OPTOVIBRONEX

The Science of Material Characterization

"Virtual Biopsy"

Changing Early Disease Diagnosis and Treatment Efficacy Tracking

The Skin and Eyes – Windows to Diseases Diagnosis of the Whole Body

Medical Applications for the Technology

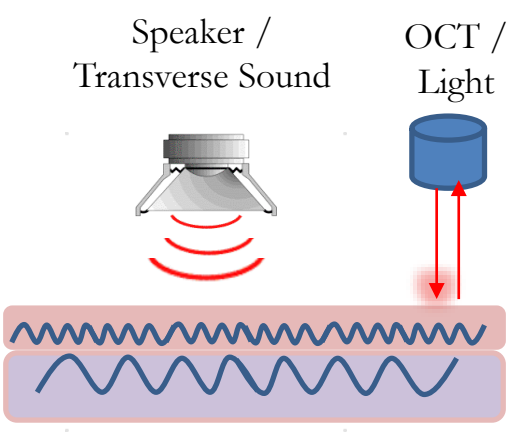
- **Dermatology**
  - Skin Cancer Detection
  - Wound Healing Treatment Monitoring
  - Quantifying Aesthetic Treatment Effectiveness
  - Quantifiably Tracking Acne Treatments
  - Determination of Fibrotic Diseases
  - Determination of and Tracking of Rosacea and Psoriasis
- **Ophthalmology**
  - Quantifiable Detection and Tracking of Various Diseases - Keratoconus, Myopia, Macular Degeneration, Glaucoma, etc.
- **Breast Cancer Surgery Healthy Tissue Detection**
- **Peripheral Vascular Disease**
- **Peripheral Neurological Disease**

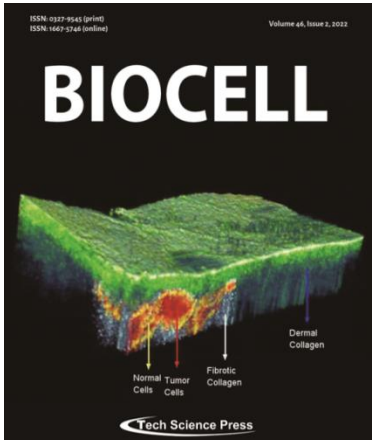
Unmet Market Need - Dermatology

- **Skin Cancer Most Common form of Cancer**
  - 5.4 M skin cancers annually; 25M by 2050
  - 1 in 5 Americans by age 70
  - 41% increase in probability of dying if treatment is delayed

- **Current Methods Imprecise, Inefficient and Costly**
  - 6-12 months' wait for an appointment with a dermatologist
  - 50 - 55% of all biopsies are benign and thus may not be necessary
    - At a cost of ~ $2.5B; ~$10B by 2050
  - Mohs Surgery cuts - average ranges from 1.09 – 4.11

Our Solution: Vibrational Optical Coherence Tomography





<u>Virtual Biopsy</u> non-invasive PHYSICAL analysis

- More **accurate** than current visual screening & dermoscopy
- **Precise** skin lesion margins & depth in 5 minutes (physical biopsy = up to 72 hours)
- **Minimizes incomplete removal** of malignant tumor
- **Preserves** maximum healthy tissue – minimize scarring

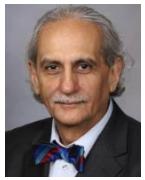
Management Team / Key Advisors

- **Lisa Lutz Silver** (51% ownership)
  - **Co-Founder** – President
- **Business Expertise**
  - Prior: Sales Executive at IBM (25+ years)
  - Entrepreneur/Small business owner (10+ years)

Clinical Advisors

- **Dom Benedetto, MD** *(Ophthalmologist)*
- **Hari Nadiminti, MD** *(Dermatologist – Summit Health – New Jersey)*
- **Sean McGregor, DO, PharmD** *(Dermatologist, Mohs Surgeon – Cleveland Clinic, Vero Beach Florida)*
- **Jose Pulido, MD, MS, MBA, MPH** *(Wills Eye Hospital – Director Translational Medicine)*
- **James Grichnik, MD, PhD (**Professor and Chairman, Department of Dermatology & Cutaneous Surgery at University of South Florida)



Commercializtion/Business Advisor

- **Andrew Shales** (1% ownership)
  - **(**CEO ResiliaPharma)

