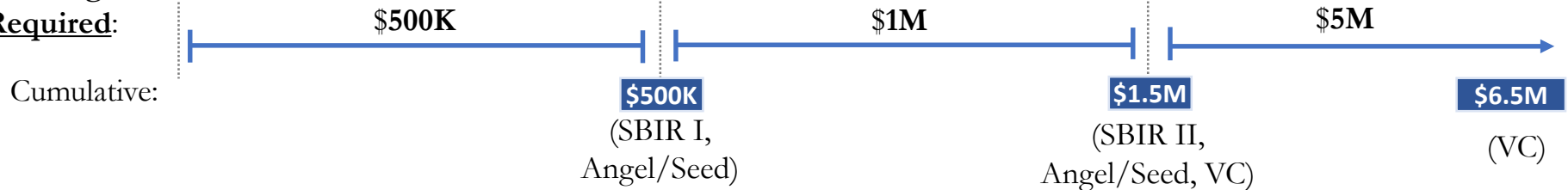
Key Tasks & Milestones:

- **First 510(k) FDA clearance**
 - \$200k: indications for surface imaging of tissue
- **Expand commercialization activities**
 - \$150K: build commercial units for testing in NJ, PA, and FL
 - \$150K: Collect excised lesion data (n=100)
- **Second 510(k) FDA clearance**
 - \$250k: indications to assist the surgeon with identifying lesion margins and characteristics
- **Expand data collection**
 - \$500k: collect clinical in-vivo data (n=400)
- **Refine working prototype**
- **Full product launch**
 - Initially:
 - 10 sales representatives
 - 5 software engineers
 - 5 back-office/executives
- **Consider M&A**
 - Medical device companies with scale and established distribution channels

Timeline:



Funding Required:



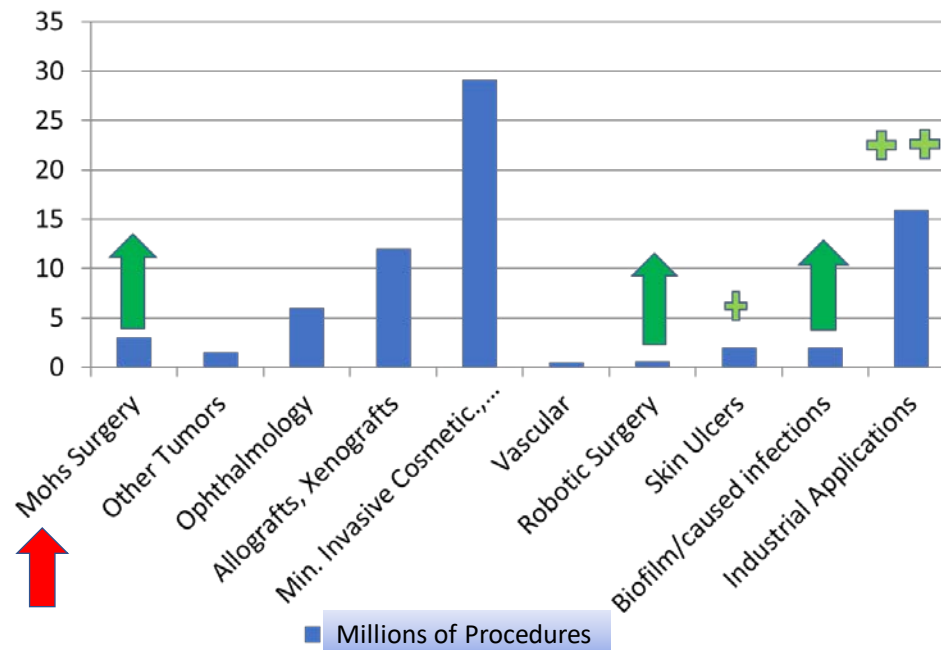
Other Notables:

- **Cumulative Funding To-Date:**
 - Co-Founders personal capital (~\$100K)

Goals & Milestones – Long Term Goals

- **Leverage our innovation into other fields of use**
 - Preliminary discussions with US and European patent examiners indicate further potential claims that are patentable.
 - Our technology can be used for quality control, viscoelasticity analyses, fatigue lifetime and processing evaluations for automotive and industrial materials.

Platform Technology: Expandable Into Multiple Markets



Current Team

Scientific Expertise

- **Fred Silver, PhD**
 - Professor of Pathology at Robert Wood Johnson Medical School



Business Expertise

- **Lisa Lutz**
 - President, OptoVibronex
 - Prior: Sales Executive at IBM



Clinical Expertise

- **Dom Benedetto, MD**
 - Ophthalmologist
 - Extensive experience performing skin lesion excisions



Regulatory Expertise

- **Consultant**
- **TBD**

The “Ask”

- We are looking for a **seasoned and proven business executive to** complement our business team:
 - Become the management nucleus of OptoVibronex, LLC
 - Lead commercialization efforts
 - Help raise dilutive and non-dilutive capital
 - Coordinate relevant regulatory approval efforts
- We also welcome **partnerships with clinicians and industry participants** with deep, relevant knowledge
 - Help us gain market traction
 - Aid in execution of our regulatory plan

THANK YOU

Contact us at: fhsilverfh@yahoo.com

610-428-2173

<https://optovibronex.com/>