

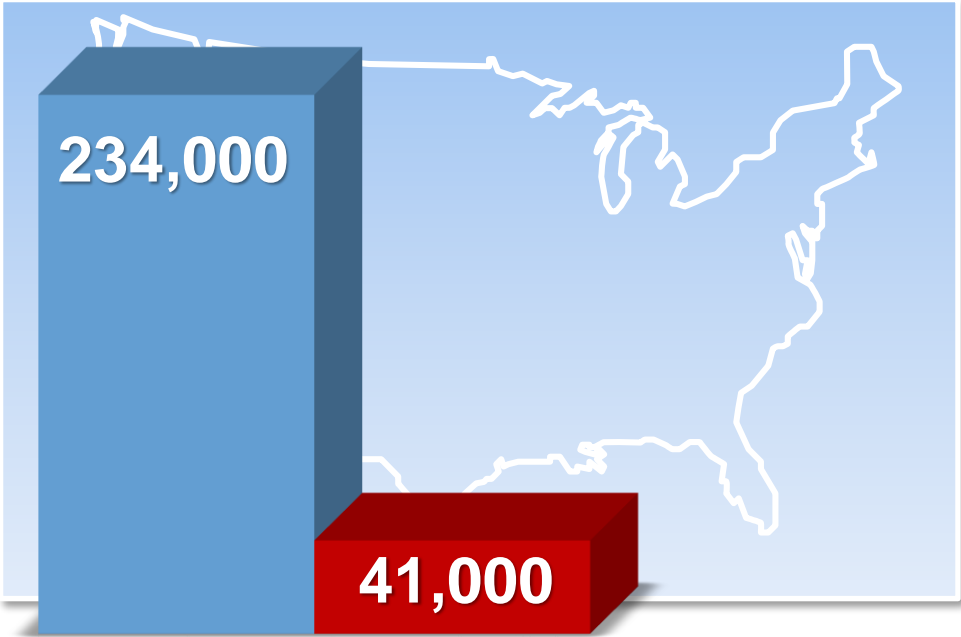
FIRSTSENSE MEDICAL™

TECHNOLOGY SAVING LIVES

Paul Angott
Founder & President



2015 U.S. Invasive Breast Cancer



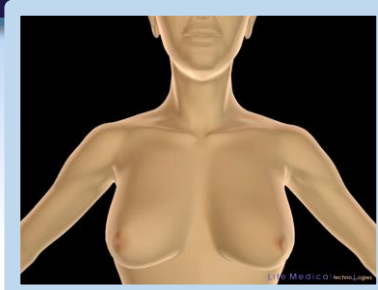
CASES

DEATHS

Lifetime Risk



Current Screening Methods, Poor Detection



Clinical Breast Exam (CBE)

Part of annual physical or stand alone

10% Detection rate (daily practice)

MANUAL (Hand) - subjective

FSM*

~ \$30 - \$40 & 90%

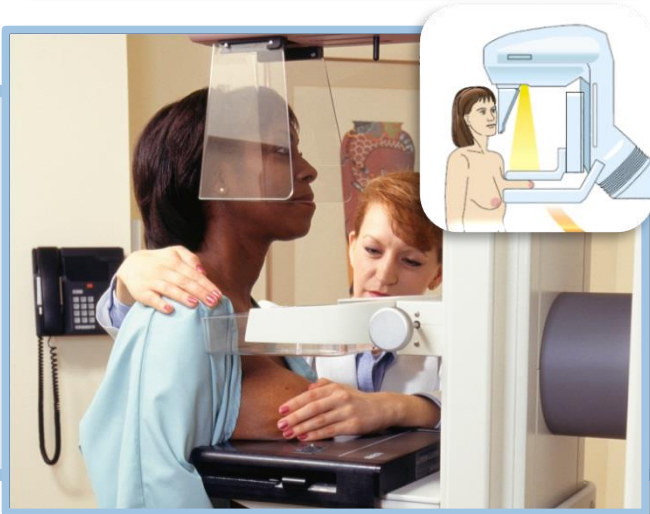
Adjunct

Mammogram (MMG)

