Real-Time In-Vivo Measurement for Precision Cancer Surgery

Navigation Sciences™ is a clinical stage company developing the NaviSci™ Intelligent Surgical System for the tissue conserving removal of soft tissue tumors. The system integrates Augmented Reality (AR) and advanced software with surgical hardware to guide precise surgical resection by enabling for the first time, real-time in-vivo measurement. The system is designed to improve surgical outcomes and enhance surgical workflow.

The NaviSci System has completed a 25- patient clinical trial under an IDE for treating early-stage lung cancer that is designed to support a submission to the FDA for U.S. market clearance.

Opportunity to transform soft tissue cancer surgery

There are approximately 500,000 surgeries per year in the U.S. for soft tissue cancer, including lung, liver, head and neck, brain, thyroid, muscle, and breast. The NaviSci System has the potential in soft tissue to transform surgical treatment the way early-stage breast cancer surgery has evolved from mastectomy to lumpectomy – to the benefit of patients, physicians, providers, and payors.

Detection of small, potentially curable, early-stage lung tumors is increasing due to the emergence of low-dose CT scanning in high-risk lung cancer populations as the standard of care. By 2028, an estimated 60 percent of diagnosed lung nodules will be Stage 1.Prospective clinical trials, including a New England Journal of Medicine (NEJM) - published study have demonstrated long-term survival with sublobal (less than the entire lobe) surgeries are equivalent to lobal resection with better lung function. However, local recurrence rate with sublobal resections was higher, suggesting achievement of adequate surgical margins (distance between the nodule and resection line) is a challenge.

For these procedures, resection at the appropriate tumor margin - the fringe of normal tissue surrounding the tumor - is critical to preventing recurrence. However, determination of the appropriate margins during lung cancer surgery, and in other soft tissue procedures, presents a significant challenge to surgeons.

"With lung wedge resections and segmentectomies, margins become critical to reducing the risks of recurrence and thus improving patient survival."

Raphael Bueno, M.D. Co-founder and Chief of Thoracic Surgery, Brigham and Women's Hospital

COMPANY PROFILE

INDUSTRY: Surgical Precision Technology

FOUNDED: 2017 | $5.5M capital raised, Two $400K NCI SBIR/STTR program grants

BUSINESS MODEL: Minimally invasive surgical instruments and software

ADDRESSABLE MARKET: $980M | ~450K procedures

PATENTS: 8 U.S. and 4 foreign patents; others pending

HOSPITAL PARTNERSHIP: Mass General Brigham

MANAGEMENT AND DIRECTORS:

- **Alan Lucas**, CEO, Co-founder and Director
- **Raphael Bueno, M.D.**, Co-founder, Director, and SAB Chair | Chief of Thoracic Surgery, Brigham and Women's Hospital
- **Jayender Jagadeesan, Ph.D.**, Co-founder and SAB Member | Associate Professor of Radiology, Brigham and Women's Hospital
- **Gabriele Brambilla**, Director | CEO, Alira Health
- **T. Forcht Dagi, M.D., D.Med.Sc, D.H.C, F.R.C.S.Ed**, Director | Neurosurgeon|Investor | Entrepreneur | SAB Member
- **Steve Gullans, Ph.D.**, Director | Principal at Gullans Advisory, LLC | Venture Investor | Scientist | Entrepreneur | Author
- **Cynthia Ekberg Tsai,** Director | CEO Healthquest | CEO Tana Systems | Director, Certus Critical Care
- **Rick Williams**, Director | Managing Director of Williams Advisory Partners
- **David Fogel**, CPA, CFO

SCIENTIFIC ADVISORY BOARD:

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- **Bryan M. Burt, M.D.**, Professor and Chief of the Division of Thoracic Surgery, UCLA
- **David Feller-Kopman, M.D.**, Professor of Medicine, Geisel School of Medicine
- **Robert J. McKenna, M.D.**, Professor of Thoracic Surgery, Stanford University (ret.)
- **Brian Mitzman, M.D.**, Associate Professor in the Division of Cardiothoracic Surgery, University of Utah
- **Scott J. Swanson, M.D.**, Director, Minimally Invasive Thoracic Surgery, Brigham and Women's Hospital (ret.)
- **Jeffrey Velotta, M.D.**, Cardiothoracic Surgeon, Kaiser Permanente

BUSINESS ADVISORS:

- **Kurt Kruger**, Former analyst and investment banker
- **Christopher von Jacko, Ph.D.**, CEO, Polarian
- **Heather Hudnut Page**, Former executive, Philips and Medtronic
- **Robert Whalen**, Strategic Business Advisor

NaviSci System

The NaviSci system is designed to provide a 'GPS' for the surgeon to enable the physician to know precisely where the tumor and surrounding tissue are in relationship to the surgical instrumentation. The System is the first to provide real time in vivo measurement, enabling significantly enhanced precision in tissue resection and ensuring a sufficient margin of lung tissue surrounding the tumor.

Specifically, the system consists of:

- An active fiducial marker (called a J-Bar) that is placed next to the tumor to localize and track its position
- A surgical instrument with a second position sensor
- Proprietary software that links the sensors on the J-Bar with the cutting instruments and provides visual as well as quantitative information to provide real-time, in vivo measurement.