Regulatory Consultant

- **Susan Alpert, MD, PhD.**

Reimbursement Consultant

- **Joel Brill, MD, AGAF, FASGE, FACP, FACG, CHCQM**

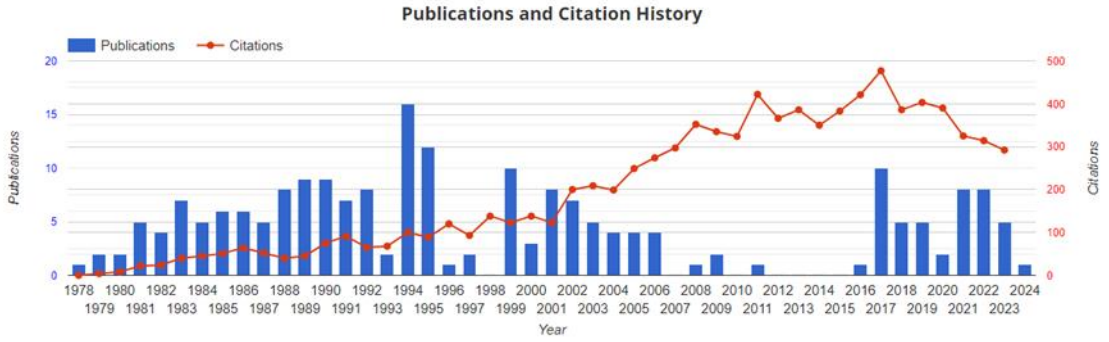

- **Fred Silver, PhD** (42% ownership**)**
  - Professor of Pathology at Robert Wood Johnson Medical School
  - **Co-Founder** - Chief Technology Officer
- **Scientific Expertise**
  - Ph.D. from MIT
  - 20+ patents; published 220+ papers (30+ on VOCT)
  - Entrepreneur / Small business owner (30+ years)

- **Clinical Expertise**
  - Dermatology
  - Ophthalmology
  - Mohs Surgery
  - Extensive microsurgical experiences and research publications
- **Commercialization/Business Expertise**
  - Led U.S. pre-launch & launch of UCB Pharma's Keppra® - blockbuster seizure drug
  - Authored first Cologuard® commercial plan
- **Regulatory Expertise**
  - Former Director of Device Evaluation for FDA
- **Reimbursement Expertise**
  - Extensive CMS and AMA Experience

Dr. Frederick Silver Recent Special Recognition

ScholarGPS™
Powering Scholarly Analytics

"Dr. Silver,
CONGRATULATIONS! ScholarGPS celebrates Highly Ranked Scholars™ for their exceptional performance in various Fields. Your prolific publication record, the high impact of your work, and the outstanding quality of your scholarly contributions have placed you in the top 0.05% of all scholars worldwide."



"On the occasion of the 15th anniversary of International Association for Advanced Materials (IAAM), award and recognition committee has elected you as recipient of the IAAM Scientist Medal (www.iaamonline.org/advanced-materials-award) in recognition of your outstanding contributions to the advanced materials science and technology."

Current Status

- **Exclusive worldwide license** rights from Rutgers University
  - **Patent issued** in the US (10488277); and in Europe (3376945)
- **FDA Breakthrough Device Designation**
  - **with 3 indications**
- **Achieved Extensive Customer Discover Efforts**
  - 2 NSF I-Corps
    - Rutgers & MD Anderson Cancer Center in Houston
- **MVP Developed**; 5 Units using for Research or Clinical Work
- Clinical Studies ongoing with **Summit Health, New Jersey, FL**
- Initiating Clinical Studies with **Rutgers University, New Jersey**

Breakthrough Device Designation

- **First FDA Approved Indication**

  1) To be used as an aid for the dermatologist to augment visual and dermoscopic analyses with a novel non-invasive quantitative determination of biophysical markers of fibrous & cancerous tissues
  2) To enable the dermatologist to identify the lesion margins and depth non-invasively
  3) To allow the dermatologist and patient to know more precisely how much surgery is needed to remove the whole tumor in one surgical procedure and to minimize the unnecessary removal of healthy tissue

Insights from Prospective Customers *(70+ Interviews in the Dermatological Ecosystem)*

"help me **find the margins**.. more cuts .. big problem."

Monika Srivastava, M.D.
Dermatologist/Mohs Surgeon

"Give me a **stiffness map** superimposed over an image."

