Tender Light Scientific US

Non-invasive

blood testing device

I-Ting Wu

CEO

NIH Applicant Assistance Program

Management and R&D Teams

I-Ting Wu, CEO
Ph.D. candidate
25+ yrs
RN, researcher, biomedical
informatics, health care and
Behavioral Health Management

Alex Wang, M.D.
20+ yrs,
Primary care, EHR
expert, biomedical,
informatics

Sheng-Hao Tseng, Ph.D.
Inventor
15+ yrs
Biophotonics

Consultants

Robert S. Green, JD.
40+yrs
Legal, business
development, FDA,
medical devices,
strategy, startups

Sunil Maulik, Ph.D.
25+yrs
Commercialization,5
startups, acquisitions,
biomedical, device,
informatics

Monica Jain, M.D.
10+yrs
Surgeon, surgical
innovation officer at
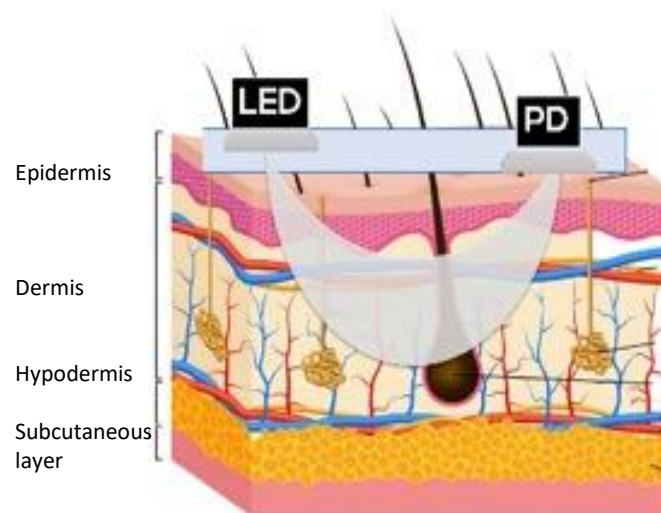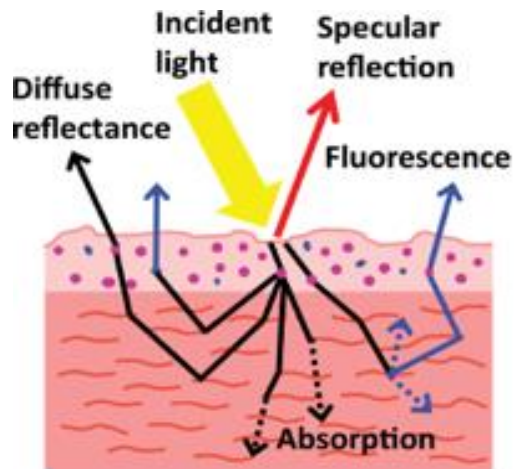**Cedars-Sinai**

Jinn-Kong Sheu, Ph.D.
20+ Photonics
Distinguished Professor of
Department of Photonics

Technology

The Multifunctional Optical System (MOS)

TLS Diffuse Reflectance Spectroscopy (DRS) technology measure patterns created when light is scattered in the skin.

Intellectual Property:
- 27 conference papers
- 26 international publications
- 7 international patents (4 US, 2 Taiwan, and 1 China)

Benefits:
- No needles, no blood sample required.
- Safely perform repeated measurements without injuring the skin.
- Instant results.

Problems/Solutions

US

- 7 billion blood test

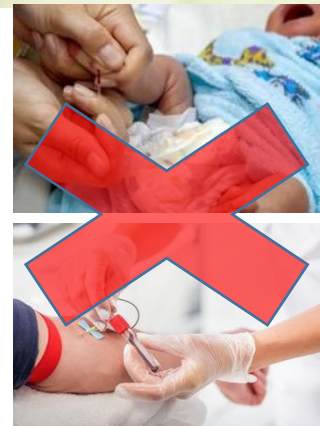- 80%, 322,488 private clinic laboratories

Anemia

- 3 million Americans

- Hospital ED, ICU, trauma population, GI bleeding

Jaundice

- 3.6 million babies
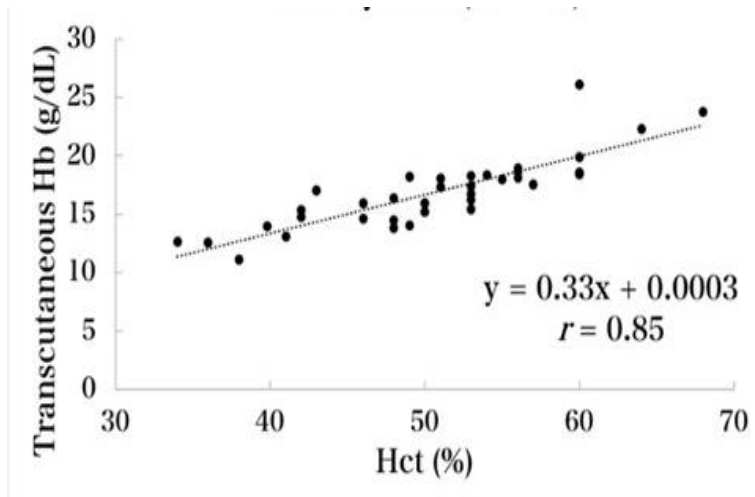
- 50% term and 80% preterm

