

Skin Cancer Diagnostics by Unique Dual Deep Learning Algorithms

Overview & Opportunity March 2021





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## The problem...

- Skin cancer is common, with increasing incidence, morbidity, and mortality
- Diagnosing skin cancer is inaccurate and involves time-consuming diagnostic procedures
- Delayed diagnosis leads to more advanced, more lethal, and more costly cancers
- COVID-19 era: Diagnostic accuracy is of poorer quality with less direct physician-patient interactions and regular telemedicine
- Telemedicine is not supported by a reliable clinical decision support tool



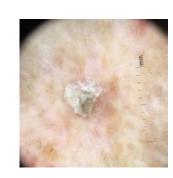
## Skin Cancer is...Common, Increasing, and Harmful

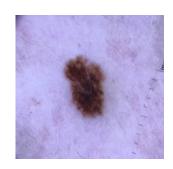
#### **NON MELANOMA SKIN CANCER (NMSC)**

- 4,300,000 Basal Cell Carcinomas (BCC) and 1,000,000 Squamous Cell Carcinoma (SCC)
  evolve yearly in U.S.
- 1 in 5 Americans will develop skin cancer by the age of 70
- 2000 people die every year of squamous cell carcinoma of the skin in the U.S.

#### **MALIGNANT MELANOMA (MM)**

- About **195,000** new Melanomas diagnosed in US each year and 7000 deaths
- Amongst, 95,000 noninvasive (in situ) and 100,000 invasive
- Melanoma is the most lethal form of skin cancer, a 1:38 lifetime risk
- >1 million Americans are living with melanoma
- A delay in diagnosis of MM can cut survival chance by 5-100%





### Diagnosing Skin Cancer is ... Inaccurate, Inefficient, and Expensive

Trained dermatologists achieve only 40% detection sensitivity for malignant melanoma; for complex melanomas detection rate is no better than chance J. Eur. Acad.

Dermatol. Venereol. 2017 Jun;31(6):972-977

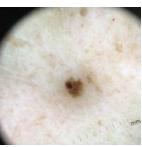
#### Low accuracy results in needless biopsies, scarring, and economic impact

 MM requires 58 lesions excised to identify 1 melanoma for those aged less than 50, and 28:1 for all ages

Biopsies are expensive (\$3.3 billion/year) and slow (biopsy, pathology, & scheduling  $\sim 1-2$  months)

Biological treatment for advanced stage MM: \$300K/2yrs per patient

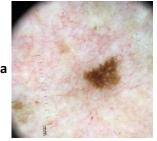
Benign Nevus



NMSC



Melanoma



# Diagnosing Skin Cancer...Impacted by Telemedicine (& COVID-19)

Fewer patients accessing medical services, including dermatology

- Concerns about contracting COVID at doctor's office
- General belief that dermatology "can wait"
- Those treated have a higher histopathological upgrade rate.

#### Fewer Basal Cell Carcinomas treated during the COVID-19 pandemic

#### Use of Telemedicine has become mandatory

A computer-aided diagnosis or decision support system is lacking



COVID-19 restrictions increase wait times and worsen outcomes for patients; require remote engagement of healthcare professionals; and result in higher costs to payers.

## The Team...

**Solution** Bostel Technologies

### **Development Team**

Bruce N. Walker, PhD: Professor of Psychology & Computing, Georgia Institute of Technology (Atlanta)

Expert in Human-Computer Interaction, sonification, and multimodal user interfaces
 Dr. Walker is the President of BosTel Technologies, LLC

Avi Dascalu, MD, PhD: Specialist in Dermatology

· Expert in image and sound analysis

James M. Rehg, PhD: Professor of Computing, Georgia Institute of Technology

Expert in Deep Learning

Ankur Kalra, MEng: Founder of Hop Labs, Atlanta, GA

· CEO of an artificial intelligence laboratory focusing on software and machine learning development

Eli O. David, PhD: Consultant

Expert in deep learning and evolutionary computation

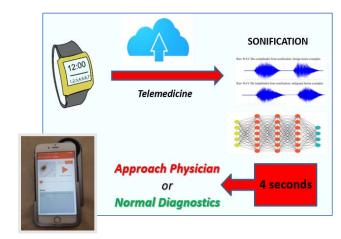
## A novel and powerful solution...



