## Advanced Scanners

Introducing OR Vis, the Optical Data Platform for Continuously Accurate Digital Surgery



Raising: \$8M-\$12M Series A

Established: 2017

Location: Austin, TX

## Summary Slide

#### Problem:

Current technologies fail to adequately track anatomy during surgery

#### Solution:

A patented optical Scanner and data platform that tracks anatomy in real time

Beachhead Market:
11 Million US based
surgeries with a \$200B
procedural spend

Business Model:
Capital equipment and

bundled software provider to medical device companies

Regulatory
510(k) Class II Device
No clinical evidence
required

Raising: \$8-\$12M Series A Prior Funding: \$4.5M

# These digital Technologies Rely on 3D Positioning Data to Guide Surgeons and Tools During Surgery

**Surgical Navigation** 

Robotics

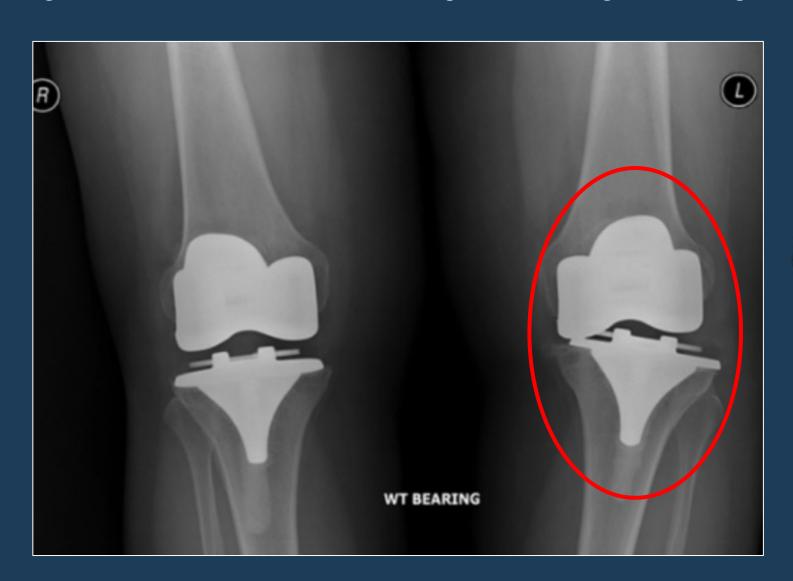
**AR/VR Visualization** 



### Inaccurate Positioning Data Leads to:

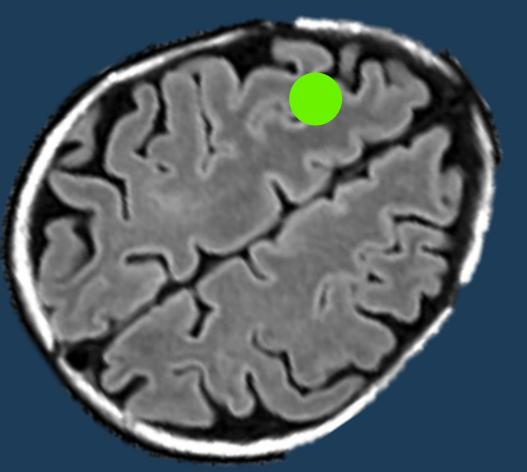
### Misplaced Implants

navigation error ... can occur even with intraoperative 3D image-based navigation

