



ARTIFICIAL INTELLIGENCE FOR WOUND HEALING DIAGNOSTICS

Wensheng Fan, CEO



Key investment highlights



Spectral MD is building on \$100+ million U.S. Government (BARDA) contracts for the Burn indication to expand our AI technology platform into Diabetic Foot Ulcers (DFU) and other indications

I. Substantial, high growth wound healing diagnostic market opportunities

Global, multi-billion-dollar total addressable market in Burn and DFU

DeepView® Day 1 wound healing diagnostics revolutionizes standard of care and healthcare economics

II. Breakthrough designated AI technologies for wound healing diagnostics

High resolution full range spectral imaging and first Artificial Intelligence solution


Leveraging BARDA support to expand platform into DFU and other indications

III. Robust ready-to-execute commercialization strategy

Burn commercialization with BARDA and potential Project BioShield for federal procurement

FDA Breakthrough Designation and MCIT reimbursement pathway





Substantial, high growth wound healing diagnostic markets in:

- Burns: \$3.7 Billion, CAGR 6.9%⁽¹⁾
- DFU: \$11 Billion, CAGR 6.8%⁽²⁾
- Other indications – VLU, CLI⁽³⁾
- DeepView® Day 1 wound healing diagnostics – revolutionizes standard of care and healthcare economics

1. By 2028, "Global Burn Care Market Size & Share Report, 2021–2028." [www.Grandviewresearch.Com](http://www.grandviewresearch.com), 2021, www.grandviewresearch.com/industry-analysis/burn-care-market.

2. By 2026, Fortune Business Insights. "Diabetic Foot Ulcer Treatment Market Worth \$11.16 Billion at 6.8% CAGR; Rise in Clinical Trials to Augment Market, Says Fortune Business Insights™." GlobeNewswire News Room, 15 Jan. 2020,

3. VLU refers to Venous Leg Ulcer, and CLI refers to Critical Limb Ischemia

Challenges in early burn wound healing diagnostics



7-year-old girl from Texas went through 21 extra days of avoidable pain and suffering



Initial burn wound appearance



It was a non-healing burn that required surgery!

- **Burn wound healing diagnosis is difficult – Burn Experts: 70% accuracy, Non-Specialists: <50% accuracy**
- **Visual assessment is not reliable with no objective tools to provide early burn wound healing prediction**
- **Standard of care is to adopt a wait-and-see approach, delaying treatment and furthering complications**
- **A non-healing burn destroys the skin's capacity to regenerate – surgical excision and grafting is required**

A true clinical unmet need!



“All I need to know is whether a wound will heal or not. Then I can take care of the patient appropriately.”



Prof. Keith Harding

- Director of TIME institute and Head of the Wound Healing Research Unit in the School of Medicine at Cardiff University, U.K.
- Chair of the International Working Group on Wound Healing in Diabetic Foot Disease
- Past President of the European Tissue Repair Society
- First President of the European Pressure Ulcer Advisory Panel
- First Recorder of the European Wound Management Association
- Member of Strategic Advisory Board, Spectral MD

Burn wound market opportunity



Current market situation⁽¹⁾

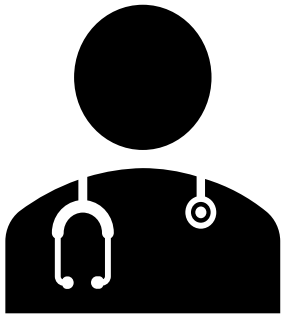
~486,000 U.S. ER (A&E) burn patients/year
53,220 burn-related stays/year