### App-Based Diagnosis via Unique Deep-Learning +& Sonification

#### End-to-end classification and diagnosis solution

- Images of lesion captured with smartphone app (with or w/o dermoscope)
- Instantaneous diagnosis (Malignant/Benign) via cloud-based servers
- Unique algorithm: Deep Learning Image Classifier + Sonification
- Classifications used as a screening tool by healthcare professionals
- API operational and detects BOTH Melanoma and Non Melanoma cancers
- DERMOSCOPIC Sensitivity of 90% for MM and NMSC
- Applicable to either dermoscopic images or smartphone photographs
- Applicable to either professional or home-quality dermoscope





## Multiple Use Cases...



### **Use Case A. Professional Dermoscopy**

#### Dermatologists and/or trained GP's use phone + dermoscope with software

- Capture dermoscopic images, pro quality
- Cloud-based diagnosis
- Physician leverages diagnostic results in treatment plan

#### Additional website-based diagnosis tool

- Images uploaded via desktop computer or tablet
- Cloud-based diagnosis
- Physician leverages diagnostic results in treatment plan

Prospective Clinical Study of Sonification algorithm system effectiveness with professional dermoscopic device

89.5% Sensitivity for malignant lesions (MM, Dysplastic nevus and NMSC) and 57.8%
 Specificity





Professional Demoscope

DermLite DL4

### Use Case B. Home Consumer, Dermoscopic add-on

#### Low cost (100 USD) skin magnifier with polarized light attached to a smartphone

- Directed at a Home user as a smartphone add-on or watch gadget
- Dermoscopic images, of moderate quality

Tested in a **Prospective Clinical Study** and validated by peer review eBioMedicine publication: https://doi.org/10.1016/j.ebiom.2019.04.055

- 91.7% Sensitivity for malignant lesions (MM, Dysplastic nevus and NMSC) at 41.8%
   Specificity
- Our system identifies even small melanomas



DermLite HÜD

Home Dermoscope

## Validation...

**Solution** Bostel Technologies

### **Prospective Clinical Study**

## IRB approved clinical study performed at healthcare provider (Maccabi, Israel)

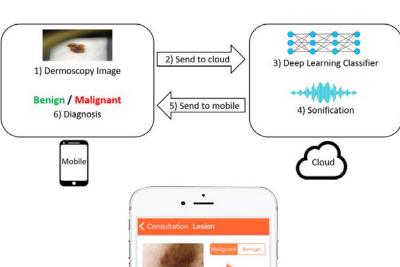
- N=75 subjects
- All skin lesions recorded by both professional and home dermoscope
- App sent images to/from cloud, near instantly
- Results reported as benign (normal/dysplastic nevi) or malignant (MM and NMSC)

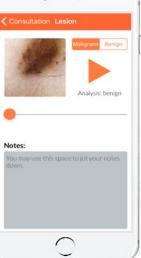
## Audio/Visual Classifier using our *Unified Model* identified skin cancer (small Melanoma and NMSC) with:

Sensitivity 93.3% Specificity 68.3%



Cited in *Nature* as one of only 11 clinical trials of AI in medicine that is randomized and conforms to new guidelines for AI clinical research. *Topol, E.J. Welcoming new guidelines for AI clinical research. Nat Med 26, 1318–1320 (2020).* https://doi.org/10.1038/s41591-020-1042-x





## Key publications in *The Lancet* and *ICAD*

## EBioMedicine Published by THE LANCET



EBioMEdicine; February 2019, Volume 40, Pages 176–183 https://doi.org/10.1016/j.ebio m.2019.01.028

## EBioMedicine Published by THE LANCET



EBioMEdicine; May 2019, Volume 43, Pages 107–113 https://doi.org/10.1016/j.ebiom .2019.04.055





International Conference on Auditory Displays (ICAD); June 2019

http://hdl.handle.net/1853/61501

## EBioMedicine Published by THE LANCET



EBioMedicine – manuscript in preparation regarding NMSC success



## Patent filings under prosecution with USPTO

Serial No.	Filing Date	Title	Status	OLG Ref. No.
16/311,372	12/19/2018 (06-26-17)	PHONODERMOSCOPY, A MEDICAL DEVICE SYSTEM AND METHOD FOR SKIN DIAGNOSIS	Pending National Phase in US (30 month)	637-01-UTIL-07
17820991.2	1/23/2019 (06/26/2017)	PHONODERMOSCOPY, A MEDICAL DEVICE SYSTEM AND METHOD FOR SKIN DIAGNOSIS	Published National phase in EP (31 month)	637-01-EP-08
62/688,062	06/21/2018	DERMOSCOPY DIAGNOSIS OF CANCEROUS LESIONS UTILIZING DUAL DEEP LEARNING ALGORITHMS VIA VISUAL AND AUDIO (SONIFICATION) OUTPUTS	Pending and to be filed as CIP by 6/21/2019	637-04-PROV
62/765,042	08/17/2018	DERMOSCOPY DIAGNOSIS OF CANCEROUS LESIONS UTILIZING DUAL DEEP LEARNING ALGORITHMS VIA VISUAL AND AUDIO (SONIFICATION) OUTPUTS	Pending combine with 62/688,062	637-05-PROV