Our device can

- Replace painful, blood sample collection

- Obtain results in second

- Accurately measure bilirubin - neonatal jaundice

- Accurately measure hemoglobin - anemia

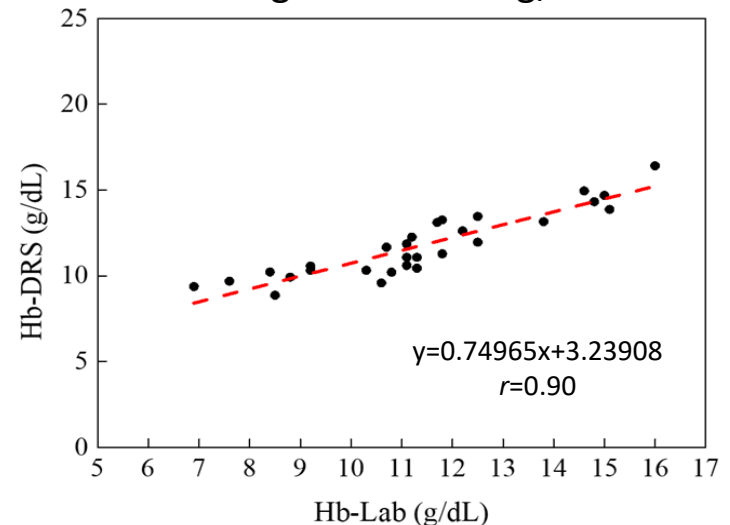- Measure indicators for cardiovascular risk (HbA1c, serum bilirubin)

Clinical Trial Results

Hemoglobin (Hb) Measurement
TLS MOS to blood samples

TLS MOS on Newborns (n=38)
Hb range 10.67 -24 g/dL

$y = 0.33x + 0.0003$
$r = 0.85$

TLS MOS on Adults (n=29)
Hb range 6.9 to 14.2 g/dL
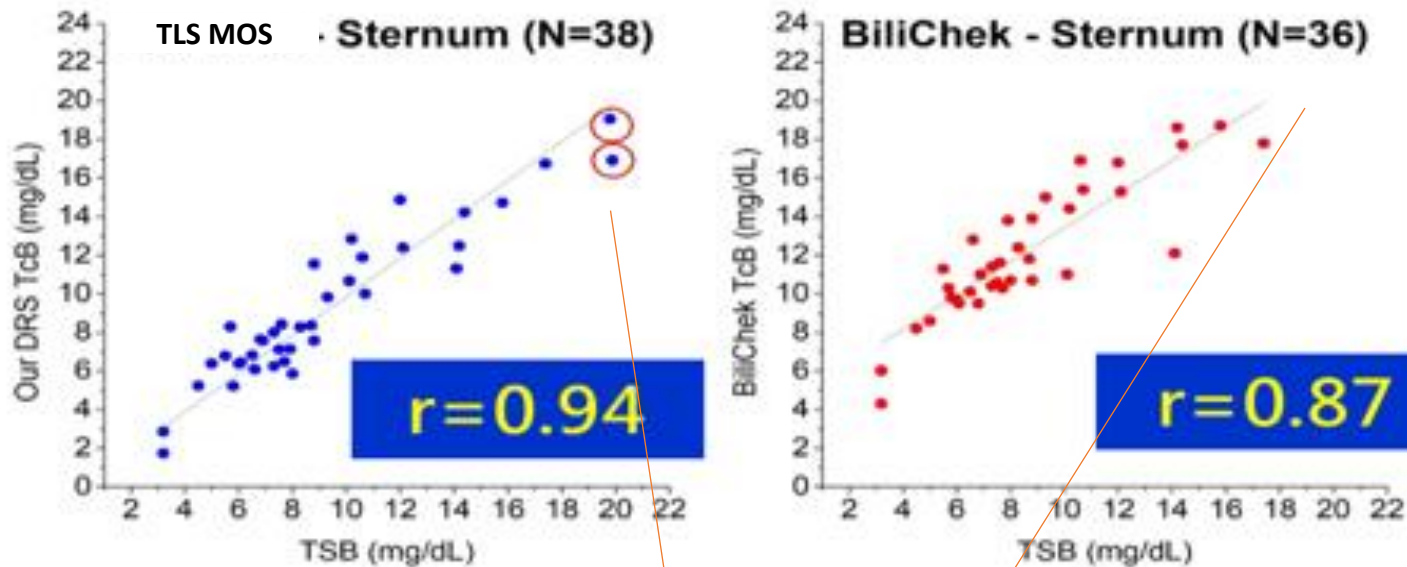