James Grichnik, M.D., Ph.D.
Dermatologist/Mohs Surgeon
University of Southern Florida

Hari Nadiminti, MD
Summit Health

"Differentiating pigmented lesions and Melanoma with VOCT would be a MAJOR breakthrough."

"I can't afford to hit a **blood vessel**"

Michael Richard, M.D.
Oculofacial Plastic Surgeon

"I often **cut in excess of 5 times."**

Stephen Spates, M.D.
Dermatologist/
Mohs Surgeon

"is it cancerous or not. I don't want to **wait for biopsy results.** How much does it **cost**?"

Matt Halpern, M.D.
Dermatologist/
Mohs Surgeon

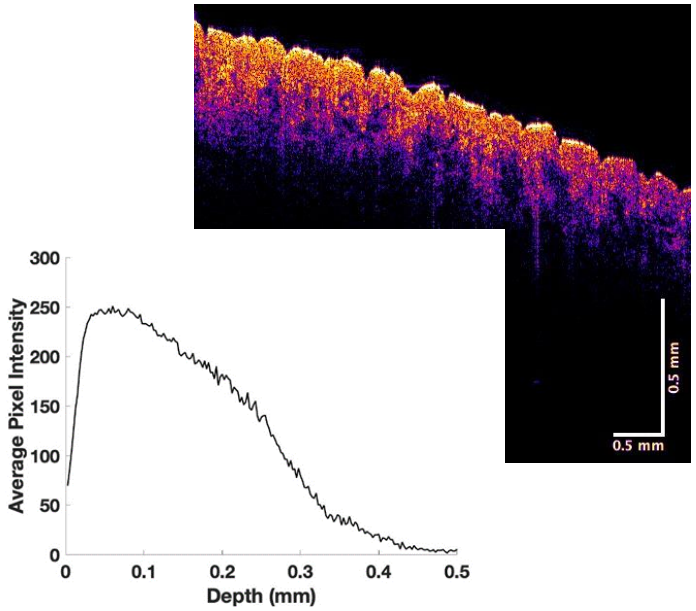
"**I just biopsy everything**… not everyone wants a biopsy."

Ian Odell, M.D., Ph.D.
Dermatologist - Yale
New Haven Hospital

Cross Sectional Images

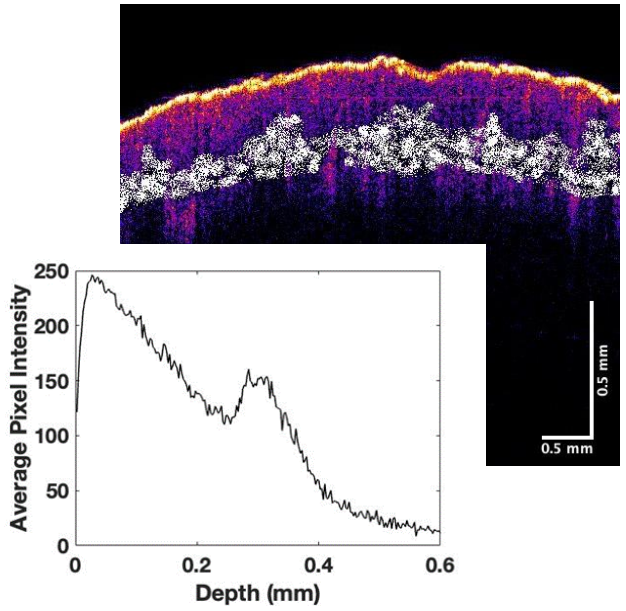
Not Just Pretty Pictures - QUANTIFIABLE DATA to Colorize Images

Normal Skin



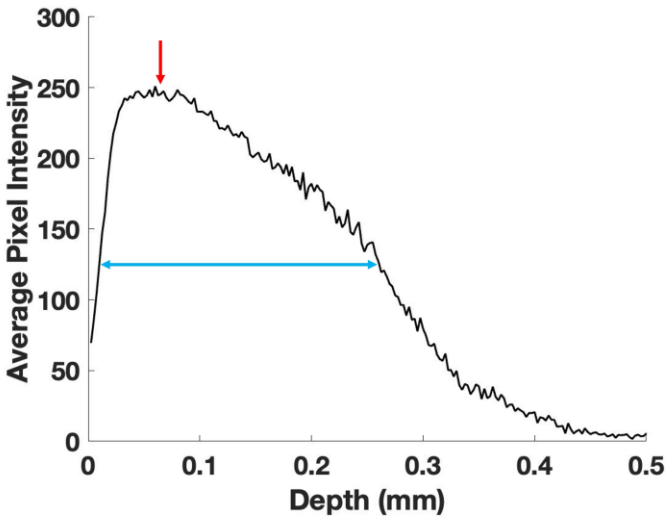
Note the Linear Decrease in Pixel Intensity in Normal Skin