Average reimbursement - **\$130**

75 - 90% Detection rate

MANUAL (Radiologist) - subjective



*Designed to achieve

Compliance to Mammography Guidelines

Guidelines

- Screening guidelines range from annual to biennial mammograms for women 40 years of age or older
- 41% of eligible women surveyed did not have a mammogram in the past year*
 - 33% in the past 2 years

Reasons for Non-Compliance

- Fear of radiation
- Embarrassment
- Cost
- Age <40 years old
- Pain
- Convenience
- Access to care
- False positive rate



*American Cancer Society Surveillance and Health Services Research, 2013

Solution



FIRSTSENSE
BREAST EXAM

Semi - Automated & Manual Analysis

Adjunctive breast cancer screening devices for use with other early breast cancer detection modalities, designed to:

- Remove barriers to breast cancer screening
 - No exposure to radiation
 - No pain or breast compression
 - No physical contact with the patient
- Take breast cancer screening to where the patient is - in the primary care physician's office
- Make healthcare affordable for the patient - below the cost of out-of-pocket co-pays
- Maintain quality diagnostic analysis and reporting through a centralized reference lab



Sentinel BreastScan

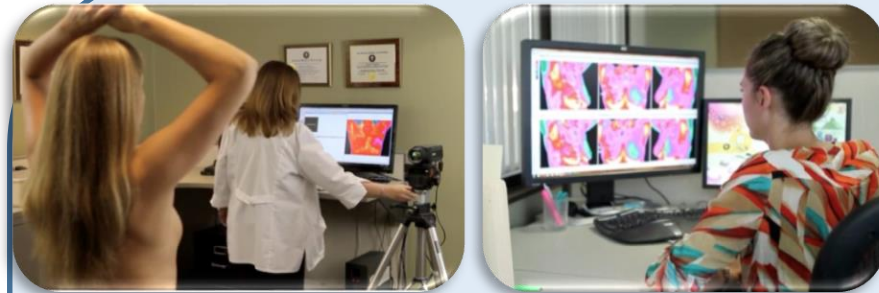


FIRSTSENSE Breast Exam

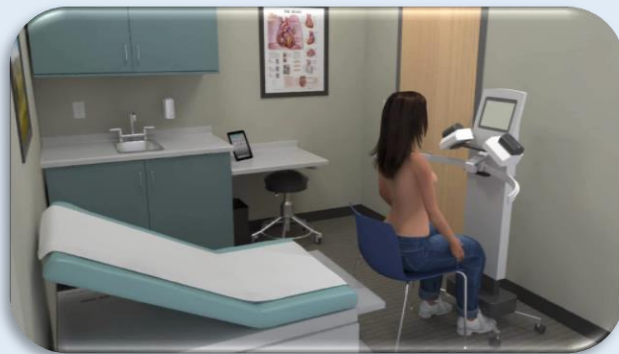
Solution



FIRSTSENSE
BREAST EXAM



Manual System



Semi - automated & manual analysis

- Based upon
 - Clinically proven, manual system
- FSM Robotic System provides data
 - Military grade infrared camera
 - Long term analysis in cloud
- Reduces labor
- Therma-Scan results within 48 hours
 - Normal No problem
 - Abnormal Problem
- Internet & cloud - data & backup
 - Site: Data Viewer & Report Writer
 - *Later: Analysis, biopsies, algorithms*
 - *Compare annually, lifetime customers!*

Sentinel - First Sense Solution

- **New name - Sentinel II**
- **Small & portable - see following slides**
- **Affordable doctor cost of \$18,000 plus \$12 per test**
- **Estimated patient cost: \$30 - \$40 per test**
- **Strong Doctor Value Proposition**
 - **Better patient care**
 - **Data uploaded into cloud**
 - **Analysis at Therma-Scan Reference Lab**
 - **No test analysis learning curve**
 - **Results sent to doctor within 48 hours**
 - **Doctor can typically make \$2 - \$3k per month with lease w/ no money down**



Rendering - Sentinel II



Rendering - Sentinel II tester in a doctor's office with patient

First Sense Sentinel II Tester



- **Tester moves up & down to align with breasts**
- **Tester motor lifts chair off floor**
- **Moves as a unit (patent pending)**
- **Easy to move**
- **Compact for storage**