### **Current Operational and Development Status**

- Bostel founded in 2016 as Delaware LLC. Headquarters in Atlanta; additional teams in Boston and Israel
- Atlanta-based development team and cloud servers
- App and web-based interface operative
- Registration strategy mapped
- Validation by Prospective Clinical Study
- Validation by 3+ peer-reviewed articles



## The Opportunity ...

Bostel Technologies

### **Market Size and Competitive Landscape**

The global dermatology diagnostic device market is expected to exceed \$5.0 billion by 2026 at a CAGR of 7%. Market Research Engine. Dermatology Diagnostic Devices by market by product analysis. December 2018

Bostel Technologies' skin cancer diagnosis technologies are more robust, more flexible, more rigorously validated, and easier to use.



**SkinVision** was evaluated in three studies (n=267, 66 malignant or premalignant lesions) and achieved a sensitivity of 80% ... and a specificity of 78%. However, it seems to be unreliable with 45% rate of non diagnostics. App has only moderate ratings.

Skin Analytics device study leaves open critical questions: Study looked for and identified only BIG MELANOMAS (>76%), which can easily be accurately identified by an unaided human eye.

Variable	Category		Percent
Lesion diameter (Geometric mean diameter=6.75 mm (6.49-7.02))	< 5 mm	110	20.0%
	5-9 mm	266	48.3%
	10-14 mm	155	28.1%

## **Development Pathways**

**OPTION A. Dermoscopic Home Device** (9-12 mo)

Professional-grade diagnostic capability, available via smartphone app and low-cost accessory.
PMA 3 approval.

Pivotal clinical study of 1500 biopsies, **9-12 mo** to approval for NMSC (see Nevisense, SciBase, AB, 2015)

Start of agreements & sales within 12 mo

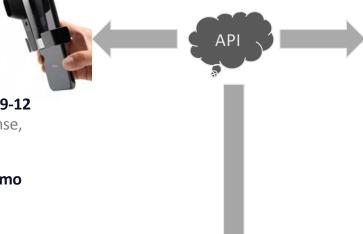
**OPTION B. Professional Diagnostic Tool** (18-24 mo)

Cutting Edge Clinical Decision Support, leveraging professional dermoscope.

Developed for GPs/Dermatologists Fast track. PMA 3

Pivotal clinical study of 1500-2000 biopsies, **18-24 mo** to approval for MM (see Nevisense, SciBase, AB, 2015)

Start of agreements & sales within **24 mo**.









### **Opportunity**

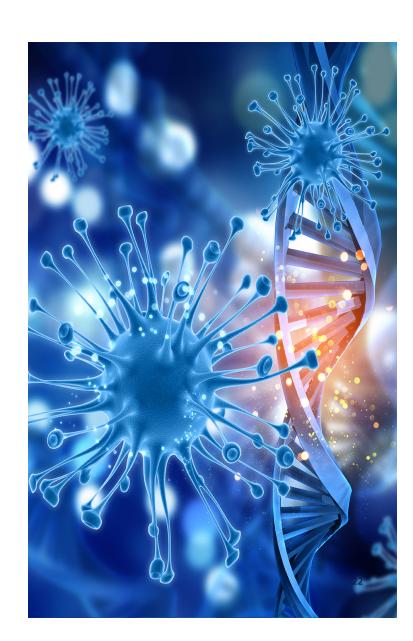
## Bostel Technologies is seeking strategic options for its platform and business

#### **Current investment opportunity:**

Bostel Technologies LLC achievements

- Web-based API operative, for instantaneous diagnostics
- Unique and powerful technology advantage: Dual deep learning algorithms using Image Classifier and Sonification
- Suitable for Home and Professional usage
- Targets GP's
- Applicable to both dermoscopic images and smartphone photos
- Diagnostic high accuracy validated by three scientific publications
- Internationally validated Prospective Clinical Study





## **Thank You!**

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