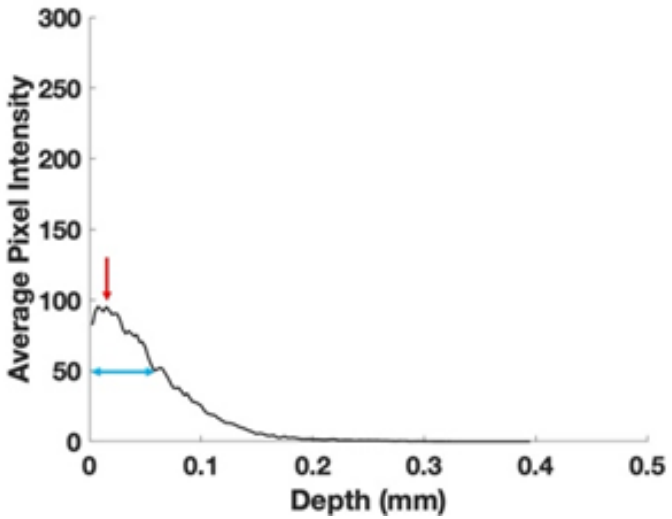
Benign Skin Lesion with Fibrotic Tissue



Note the increase in pixel intensity at 0.3 mm where the Fibrosis is seen in the Benign Lesion.