8.1 days in-patient average length of stay
Average cost of \$24,000 / stay

Problem⁽²⁾⁽³⁾⁽⁴⁾

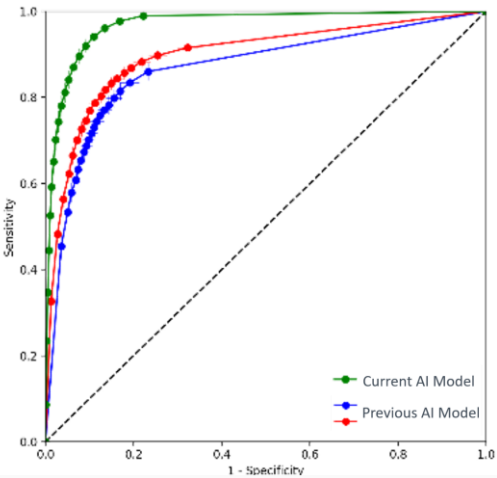
50-70% Accuracy



Wait up to 21 days to determine the need
for surgery

DeepView[®] impact⁽⁵⁾

Burn: 91% Accuracy on Day 1



Reduce average length of stay by 4.9 days
and cost savings of ~\$14,500 / stay

Physicians currently rely on a wait-and-see approach of up to 21 days to determine the need for surgery, resulting in higher probability of infections, additional costs, longer hospital stay, and over-excision of viable skin.

Total addressable market: \$3.7 billion, CAGR 6.9%⁽⁶⁾

1. K. McDermott, A. Weiss and A. Elixhauser, "Burn-Related Hospital Inpatient Stays and Emergency Department Visits, 2013: Statistical Brief #217," Healthcare Cost and Utilization Project (HCUP) Statistical Briefs Rockville (MD): Agency for Healthcare Research and Quality (US), 2016.
2. Pape SA1, Skouras CA, Byrne PO. An audit of the use of laser Doppler imaging (LDI) in the assessment of burns of intermediate depth. Burns. 2001 May;27(3):233-9
3. J. Jeng, A. Bridgeman, L. Shivan, P. Thornton, H. Alam, T. Clarke, K. Jablonski and M. Jordan, "Laser Doppler imaging determines need for excision and grafting in advance of clinical judgment: a prospective blinded trial," Burns, vol. 29, no. 7, pp. 665-70, 2003
4. P. Hlava, J. Moserová and R. Königová, "Validity of clinical assessment of the depth of a thermal injury," Acta Chir Plast, vol. 25, no. 4, pp. 202-8, 1983
5. Data from Spectral MD's IRB approved Proof of Concept Clinical Study
6. By 2028, "Global Burn Care Market Size & Share Report, 2021-2028." Www.Grandviewresearch.Com, 2021, www.grandviewresearch.com/industry-analysis/burn-care-market.

Diabetic Foot Ulcer (DFU) market opportunity



Current market situation ⁽¹⁾⁽²⁾

5.2 million DFU patients / year⁽³⁾



15.5 visits per year
Cost of up to \$63,100 / DFU patient per year

Problem⁽²⁾

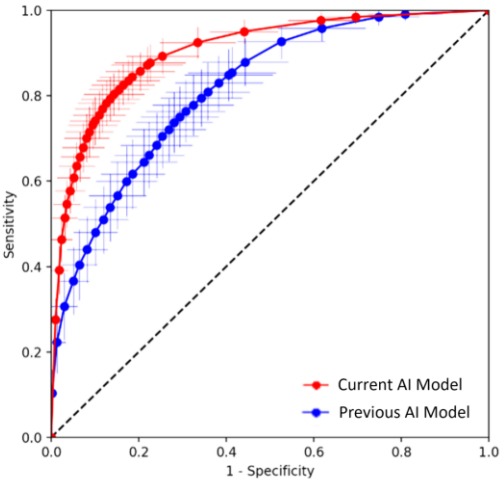
No Diagnostic Available!⁽⁴⁾



30 days of standard wound care for all DFUs.
40% do not respond and require advanced therapy or revascularization.

DeepView[®] impact⁽⁵⁾

DFU: 83.3% Accuracy on Day 1



Quicker time to advanced therapy, better wound healing and reduce overall visits/utilization

Due to U.S. reimbursement rules, physicians currently are required to wait 30 days to designate a DFU as non-healing before using advanced wound care therapies⁽⁶⁾, resulting in higher probability of infections, longer healing times and significant lifetime medical costs for the patient.