Sentinel II Product Plan in 2016

- | | |
|--------------------------------|-------------|
| 1) Complete acquisition | June |
| 2) Redesign product | June |
| 3) Build 6 prototypes | June |
| 4) Get UL | Aug |
| 5) Get FDA | Dec |
| 6) Tooling | Dec |
| 7) Start sales | 1Q17 |

Sentinel Clinical Trial Results^a

<u>Journal Date</u>	<u>#</u>	<u>Date</u>	<u>Sens</u>	<u>Spec</u>	<u>Notes</u>
SPIE, Bretz	500	2012	96%	79%	Technology review, not a clinical trial ^b
Am. J. of Surgery	92	2008	97%	12% ^c	Sentinel screening report
			97%	27%	Neural network analysis
IEEE, 2 Groups	110	2003	99%	n/a	Sensitivity group (abnormal)
	343		n/a	51%	Specificity group (normal)

^aBlowing cool air.

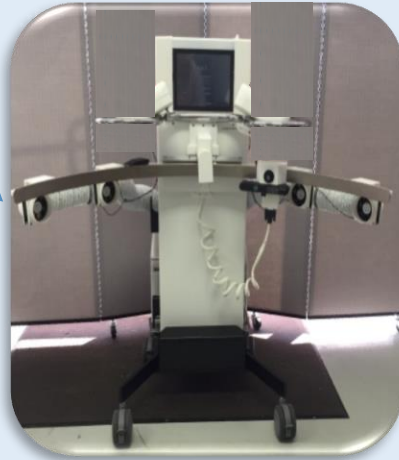
^bPlan is to determine if we can expand study & publish new results as a clinical trial.
Combined results from woman's health, Sentinel test & ultrasound test.

^cPlan to improve specificity by offering a free test in 1 to 3 months in some cases.

First Sense Tester Blowing Cool Air



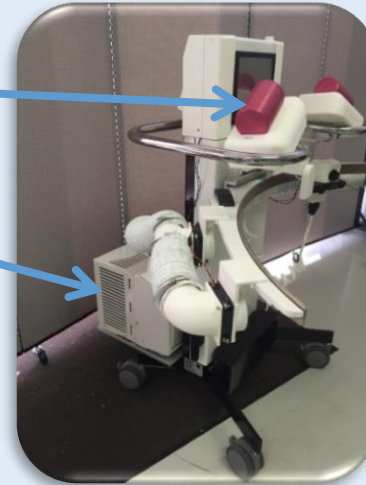
4 fans
are
added



Tester w/ air conditioner, front view

*Cold bars are
removed*

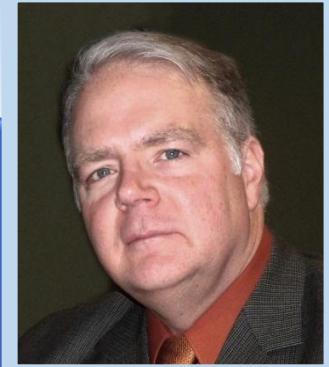
Air conditioner



Tester w/ air conditioner, side view

- Tester is being streamlined
- FDA clearance (substantially similar to predicate)
- IR Camera with motor moves around patient

HOEKSTRA System



Phil Hoekstra, PhD
Therma-Scan, LLC

- Phil Hoekstra, PhD, founded Therma-Scan (1972)
- 500,000+ WOMEN TESTED (35 US offices)
- COLD CHALLENGE (Exclusive)
- MEDICINES & OPERATIONS (Exclusive)
- Manual analysis - ¼ to 2 hours per patient
- Cost - \$150 (not paid by insurance)
- World leader in thermal imaging
- Results, 2000 women study (biopsy based)
 - Sensitivity (detection rate) - 95%
 - Specificity (non-detection rate) - 91%
- FSM has exclusive, worldwide license

9% false positives

A Woman's Perspective

- Lifesaving
 - Early detection
 - High detection rate
- No radiation/X-rays
- No pain
- No embarrassment
- Convenient
- Low cost



FIRSTSENSE
BREAST EXAM

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FIRSTSENSE MEDICAL



Doc Value Proposition

Affordable Care Act

- < 50 CBE
- 50 - 74 MMG
 - Every 2 years

- Early Adopters
- Better patient care
- Add new patients
- Adds \$2 - \$3k+ per month