Quantifiable Data



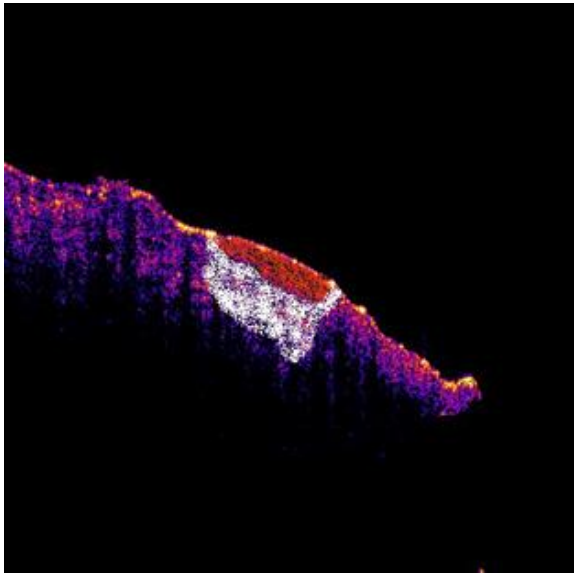


Normal Skin

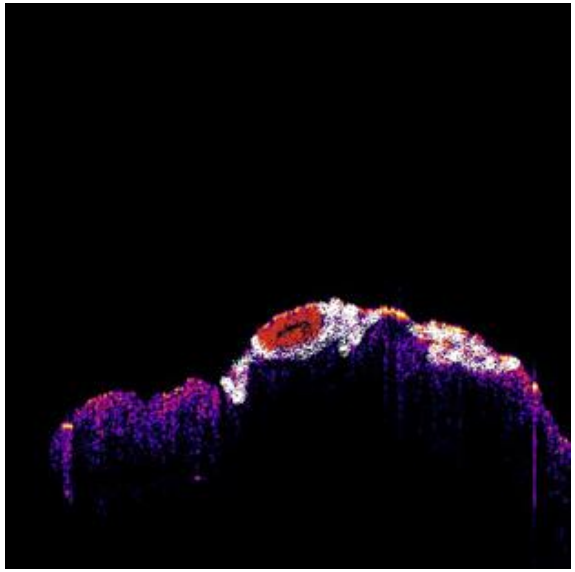
Melanoma

Color Coded Images of Basal Cell Carcinomas

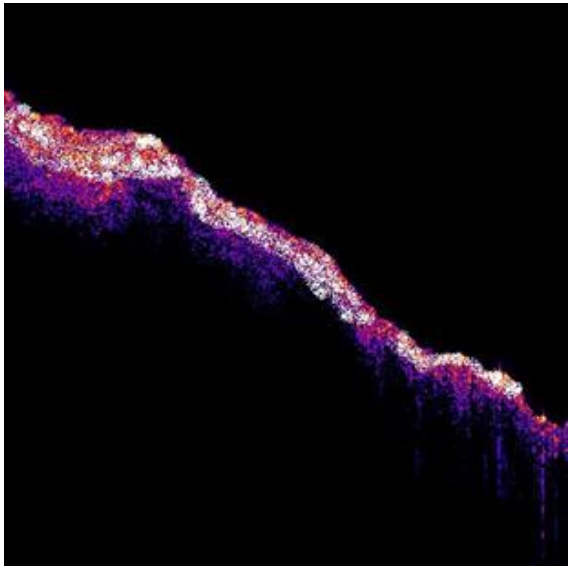
Nodular BCC



Linear BCC



Sclerosing BCC



The cancerous cells are denoted in red and the fibrosis in white.

Our Value Proposition

- **For the Physician**
  - Increase patient **surgical throughput by up to 50%**
  - **Increase volume of patients** accurately screened
  - Minimize diagnostic time – **better patient outcomes**
  - Increase patient satisfaction
- **For the Patient**
  - Minimize **wait time** for biopsy results from 1 hour to days **down to 5 – 15 minutes**
  - Minimize the number of cuts
  - Minimize healthy tissue removal – **especially on the face**
- **For the Payer**
  - **Decrease number of payments** for benign biopsies – **currently 55% of total**

Sent: Sun, Nov 24, at 7:23 PM Patient: Peter H

”Basil Cell Carcinoma, on my lip…

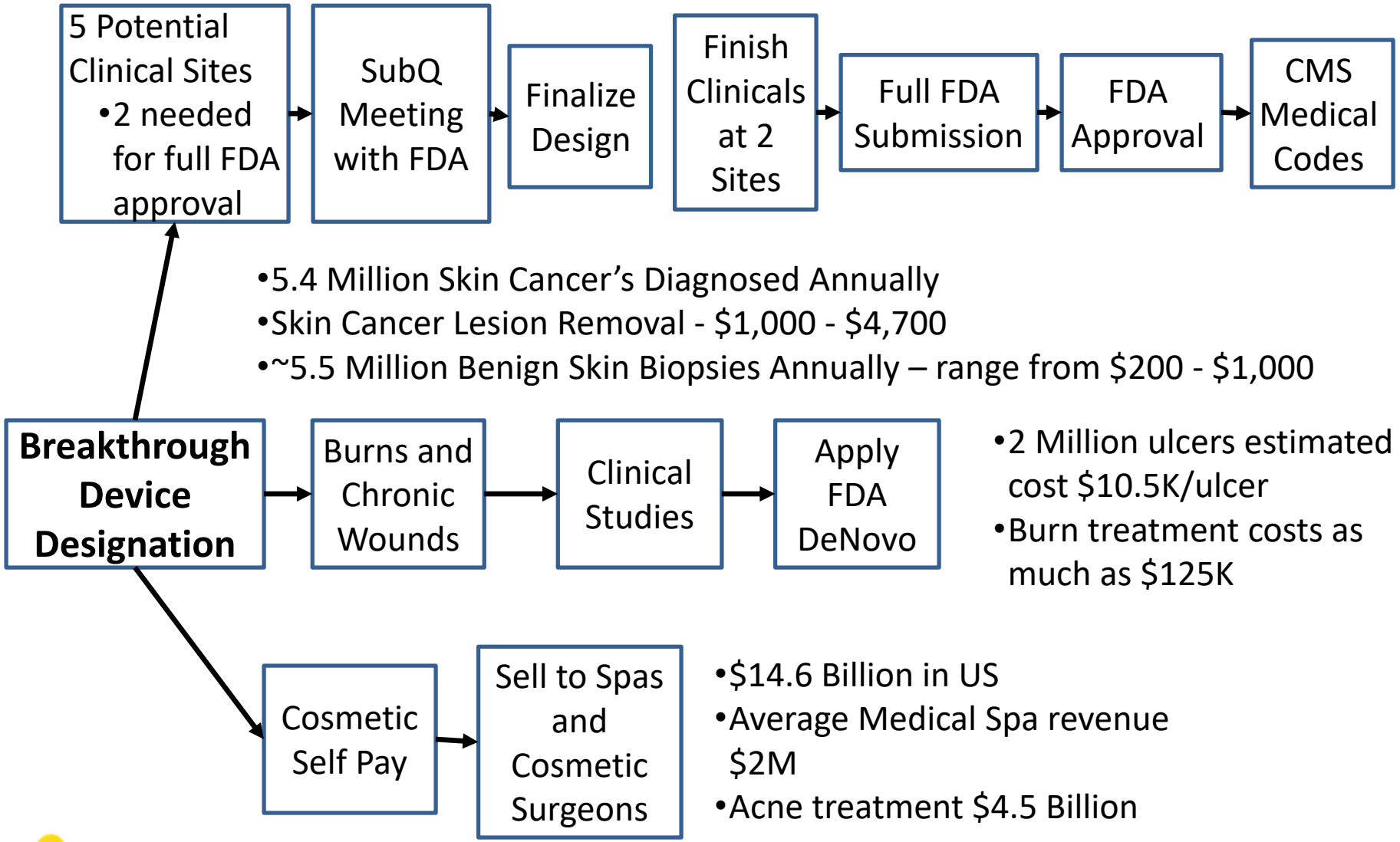
The Dermatologist could not tell me the extent of the remaining cancer cells. I have to have Mohs Surgery….