Total addressable market: \$11 billion, CAGR 6.8%⁽⁷⁾

1. DelveInsight, "Diabetic Foot Ulcer (DFU) Market Insights, Epidemiology, and Market Forecast—2030", Jan 2021
 2. <https://pubmed.ncbi.nlm.nih.gov/29611155>
 3. DFU patients in U.S., U.K., Germany, France, Italy and Spain
 4. Ilonzo N, Patel M, Lantis JC 2nd. Managing the Diabetic Foot Ulcer: How Best Practices Fit the Real 2018 United States. Surg Technol Int. 2018 Jun 1;32:49-59. PMID: 29611155.

5. Data from Spectral MD's IRB approved Proof of Concept Clinical Study
 6. Advanced wound care therapies: synthetic skin substitute grafts, negative pressure wound therapy, hyperbaric O2 therapy
 7. By 2026, Fortune Business Insights. "Diabetic Foot Ulcer Treatment Market Worth \$11.16 Billion at 6.8% CAGR; Rise in Clinical Trials to Augment Market, Says Fortune Business InsightsTM." GlobeNewswire News Room, 15 Jan. 2020



Breakthrough designated AI technologies for wound healing diagnostics

- High resolution full range spectral imaging and First Artificial Intelligence Solution
- Leveraging BARDA support to expand platform into DFU / other PAD indications

DeepView®: medical imaging + AI predictive analytics



DeepView® imaging

- **Patented Proprietary multi-spectral** imaging data acquisition in milliseconds
- Wound tissue physiology and viability biomarkers captured



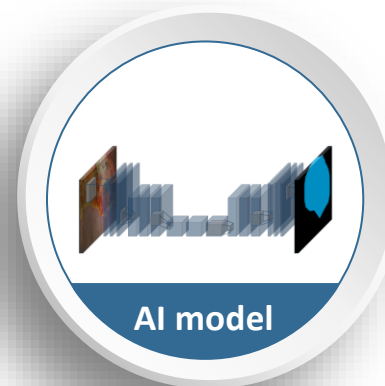
Data extraction

- Extraction of **AI model features** from raw imaging data
- **Patient health matrix**
- Pre-processing for AI



AI model building

- AI model trained and tested against a proprietary clinical database of **53.4 billion** and growing clinically validated data points
- AI algorithm integrates image and clinical data for model training



AI wound healing prediction

- **Day 1**, objective, accurate and immediate binary wound healing prediction:
Non-healing – Surgery;
Healing – Routine care



DeepView[®] competitive advantages



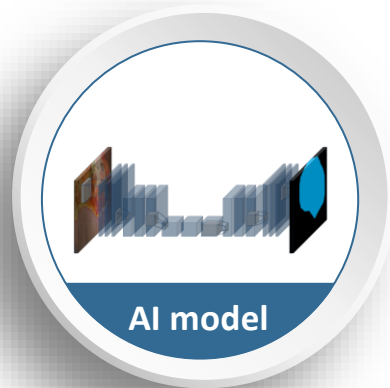
DeepView[®] imaging

- Wide MSI wavelength range
- High resolution wavelength sampling points



Data extraction

- Proprietary 3D wound tissue spectral data
- World's largest burn tissue biopsy database



AI model building

- Over 53.4 billion clinically validated data points
- Most common tissue physiology measurements included