Market

Doc Offices

1.2 M
\$18 k per tester
\$22 B

Women

675 M
\$8.00 per test, net
\$5 B per year



Management

Award "Top 50 Companies to Watch in Michigan"



Paul Angott

Founder, President & COO

- Sold 10 M, patented products
- Entrepreneur of the year (MI)



Alan Klevens

Chief Executive Office

- Strong clinical trial & FDA background
- Extensive marketing & sales experience



Pavan Vempaty, PhD

Director of Software

- Robotics, Machine vision , AI
- Has 3 patents and several publications



Gokhan Ozalp

Quality Assurance Manager

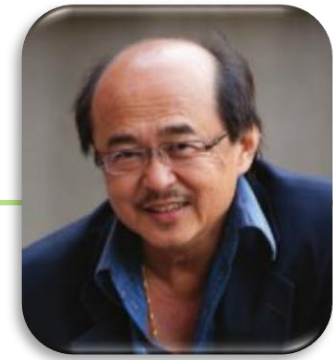
- Extensive FDA experience in medical devices.
- Software Quality Engineer with 510(k) experience



Steve Henke

Sr. Mechanical Engineer

- Expert in 3D conceptualization
- Patents in Mechanical Mechanisms



KaC Cheok, PhD

Engineering Consultant

- One of top robotic experts in the country
- Stabilized platform M1 tank & Segway

Board of Managers



Paul Angott
Chairman of the Board



Gina Fundaro, MD
Radiologist, Henry Ford
Publications



Mark Mitchell
Previous CEO
US Medical Management



Roger Newton, PhD
Angel Investor
Co-developer **LIPITOR®**



Brad Oleshansky
Angel Investor
Medical Device Marketing Expert

First Sense Marketing & Sales

➤ Go To Market Plan

➤ Sales: 1Q17

➤ Clinical trials - plan to publish data

- University of Toledo - FSBE, screening, Jan, 2016
- UCLA, biopsy [FSBE], July) & screening [Sentinel], Aug] - 2016
- IHA (owned by St. Joseph Mercy) - FSBE, July, 2016
- Others - in discussion

➤ PR & Key Opinion leaders - promotion

➤ Pull: women - social media, PR, TV, print, digital web, breast cancer groups, office & tester videos

➤ Push: doctors/hospitals - trade shows, journal ads

➤ Influencers - insurance companies and CMS*

*Expect new CPT code in future with reimbursement Centers for Medicare & Medicaid Services

Point of
Sale
Video



Watches Video

FDA Process & Clinical trials

➤ FDA

- Class I
- 510(k)

- 2 Predicate Devices
 - Sentinel
 - No Touch



➤ FSBE

- Submitted - 2Q14
- Not Substantially Equivalent - 3Q15
- FDA clearance received - 2Q16