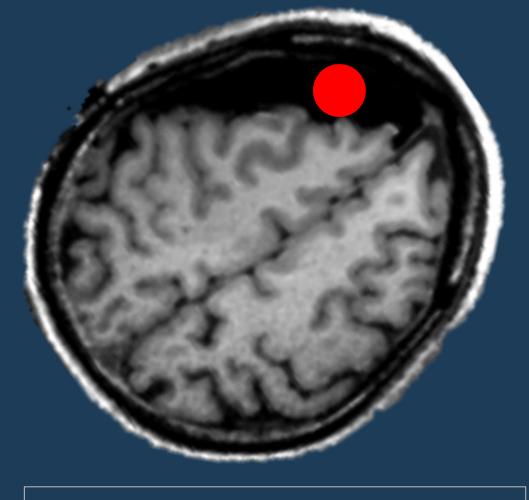


### Inaccurate Targeting

the neurosurgeon cannot really rely on the navigation system's guidance



Preoperative Position



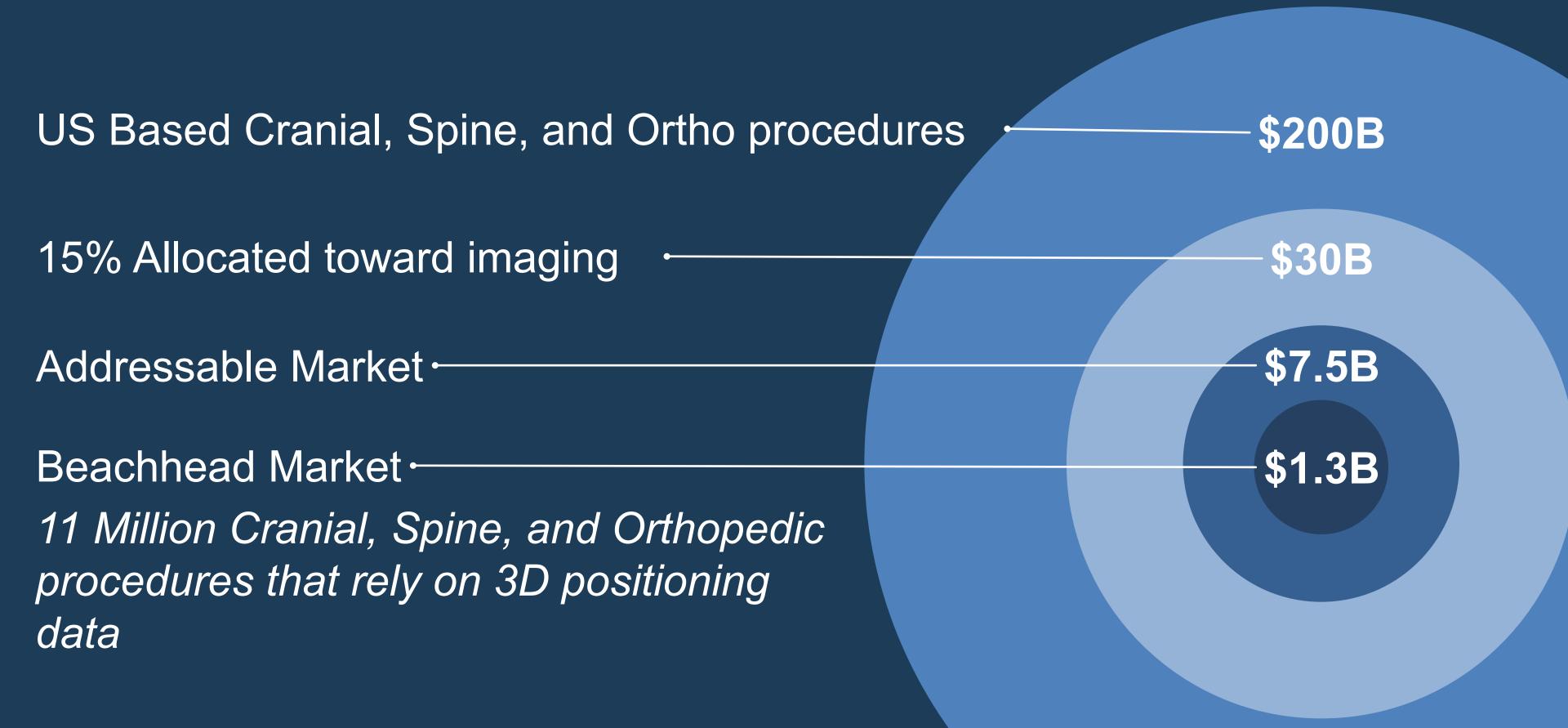
Intraoperative Position



### Unmet Clinical Need: Continuously Accurate Positioning Data

The failure to adequately track changes in the position of patient anatomy during surgery is leading to "patient deaths, life-threatening injuries, and failed, aborted, and prolonged medical procedures."