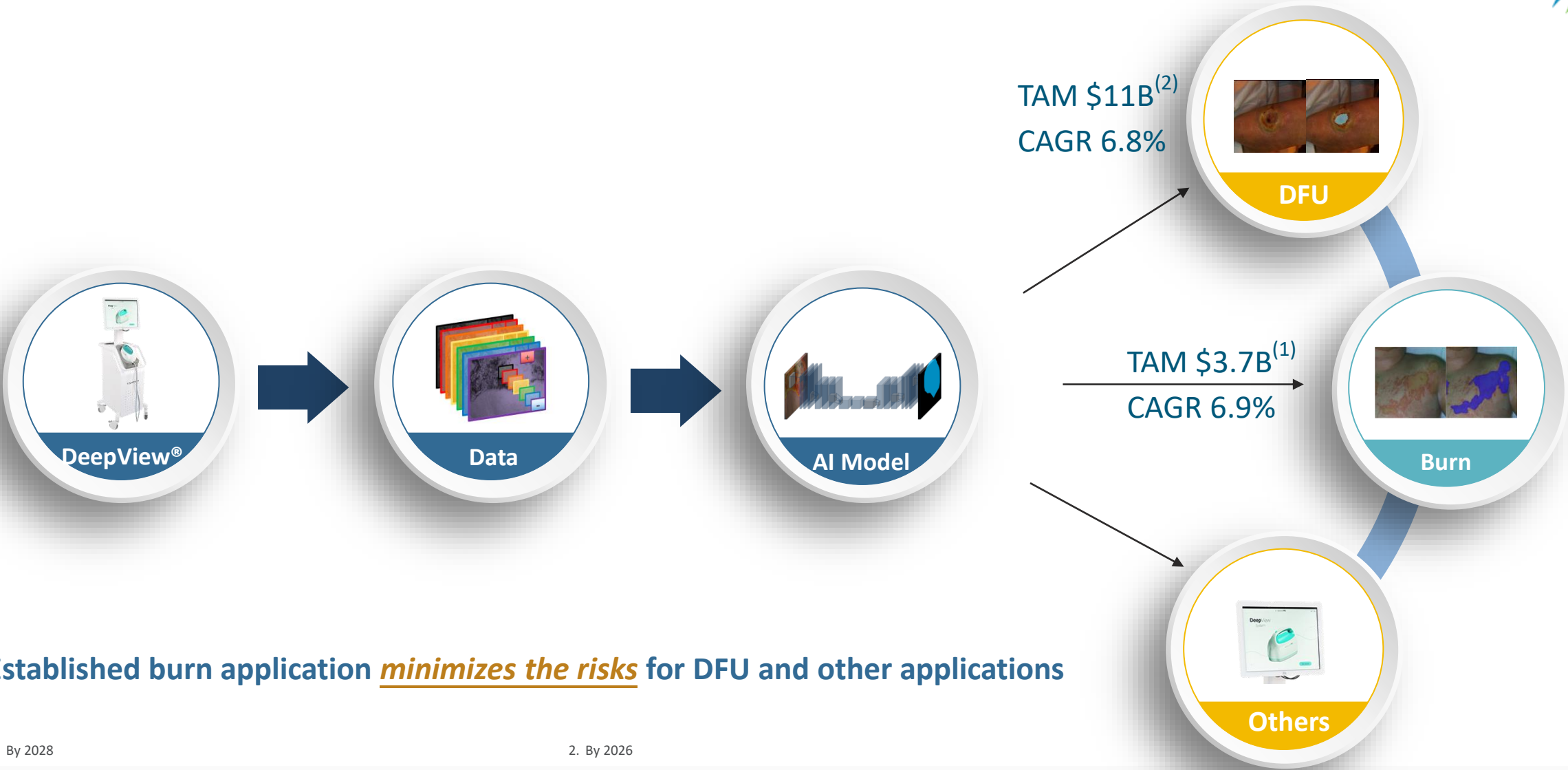


Healing prediction

- FDA breakthrough designated Day 1 healing/non-healing binary outputs
- Cross-country multi-center clinical practice variance verified

Significant differentiation, patent protected

DeepView®: One technology platform, many applications



Established burn application minimizes the risks for DFU and other applications

1. By 2028

2. By 2026



Robust ready-to-execute commercialization strategy

- Burn commercialization pathway supported by BARDA Partnership, and potential Project BioShield for federal procurement and deployment
- FDA Breakthrough Designation and MCIT reimbursement pathway
- Strategic clinical and manufacturing partnerships built in U.S. and E.U. for DFU commercialization

Business and commercialization strategy



- ❑ U.S. Government's Project BioShield Act (BARDA) to potentially procure and place DeepView® in approximately 5,400 U.S. federal and community hospitals⁽¹⁾
- ❑ SaaS model comprising a per click element, and a subscription element in annual software licensing fee with maintenance, image hosting, access to the AI, cloud-based access and improvement updates
- ❑ Capital sales at competitive pricing to enable 1st-year-payback for clinics