the Dermatologist is preparing me for the worst.”

Addressable Market

- **Approximately 10,000 Dermatologists in the US**
  - Dermatology diagnostic device market: **$28B annually (**2021)
    - Expected to grow to $49B by 2026 *(+7% CAGR)*
    - Skin Cancer Diagnostic market segment - forecasted $6.2B in 2026
  - Currently Spending ~ $2.5B for benign biopsies by 2050 will be over $10B
    - If we can save them 10% that is $1B
- **Additional Product Placement Opportunities**
    - Integrated Health Care Systems
    - Urgent Care Centers
    - General Practitioners
    - Pharmacies
- **Long-term vision:**
  - Platform technology - other medical & industrial applications

High Level Road Map



Product Launch/Revenue Generating Plan

- **Phase I:**
  - **Fee for service screening** of patients (**no capital investment** for early adopters)
    - Estimated to be $200 per scan initially
    - Lower barriers for adoption; align with customer revenue model
  - **First targeted markets**: FL, NJ, PA, MD, CT, NY (28% of total)
    - Due to proximity and **access to KOLs and leading surgeons**
  - **Maximize participation in industry conventions and educational forums**
  - **Continue publishing in scientific journals & industry publications i.e. AARP**
  - **Target younger-generation dermatologists where patient thruput and satisfaction "steal patients" and keep current patients**
  - **Consultant looking for effective sales channels**
    - **Partnering with companies currently selling into this space**
      - **Topical Creams for Basal Cell Carcinoma**
      - **Aesthetic/Cosmetic Sales companies – fillers/laser treatments**

- **Phase II:**
  - **Direct sale** or rental of device; *fee for service reserved for initial customers only*
    - OptoScope price $50K base unit purchase (estimated COGS per unit $15K)
    - To seed the market we will discount Early Adopters (~ $25K)

- **Phase III:**
  - Generate Stream Revenue - Ramp up **software sales and ongoing services revenue** (software upgrades estimated every 2 yrs)

Competitive Landscape

	VOCT	Visual	Dermo-scope	OCT	Elastography	Confocal Microscopy	Near Infrared Microscopy	Ultrasound
Current Usage	**Clinic**	Clinic	Clinic	Clinic/Lab	Lab	Lab	Lab	Clinic/Lab
Screening time 15 minutes	✓	✓	✓	✓	X	X	X	✓
Cost (<$100 per procedure)	✓	✓	✓	X	X	X	X	✓
Ease of use	✓	✓	✓	✓	X	X	✓	X
Sound Wave	Transverse	N/A	None	None	Shear	None	None	Shear
Measure cellular and collagen **stiffness**	✓	X	X	X	X	X	X	X
Image Quality	Moderate	Moderate	Moderate	Moderate	Moderate	High	Moderate	Poor

Development Plans: Technology and Funding Requirements and Exit Strategy

Key Tasks & Milestones:	• **First 510(k) FDA clearance**
	  • Class II Device
	  • Based on breakthrough device designation & existing predicate
	  • Image scanning only
	• **Collect additional lesion data**
	  • n=200 ex-vivo
	  • n=50 in-vivo
		• **Second 510(k) FDA clearance**
		  • Class II Device
		  • Chronic wounds, burns and skin ulcers
		• **Expand data collection**
		  • n= 400 in-vivo
		• **Market Entry for first indications**
			• **Full product launch**
			  • Outsource device manufacturing
			• **Consider M&A/Licensing Technology/Other Uses**
			  ○ Medical Device Companies
			  ○ Industrial Applications