➤ Sentinel

- Expected to submit - 3Q16
- Expected clearance - 4Q16



John Smith, MD, JD
FDA Consultant
20 years medical
device experience

Intellectual Property



FIRSTSENSE
BREAST EXAM

Exclusive Worldwide License - **HOEKSTRA** System

30-step, proven thermography protocol

(7) - 2 granted patents, 4 filed & 1 to be filed

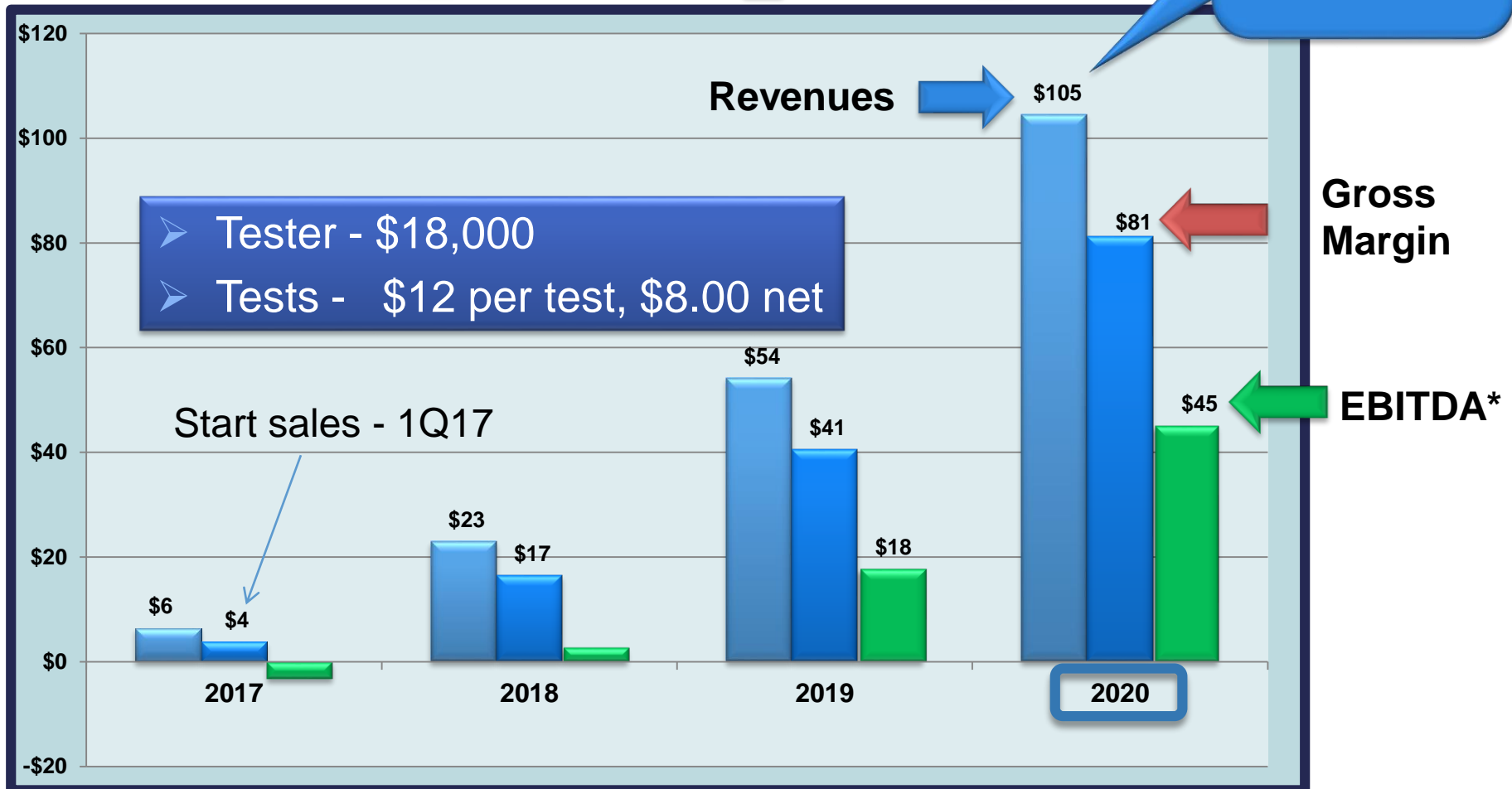
Extensive Trade Secrets

Financial Projections

Projections (\$ M)

Revenues ■ Gross Margin ■ EBITDA ■

~ 1%
63%



*Earnings Before Interest, Taxes, Depreciation & Amortization

Sales & Manufacturing Strategy

➤ Target Customers

- OB/GYN, Primary Care/Internists
- Group Practices, Hospitals or Institutions
- Oncology Focused Clinics

➤ Contract Sales Force



➤ Manufacturing

- 2 with FDA clearance
- Each with global footprint



➤ Quality Control

- Exceptional standards

5-Year Strategy



FIRSTSENSE
BREAST EXAM

- **Grow Profitable Disruptive Company**
- **Sell to Major Device Company or Private Equity**



- **Avg. Medical Device Co. EBITDA Multiple = 12 X**

Corporate Structure

➤ First Sense Medical, LLC

- New name: FSM Equity Holdings, LLC (a Michigan LLC)
- You will invest in this company
- Owns First Sense Medical, LLC (a Delaware LLC)

➤ First Sense Medical, LLC (Delaware)

- The New Investor invested in this entity
 - \$3 M at closing @ \$6 per unit
 - Gets a 4% preferred return
 - See details for ownership

➤ Investment - this round \$3 M



FIRSTSENSE MEDICAL™

TECHNOLOGY SAVING LIVES

- *Disruptive Technology*
- *Huge Market*
- *Potential ROI, new ~ 12:1*
- *Humanitarian*