- ❑ 74,000 sites of service in U.S. and E.U.
 - Hospitals (Outpatient clinics)
 - Podiatry offices/Wound care clinics
 - Vascular/Cardiology practice
 - Imaging centers
 - Ambulatory surgical centers
- ❑ Burn reimbursement pathway guaranteed through upcoming Medicare Coverage of Innovative Technologies (MCIT) for four years
- ❑ DFU reimbursement initially based on pre-existing code, plans to establish separately billable, unique code for AI analysis
- ❑ U.K. market accessed through NICE validation and NHS trust purchasing

Multiple avenues to major market commercialization

1. <https://www.aha.org/system/files/media/file/2021/01/Fast-Facts-2021-table-FY19-data-14jan21.pdf>

Expected milestones to launch and growth

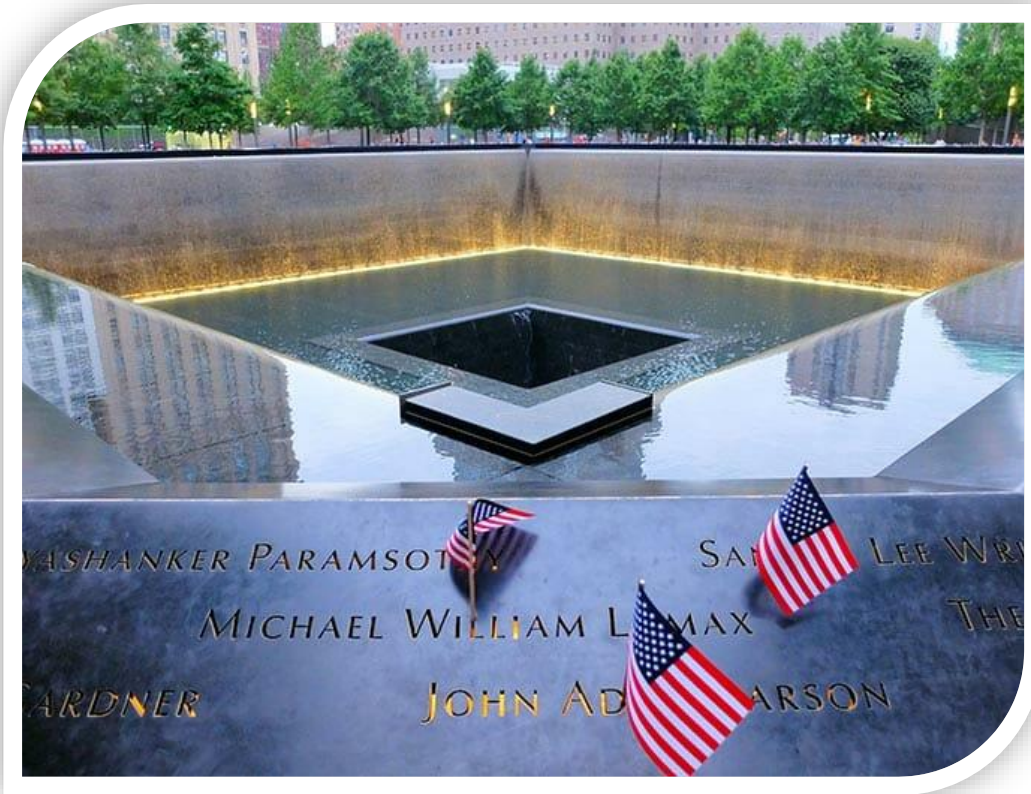


U.S. Government partnership – BARDA



BARDA: Biomedical Advanced Research Development Authority

- The U.S. federal agency that accelerates late-stage development and the manufacture of products vital to public health emergencies
- \$59.6B total value of all BARDA contracts outstanding between 2006 and 2018
- **Spectral MD** has already received **\$74M** from BARDA, with a further **\$41M** to be awarded in current contract.
- Project BioShield Act contract (**~\$400M**) potentials for federal procurement and deployment
- BARDA has **no rights to ownership**, no claims to IP, or other contractual entanglements