Development and Market Access

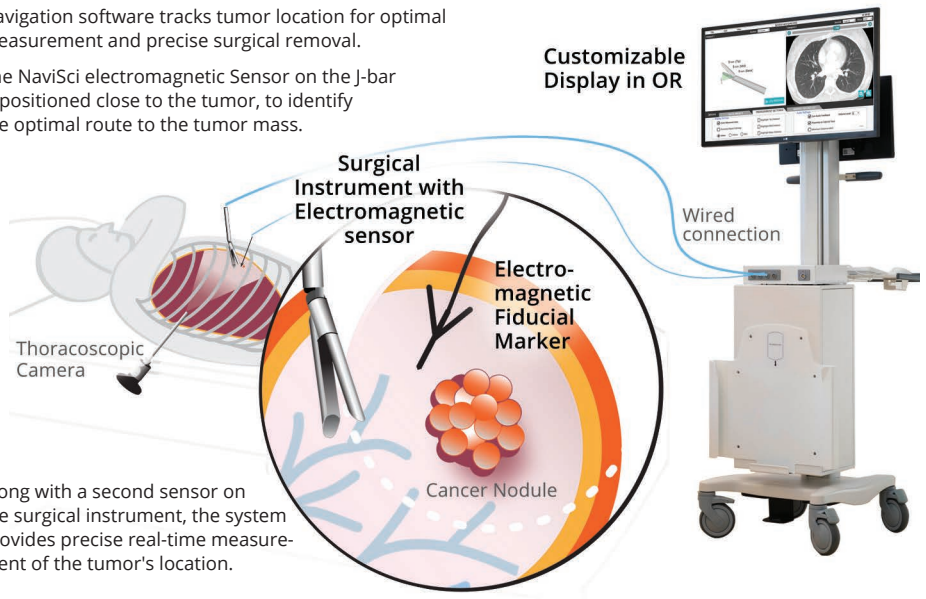
The company has completed a 25-patient clinical feasibility trial in the U.S. under an IDE with the NaviSci System. In the trial, conducted at Brigham & Women's Hospital, the System was useful in providing real time, in vivo measurement; was safe and effective; and its measurements strongly correlated with the pathology lab. The study was published in September 2025 in the peer-reviewed, American Society for Thoracic Surgery journal, *IVCVS Techniques*.

The study will support a submission to the U.S. FDA for market clearance. In Feb. 2022, CMS issued a national coverage determination, effectively expanding the population eligible for CT lung cancer screening to more than 14 million patients.

GPS Navigation For Precise in Vivo Measurement

Navigation software tracks tumor location for optimal measurement and precise surgical removal.

The NaviSci electromagnetic Sensor on the J-bar is positioned close to the tumor, to identify the optimal route to the tumor mass.



Along with a second sensor on the surgical instrument, the system provides precise real-time measurement of the tumor's location.

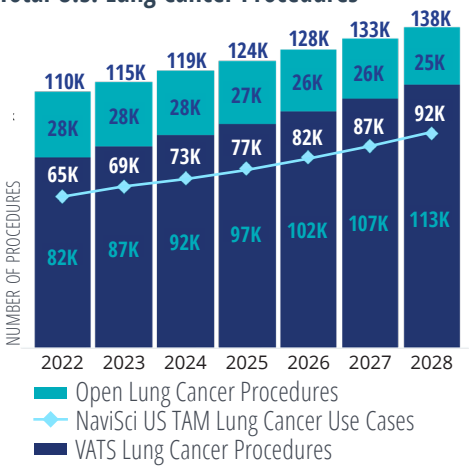
Markets

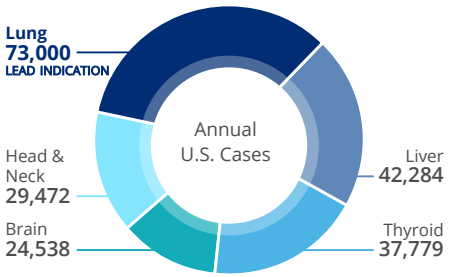
There are approximately 500,000 surgeries per year in the U.S. for soft tissue cancer, where Navigation's technology may provide benefit.

The potential use for the NaviSci System

The number of early-stage lung cancer diagnoses is expected to grow from 69K in 2023 to 92K in 2028. There are several other cancers, including liver, thyroid, and head and neck tumors , where there is a significant need for improving soft tissue surgery through minimally invasive, real-time GPS navigation to ensure appropriate margin.

Potential NaviSci Use Cases Relative to Total U.S. Lung Cancer Procedures





Potential U.S. market opportunity for the NaviSci technology is estimated at $1.26 billion including breast cancer, a longer term opportunity.

"We are providing a GPS locator for the surgeon to see beyond the tissue surface, to provide in real-time the location of the lesion and other relevant structures, determine the margin and identify precisely where to make the resection." *– Jayender Jagadeesan, Ph.D., Associate Professor of Radiology, Brigham and Women's Hospital.*

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navigationsci.com

CONTACT:
Alan Lucas +1-617-834-2829 | Navigation Sciences, Inc. | Brookline, MA
alan.lucas@navigationsci.com

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