### US Market



## Current Methods of Updating Positioning Data Increase Risk and Cost



### **Tracking Arrays**

- Must be rigidly attached to the patient's bone
- Adds risk and recovery time
- Time consuming and costly



### Intraoperative CT Images

- Provides a static update
- Exposure to harmful radiation
- Disruptive and time consuming

# Introducing the OR*Vis* Optical Data Platform for Continuously Accurate Patient Positioning Data



"OR Vis" is an optical scanner (combination HW & SW device) built on Advanced Scanners' patented technology platform. It captures and digitizes the shape, position, and surface characteristics anatomy, sharing data with other digital surgical systems via common file formats. The scientific advantage is a patented hardware-based innovation that is uniquely sensitive to certain optical signals.

### ...without Tracking or Radiation Risks.

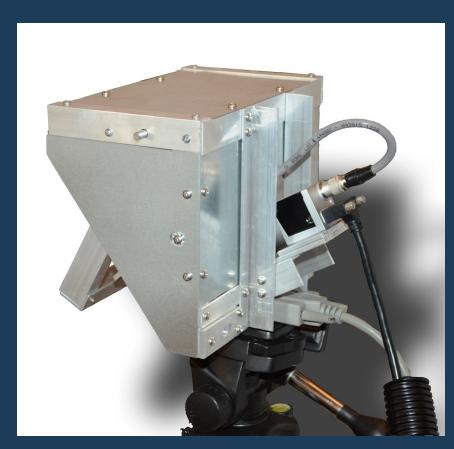
## Tracking Soft Tissue

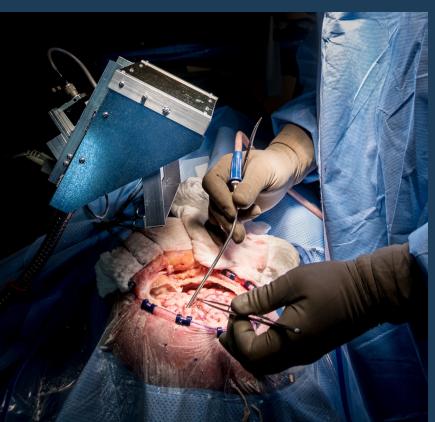
Alpha

Cadaver Study

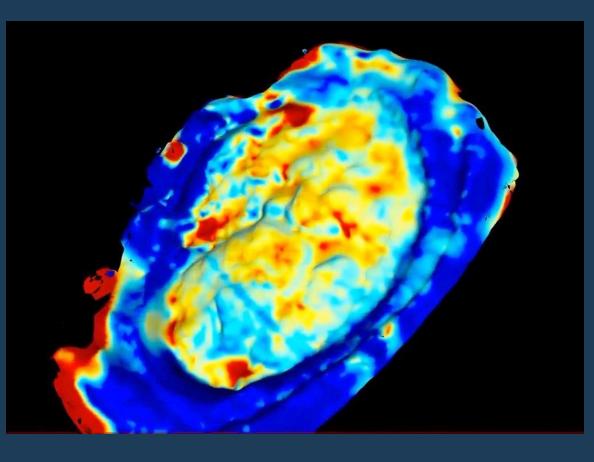
1<sup>st</sup> in human

Quantified Brain Shift









## Industry Traction — Cranial

Proven to be 50X faster & 100X more precise than the current technology, we are now working to develop customized hardware embodiments and software interfaces for and with leading medical device companies.