Strategic partnerships



Clinical

- U.K. and E.U. – Strategic alliance with Royal College of Surgeons in Ireland (RCSI) and Prof. Keith Harding, Cardiff University
- U.S. – Strategic partnership for clinical studies and clinical championship at 5 major medical centers
- Interviewed over 100 clinical professionals to identify user needs through NIH i-corps program⁽¹⁾



Development & Manufacturing

- Established external development and manufacturing ecosystem
 - Quality management systems expertise in medical devices
 - Vast domain knowledge and established development process
 - Scalable upon commercialization
- Processes in accordance with FDA and CE Mark regulations and standards
 - Mitigate regulatory, quality and operational risk



1. <https://ncats.nih.gov/pubs/features/sbir-i-corps>

UMC NOLA, Wake Forest, and Medstar are current strategic partnerships with UAB and MASSGEN in the process of signing

Proven and experienced management team



Wensheng Fan

CEO / Co-Founder

Over 20 years managing emerging technologies in AI, Imaging and NLP at Sensata, Texas Instruments, and Philips



Jeffrey Thatcher, PhD

Chief Scientist

12 years of clinical R&D of tissue optics
Served as the PI on multiple NSF, NIH, DoD grants and BARDA contracts



Wan Lung Eng, MBA

Chief Financial Officer

Over 18 years of experience as accomplished bulge bracket IB, PE and CFO



Kevin Plant

Head of Software and Data Science

Over 10 years of software and data science leadership experience at St. Jude and Abbot



Marc Dudek, MBA

Head of Business Development

Proven Business Development at Medtronic and BSW Health



Louis Percoco

Head of System and Production

Over 31 years of experience in R&D, Production with global medical device companies



Maria Cadic, PhD

Head of Operations, Government & Regulatory Affairs

Leading BARDA and FDA relationship



Jeffrey Carter, MD

Chief Medical Consultant

Medical director of top Burn Center in the U.S.
Nationally recognized burn surgeon

Financial summary and objectives



FY 2020 financial position

- R&D revenue of \$17.3M
- Adjusted EBITDA of \$3.7M
- Net cash on hand of \$4.4M
- BARDA development contract for \$21M executed on March 22, 2021
- **Sufficient resources to fund ongoing burns development**



Use of IPO proceeds

- Successfully raised \$16M from AIM listing in an over subscribed round
- Use of proceeds for DeepView® DFU application in the U.S., U.K. and Europe:
 - Clinical trials
 - Regulatory approvals
 - Initial commercialization

BARDA contracts to complete burns development; AIM proceeds for DFU development

Upside growth potential



Clinical applications

- Venous Leg Ulcers wound healing prediction; TAM \$4.84B⁽¹⁾
- Critical Limb Ischemia (post-operative perfusion assessment tool); TAM \$23B⁽²⁾



Geographic markets

- China, Japan and Korea
- Middle East, Asia and South America



Military & Government

- U.S. Department of Defense (DoD) contract for burn intra-operative AI healing assessment
- Received new DoD contract for fully handheld DeepView[®] imaging modality on June 23, 2021
- Burn triage application has relevancy to multiple Government agencies' preparation and readiness for mass casualty events stemming from disasters and terrorist attacks

Multiple potential additional large and high growth markets

1. By 2026, Fortune Business Insights. "Diabetic Foot Ulcer Treatment Market Worth \$11.16 Billion at 6.8% CAGR; Rise in Clinical Trials to Augment Market, Says Fortune Business InsightsTM." GlobeNewswire News Room, 15 Jan. 2020, www.globenewswire.com/news-release/2020/01/15/1970862/0/en/Diabetic-Foot-Ulcer-Treatment-Market-Worth-11-16-Billion-at-6-8-CAGR-Rise-in-Clinical-Trials-to-Augment-Market-says-Fortune-Business-Insights.html.