$y=0.74965x+3.23908$
$r=0.90$

- 21 anemia patients, 8 normal people
- Anemia:
  - Female below 12
  - Male below 13

Note: a higher r value closer 1.0 indicates increased accuracy

Clinical Trial Results

Transcutaneous Bilirubin Monitoring

TLS MOS to BiliChek (Philips) on Newborns

Showed "Out of range" for BiliChek

Note: a higher r value closer 1.0 indicates increased accuracy

Competitive Analysis

Device Name	Phlebotomy	HemoCue	Masimo Radical 7	TLS_DRS	BiliCheck	Drager JM 105
Methods						
Price (US)	Various	$1,200	$15,000	$3,000	$3,900	$2,500
Technology	Invasive blood draw	Invasive (Hb)	Noninvasive (Hb)	Noninvasive (Hb, TcB, HbA1c)	Noninvasive (TcB)	Noninvasive (TcB)
Measurable parts	Arms/hands	Fingertips	Only Fingertips	Forehead, chest and arms, etc. (portable)	Forehead, chest (portable)	Forehead, chest (portable)
Time factor	30 min – few days	10-60 seconds	Up to 10 minutes	10-60 seconds	10-60 seconds	10-60 seconds
Hb detection range	All range	Hb 0-25.6 g/dL	Hb 8-17 g/dL	Hb 6-23 g/dL	n/a	n/a
TcB detection range	All range	n/a	n/a	0 – 22 mg/dL	0 to 20 mg/dL	0 to 20 mg/dL
Age range	All ages	All ages	Adults	All ages	Infant only	Infant only

Total Addressable Market

Hemoglobin (Hb):

Global hemoglobin device market to reach $5 billion by 2025

Bilirubin (TcB):

Bilirubin blood test market projected to reach $1.85 billion By 2027.
Global bilirubin meters market is expected to reach $130.29 million by 2027.
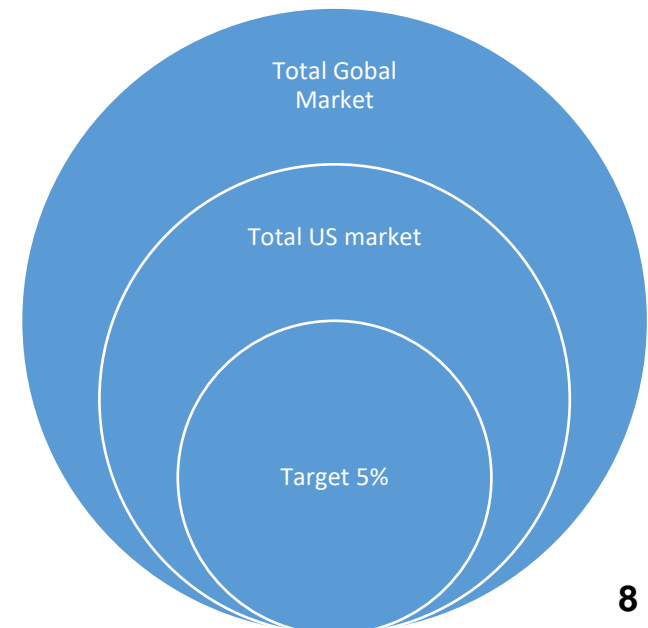
Market size (US):