## Tracking Rigid Tissue

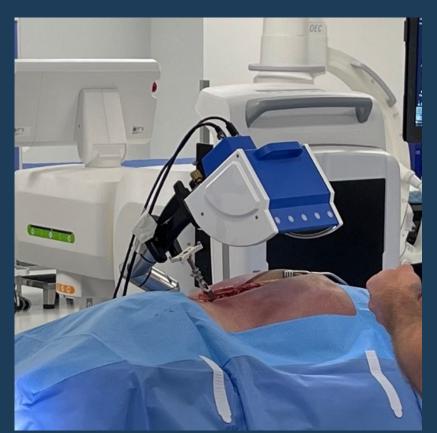
Beta

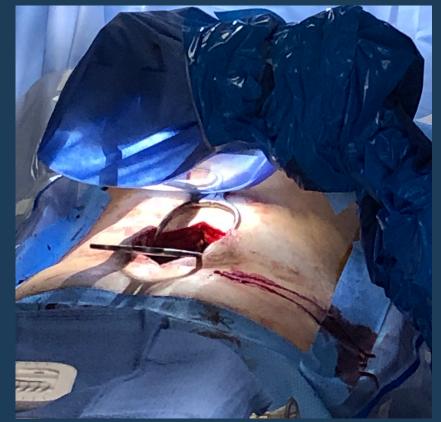
Cadaver Study

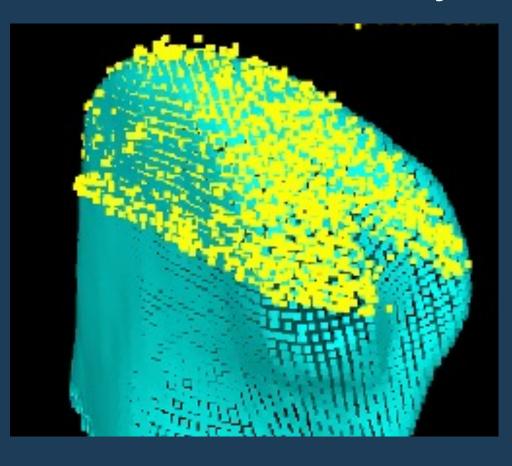
1<sup>st</sup> in human

Sub-MM w/out Arrays









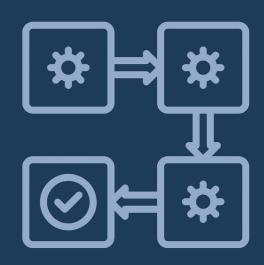
## Industry Traction - Spine

Demonstrations of array-less tracking of has led to the development of a paid statement of work to develop a custom integration with a digital surgery platform. We are in due diligence for an investment in the Series A round

### Why OR Vis is Better:

## ~50X Faster and More Automated than the leading technology

(Click to see an example scan here)



100X More Precise

(Click to see 45 second video)



## Touchless: No Trauma to the Patient

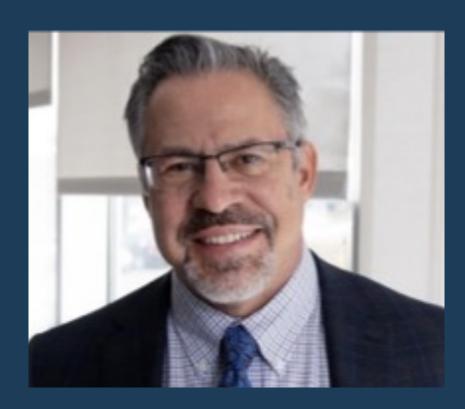


### Radiation Free



## What Surgeons say:

"This is the whole package; it will change the way we do brain surgery."



Mark Lee, MD, PhD, MBA Chief, Pediatric Neurosurgery, Children's Hospital of San Antonio "Spine surgeons in the last decade have realized the power of intraoperative navigation. However, the underlying technology driving this advance is antiquated, expensive and, at many times during the course of the procedure, unreliable. Advanced scanners 3D scanning technology has the ability to continuously re-register spinal landmarks during the surgery using a small mounted camera. It is will revolutionize the field by making intraop navigation more reliable, cost effective, and less time consuming for the surgeon. This technology has the potential to create an entirely new generation of navigation systems."



Hasan A. Zaidi, M.D.
Co-Director, Adult Deformity/Scoliosis Center
Assistant Professor of Neurosurgery
Harvard Medical School
Brigham & Women's Hospital
Dana Farber Cancer Institute

### Beachhead Market: \$1.3B+/ARR



### 1.3B Recurring Revenue:

Base Annual SW license (Base): \$6,000/yr.

Feature and specialty specific SW Modules: \$3K/ea.