2. By 2025, Market Research Future. "Peripheral Artery Disease Market Overview, Size, Share, Analysis, Industry Forecast, 2027." Market Research Future, 2020, www.marketresearchfuture.com/reports/peripheral-artery-disease-market-1540.

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Burn commercialization with BARDA and potential Project BioShield for federal procurement

FDA Breakthrough Designation and MCIT reimbursement pathway



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Appendix



Board of Directors



Martin Mellish, Chairman, Non-Executive Independent

Founding director of London-based private investment Aspen Advisory Services Ltd. Board and audit committee responsibilities include NuCana plc (Nasdaq:NCNA) and Levitronix Inc. encompassing biotech, life science and medical device sectors.



Wensheng Fan, CEO and Co-Founder, Non-Independent

Over 20 years managing emerging technologies in AI, Imaging and NLP at Sensata, Texas Instruments, and Philips.



Richard Cotton, Non-Executive Independent

Former CFO of FTSE250 animal health company Dechra Pharmaceuticals plc, and prior to that CFO of medical device and drug formulation business Consort Medical plc.



Cynthia Cai, PhD, Non-Executive Independent

Over 20 years of industry experience in leadership positions with Agilent Technologies, where she was responsible for its billion-dollar chromatography, automation and mass spectrometry business.



Gerald Beaney, Non-Executive Independent

Consultant to growth companies seeking strategic advice or funding for expansion. Former CEO of Northland Capital Partners Limited, an institutional stockbroker based in London. Former Partner and Head of Capital Markets at Grant Thornton U.K. LLP.



Erich Spangenberg, Non-Executive Non-Independent

CEO and founder of IPwe, a company using blockchain and artificial intelligence to create the IP asset class. Founder and CEO of IPNav, a pioneer and leader in patent monetization.

Strategic Advisory Board



Toby Cosgrove, MD

Former President and Chief Executive Officer of Cleveland Clinic and currently serves as an Executive Advisor for Cleveland Clinic. Dr. Cosgrove was the President of the American Association of Thoracic Surgery and has served on a Presidential Business Forum to provide strategic and policy advice on economic issues.



John Botts, CBE

Operating Partner of Corsair, based in London. He is also a Senior Advisor to Allen & Company Advisors LLP. Previously, he was the Chief Executive of Citicorp's Investment Bank in Europe, Middle East and Africa, and he also served as Chairman of CVC's Investment Committee in Europe.



Prof. Keith Harding

Prof. Harding is the Director of TIME institute and Head of the Wound Healing Research Unit in the School of Medicine at Cardiff University. He is a Past President of the European Tissue Repair Society and he was the first President of the European Pressure Ulcer Advisory Panel, and first Recorder of the European Wound Management Association. Prof. Harding was Chair of the International Working Group on Wound Healing in Diabetic Foot Disease.

U.S. and global intellectual property



6

Issued and allowed
U.S. patents

4

Issued and allowed
international patents

- Five active patent application families
- Burn/Wound classification on MSI and PPG
- Tissue classification on MSI and PPG
- Amputation site analysis on MSI, machine learning and healthcare matrix
- DFU healing potential prediction and wound assessment on MSI, machine learning and healthcare matrix
- High-precision, multi-aperture, MSI snapshot imaging
- Knobbe Marten - IP counsel

6

Pending U.S.
patent applications

21

Pending foreign and
international patent
applications

Glossary



AI	Artificial Intelligence
BARDA	Biomedical Advanced Research Development Authority
CAGR	Compound Annual Growth Rate
CLI	Critical Limb Ischemia
DFU	Diabetic Foot Ulcer
DHA	Defense Health Agency
DoD	Department of Defense
FDA	Food and Drug Administration
LOA	Level of Amputation
MCIT	Medicare Coverage of Innovative Technologies
MSI	Multi-spectral Imaging
NICE	The National Institute for Health and Care Excellence
NHS	National Health Service
PAD	Peripheral Arterial Disease
PBS	Project BioShield
SOC	Standard of Care
TAM	Total Addressable Market
VLU	Venous Leg Ulcers