Timeline:	6-12 months →	12 months →	1-3 years →
Funding Required:	**$500K**	**$1.3M -$2M**	**$2M - $5M**
Cumulative:	**$500K**	**$1.8M - $2.5M**	**$3.8M - $7.5M**
	(Grants, SBIR I, Angel/Seed)	(SBIR II, Angel/Seed, Corporate Partnerships)	(Angel, Venture Capital, Corporate Partnerships)

Other Notables:

- **Cumulative Funding To-Date:**
  - ○ Co-Founders personal capital thru 2022 (~$470K)
  - ○ Rutgers Genesis Matching Grant - $40K
  - ○ Funding from Wills Eye Hospital - $92K
  - ○ Sweat equity

FUNDING

- Steps
  - Switch from LLC to C Corp
  - Will Consider Common Stock Equity
  - Will Consider Convertible Debt
  - Entertaining Term Sheets
  - Valuation = $8 - $10M
- Uses
  - Clinical Sites for FDA approx. $55K per (need at least 2) = $110K - $165K
  - Personnel for clinicals 2 people approx. ($30K each) = $60K - $90K
  - Marketing/Consulting/FDA = $150K
  - Travel to Clinical Sites = $10K
  - Attorney Fees = $10K
  - Reincorporate C Corp in DE = $3K

Why OptoVibronex

- Experienced Team
- Patents Issued in US and Europe
- Disruptive New Testing Methodology – *Breakthrough Device Designation*
- Rutgers Genesis Matching Grant
- Funding from Wills Eye Hospital
- Ben Franklin Funding – Loan with Warrants
- Identified Large and Growing Initial Target Market
- Platform Technology with Significant Future Opportunities
  - Medical Applications – Dermatology, Ophthalmology, Breast Cancer Detection, Aesthetic/Cosmetic Dermatology, Chronic and Acute Wound Healing, Orthopedics, Neurology and Vascular Surgery
  - Industrial Applications
- Licensing Opportunities

APPENDIX

Machine Learning

- **Utilizing Machine Learning to eliminate human error - increase speed and accuracy of diagnosis**
- **Specificity and Sensitivity =** Sensitivity refers to a test's ability to designate an individual with disease as positive. A highly sensitive test means that there are few false negative results, and thus fewer cases of disease are missed. The specificity of a test is its ability to designate an individual who does not have a disease as negative.

	BCC vs Normal	Melanoma vs Normal	SCC vs Normal
True Positive Rate	77.78%	90%	91.67%
False Positive Rate	22.22%	10%	8.33%
True Negative Rate	100%	100%	87.50%
False Negative Rate	0%	0%	12.50%

Preliminary results illustrating cancer diagnosis using VOCT and machine learning

- **Data with 40 subjects demonstrates the accuracy of diagnosing different skin cancers**
- **This will improve as more data is collected**

Eleven Acquisitions 2009 to 2022

12

Company	Acquisition Year	Purchase Price	Sales at Acquisition	Revenue Multiple	Acquirer
Aspect BIS	2009	$210M	$83M	2.5X	Medtronic
Somanetics INVOS	2010	$250M	$50M	5X	Medtronic
SedLine	2010	—	—	—	Masimo
Oridion Capnography	2011	$346M	$64M	5.4X	Medtronic
BMEye	2012	$42M	—	—	Edwards
Xhale Assurance	2018	—	—	—	PHILIPS
Cheetah Medical	2019	$230M	$20M	11X	Baxter
ForeSight	2019	$100M	$23M	4.4X	Edwards
LiDCO	2020	$40M	$10M	4X	Masimo
Kestrel Labs	2021	$31M	$0M*	Pre-Approval	ZYNEX MEDICAL
RMI	2022	$44M	$9.4M	4.7X	SENZIME

Average Acquisition **is for $155M at $26M of revenue with ~6x multiple**

Noninvasix

CAP TABLE

Entity	Current % Ownership	Future % Ownership
Lisa Lutz Silver	51%	40%
Fred Silver	42%	31%
Rutgers University	6%	6%
Andrew Shales	1%	1%
Future Management Ownership		7%
Future Employee Ownership		15%