Consumables:

Sterile Drape: \$60 per case

#### \$1B Hardware MKT

Scanner HW: One Time \$15,000

(An endoscopic version in development will double this)

Brain & ENT \$163M ARR \$140M HW MKT 9,375 Global Facilities

850K Annual Procedures

\$360M ARR \$450M HW MKT 30,000 Global Facilities TBD Annual Procedures

TMS

Ortho \$570M ARR \$337M HW MKT 22,500 Global Facilities

22,500 Global Facilities
5M of 17.5M
Annual Procedures

Spine \$200M ARR \$168M HW MKT

11,250 Global Facilities
1.1M of 5M Annual
Procedures

### Path Forward: Partnerships with Market Leaders

1 Customization

Three strategic companies are negotiating contracts with us to develop products for integration with their market leading technologies.



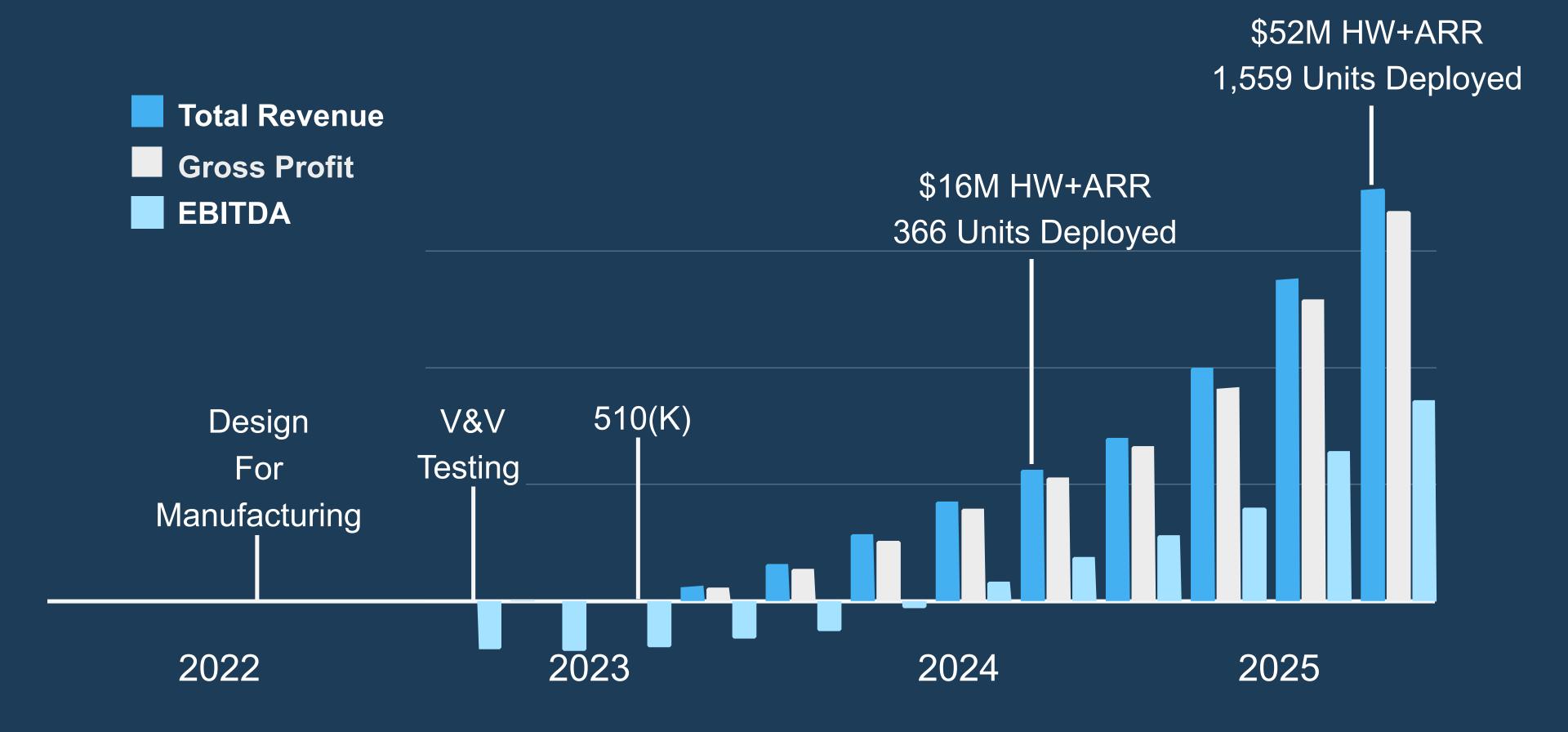
- **2** Contract Medical Device Manufacturer
  - ISO 13485 Certified
  - Quality Assurance
  - Client approved