5200 of Emergency Departments (ED)
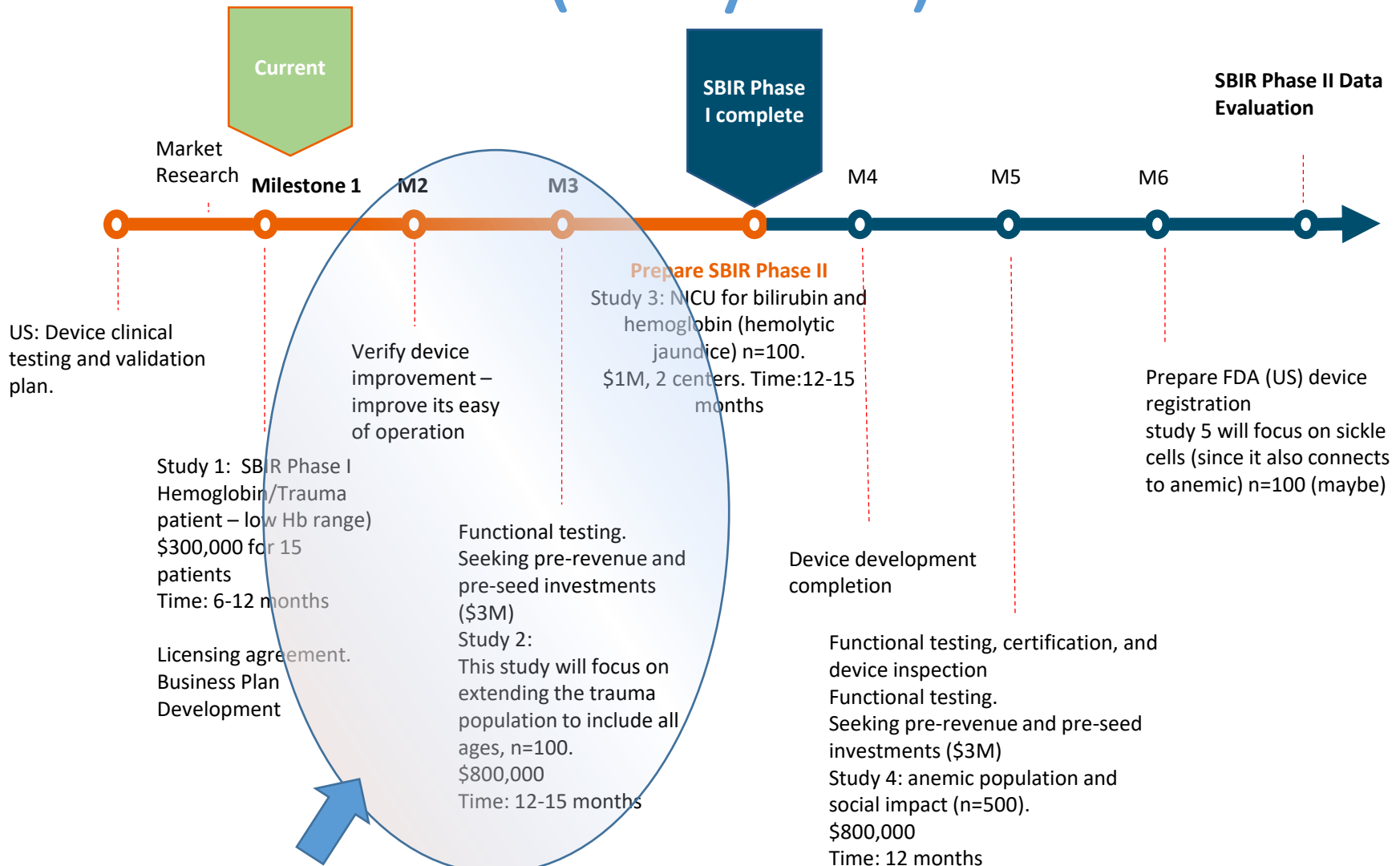130 M of ED visits
223.4 M adult trauma patients
8% pediatric trauma patients
2.8 M of anemia patients
4M babies/year screened for both Hb and TcB

Total Gobal Market

Total US market

Target 5%

Timeline – FDA Registration (3-5 years)

Current

SBIR Phase I complete

SBIR Phase II Data Evaluation

Market Research

Milestone 1   **M2**   **M3**   M4   M5   M6

US: Device clinical testing and validation plan.

Prepare SBIR Phase II
Study 3: NICU for bilirubin and hemoglobin (hemolytic jaundice) n=100.
$1M, 2 centers. Time:12-15 months

Verify device improvement – improve its easy of operation

Prepare FDA (US) device registration
study 5 will focus on sickle cells (since it also connects to anemic) n=100 (maybe)

Study 1: SBIR Phase I Hemoglobin/Trauma patient – low Hb range)
$300,000 for 15 patients
Time: 6-12 months

Licensing agreement.
Business Plan Development

Functional testing.
Seeking pre-revenue and pre-seed investments ($3M)
Study 2:
This study will focus on extending the trauma population to include all ages, n=100.
$800,000
Time: 12-15 months

Device development completion

Functional testing, certification, and device inspection
Functional testing.
Seeking pre-revenue and pre-seed investments ($3M)
Study 4: anemic population and social impact (n=500).
$800,000
Time: 12 months

Our ask

Summary

Breakthrough technology
- Unique and compelling technology (MOS DRS)

Best in class
- Strong clinical evidence showing higher accuracy of our solution over current industry standard

Multifunctional
- Only device can measure both bilirubin and hemoglobin in one single device

Cost- effective
- Low cost of ownership with technology-driven reduction in production costs
- Reduce healthcare cost

Thank you!