- **3** FDA 510(k) Submission
- 4 Sales and deployment

We sell to strategic partners and support deployment into their existing international footprint



### Forecast for the ORVis Scanner





Founders



Jeff Levine, CEO Serial Entrepreneur with multiple exits in SaaS, Risk Management, Consumer and Industrial manufacturing, sales, distribution, and service.



Aaron Bernstein, CTO
PhD Optical Physics and Engineering
Inventor of company IP

Team



Sindhu Kolluru MBE & MBME Patrick Edv SW Development Hardware a Clinical and Regulatory compliance Developer



Patrick Edwards
Hardware and Electronics
Developer



Tony Wonsyld
Director of Software Engineering



Klaudius Scheufele, Ph.D. Computer Science
V.P. Algorithmic Development and Data Science



Advanceo

Andrew Fisher, Ph.D.

Medical Engineering

Optical Research Scientist

### Industry Veterans



Advisor: Commercialization
Joe Loy, CEO ZetaGen
SVP Sales Coalign/Stryker
Sr. Group Dir. Nuvasive
National Sales Mgr.
Pfizer/Leibiinger

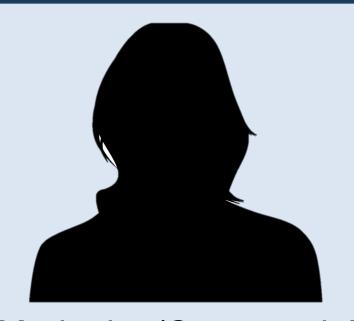






Consultant: Clinical Engineering Tim Schaewe, PhD Cranial & Spine Technologies Formerly: Principal Research Engineer, Medtronic





Future Marketing/Commercial Accounts Executive:
13 years of Medical Device exp.
Global Mktg and Commercialization
Lead for First in Human launch of robotics platform



### Raising: \$8M-\$12M Series A

To advance development and commercialization, achieving these milestones over the next 18 months:

- Commercial Product Development and Manufacturing (ISO 13485 Certified)
- Quality Assurance
- Complete commercial integrations
- 510(k) Clearance
- Prototype endoscope
- File additional IP
- Clinical Studies



### Planned Activities:

Customer Request	Estimated Duration	Estimated Revenue thru 2023
Specific HW embodiment and SW interface for integration and commercial deployment with a leading surgical navigation system.	12-18 Months	\$500k - \$1.5M
Specific HW embodiment and SW interface for integration and commercial deployment as part of a complete procedural solution for spine surgery.	15-18 Months	\$500k - \$1.5M
HW and SW interface for integration and commercial deployment as part of a transcranial magnetic stimulation device	9 -12 Months	\$200k - \$500k

<b>Major Expenses</b>	Estimated <b>Duration</b>	Est. Costs thru 2023	Status
Commercial Manufacturing	12-18 Months	\$1.5 - \$2M	We have engaged a top-tier ISO 13485 certified medical device manufacturer for manufacturing and quality assurance.
510(k) Regulatory submission	3 months, then 9- 12 months	\$500K	We are working with well-known regulatory consultants to prepare for a presubmission meeting, followed by a 510(k) application.
Prototype Endoscope	12 Months	\$1.5M	IP submitted, virtual simulations and some bench top work completed.
IP development	Ongoing	\$500K	We are preparing a $2^{nd}$ omnibus provisional for a new family of patents .
Clinical Pilots and Studies	Ongoing	\$200k	We have studies pending IRB approval in development at Brigham & Women's and Boston Children's hospitals.

### Executive Financial Summary

Assumes Series A Round Funds in Q4 2022

	2022	2023	2024	2025	2026	2027	2028
	<b>#500.000</b>	Φ0.475.000	ΦΕΩΕ ΩΩΩ	Φ0	Φ.	0.0	0.0
Revenue - NRE (\$)	\$529,000	\$2,175,000	\$525,000	\$0	\$0	\$0	\$0
Revenue - Cranial (\$)	\$0	\$0	\$835,800	\$11,416,500	\$29,177,820	\$49,907,970	\$77,749,403
Revenue - Spine (\$)	\$0	\$0	\$3,024,000	\$8,625,000	\$16,332,750	\$24,314,850	\$35,400,173
Revenue - Ortho (\$)	\$0	\$0	\$2,992,800	\$14,570,460	\$28,389,879	\$46,584,216	\$73,903,805
Revenue - Transcranial Stimulation (\$)	\$0	\$0	\$116,400	\$3,685,800	\$13,300,560	\$35,511,840	\$88,508,039
Revenue Total (\$)	\$529,000	\$2,175,000	\$7,494,000	\$38,297,760	\$87,201,009	\$156,318,876	\$275,561,419
COGS (\$)	\$0	\$0	\$1,170,601	\$6,652,814	\$15,378,912	\$28,638,111	\$52,169,210
Gross Profit (\$)	\$529,000	\$2,175,000	\$6,323,399	\$31,644,946	\$71,822,097	\$127,680,765	\$223,392,209
Sales & Marketing (\$)	\$171,508	\$858,043	\$2,876,969	\$5,251,929	\$8,807,509	\$13,653,997	\$21,895,656
Research & Development (\$)	\$1,557,148	\$6,486,097	\$6,065,249	\$8,145,480	\$13,512,998	\$18,170,926	\$24,359,068
G&A (\$)	\$492,927	\$1,634,824	\$2,477,299	\$3,853,158	\$6,841,792	\$10,533,859	\$13,455,439
OPEX Total	\$2,221,584	\$8,978,964	\$11,419,516	\$17,250,568	\$29,162,299	\$42,358,782	\$59,710,163
EBITDA (\$)	-\$1,692,584	-\$6,803,964	-\$5,096,117	\$14,394,378	\$42,659,798	\$85,321,983	\$163,682,046
Cash In Bank (\$)	\$6,971,670	\$196,440	-\$9,364,199	-\$8,123,817	\$9,443,947	\$52,256,475	\$140,163,878
* Headcount (#) *							
S&M Employee headcount (#)	3	6	17	29	50	82	130
R&D Employee headcount (#)	13	27	34	47	69	99	153
G&A Employee headcount (#)	1	5	8	13	21	34	55
Total Headcount (#)	17	38	59	89	140	215	338
Revenue per Employee (Annualized) (\$)	141,176	47,368	336,814	635,016	829,627	929,372	1,026,247
	·	·	·	·	·	·	
* Revenue Summary *							
NRE Revenue (\$)	\$529,000	\$2,175,000	\$525,000	\$0	\$0	\$0	\$0
One time Revenue (Hardware) (\$)	\$0	\$0	\$5,040,000	\$18,337,500	\$29,405,250	\$41,863,500	\$66,050,775
( / ( + /							
Recurring Revenue (Software & Consumables) (\$)	\$0	\$0	\$1,929,000	\$19,960,260	\$57,795,759	\$114,455,376	\$209,510,644
Total Revenue (\$)	\$529,000	\$2,175,000	\$7,494,000	\$38,297,760	\$87,201,009	\$156,318,876	\$275,561,419 ect to Presentation Dis

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# Horizon Market: MIS/Robotics OR*Vis* Endoscope

2<sup>nd</sup> Product

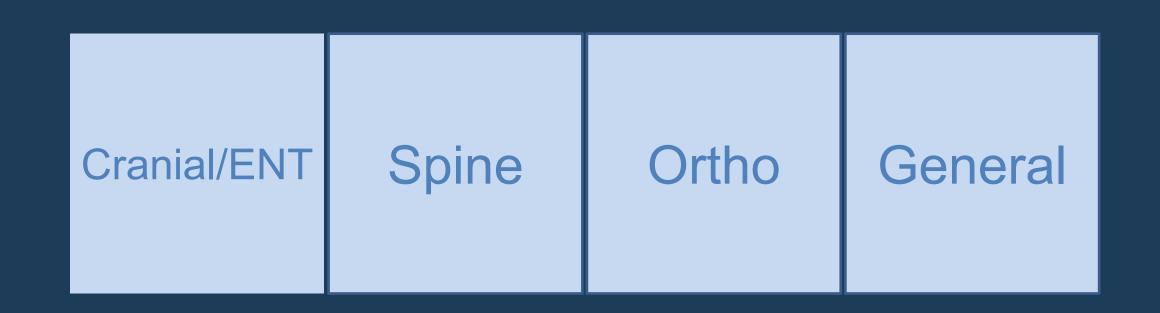


Miniaturizable technology allows us to bring our surface mapping capabilities inside the patient for minimally invasive procedures.

Unique Value Proposition

Tracking Anatomy:
Minimally Invasive Procedures

**Target Markets** 



### Horizon Market: Optical Characterization

Cadaveric and benchtop evidence indicates our current prototype is sensitive to optical signals that can be used to differentiate tissue, in vivo, without contact or dyes, or radiation.

Unique Value Proposition

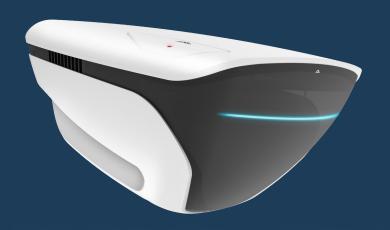
Optical Diagnostics/Tissue Characterization for Open and Minimally Invasive Procedures

\$5B ARR
Target
Market



### Other \$1B+ Horizon Markets

HW + Software



Unique Value Proposition

Optical Tracking and Diagnostics

Large opportunities in other markets

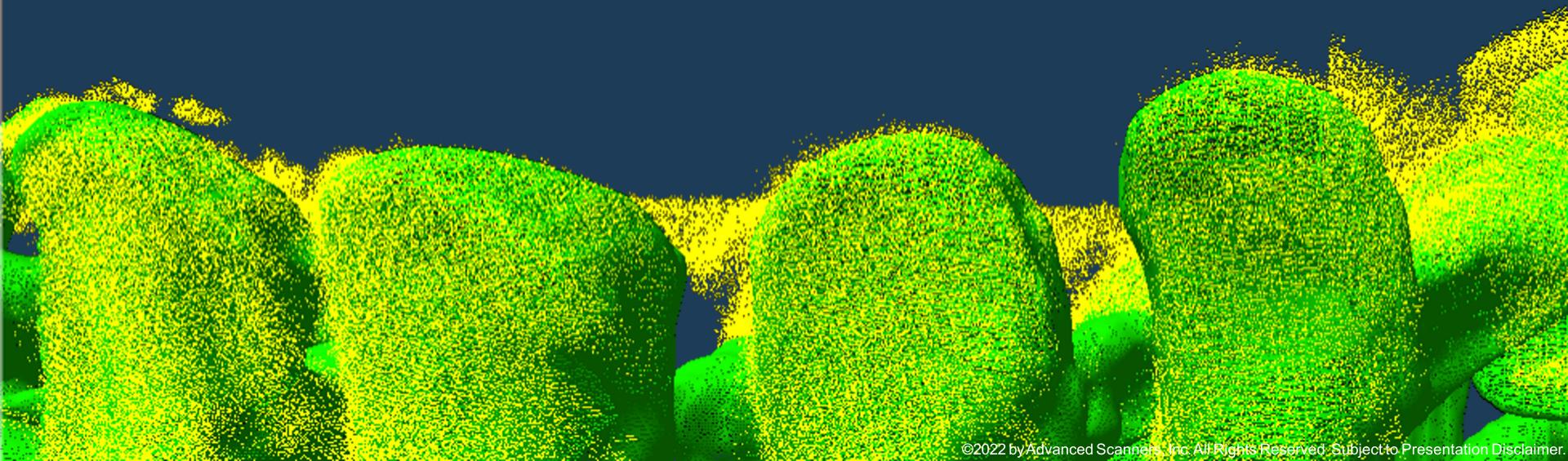
Drug Research

Robotics

Wound Monitoring Remote Medicine

### Want to learn more?

Contact:
Jeff Levine, CEO
512.750.6570
Jeff@AdvancedScanners.com
Austin, TX



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