



Real-Time Margin Measurement for Precision Cancer Surgery

Navigation Sciences™ is a clinical stage company developing the NaviSci™ System for the tissue conserving removal of lung cancer and other 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 margin measurement. The system is designed to improve surgical outcomes – reduce recurrence risk and conserve lung function – shorten hospital length of stay and enhance surgical workflow.

The NaviSci System is undergoing a 25-patient prospective clinical trial, initiated in Fall 2021, for treating early-stage lung cancer. The study is designed to support a Class II 510(k) submission to the FDA for U.S. market clearance.

Opportunity to transform lung and soft tissue cancer surgery

The NaviSci System, in its first application, lung cancer, has the potential 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. Early detection is also enabling use of surgical approaches, such as wedge resection and segmentectomy that remove less normal lung tissue and conserve lung function, rather than complete lobar resection.

For these procedures, the appropriate tumor margin 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

FINANCIAL PROJECTIONS TABLE 2021–2026 (\$'000'S OMITTED)

YEAR	2021	2022	2023	2024	2025	2026
REVENUE	\$ 38	\$286	\$2,456	\$13,190	\$28,793	\$51,666
EBITDA	(634)	(4,658)	(4,189)	110	11,851	29,441
FUNDING	\$1,800	\$5,200	\$8,200	\$ –	\$ –	\$ –

COMPANY PROFILE

INDUSTRY Surgical Technology

FOUNDED: 2017 | \$4.5M capital raised

BUSINESS MODEL

Minimally invasive surgical instruments and software

ADDRESSABLE MARKET

\$980M | ~500K procedures

PATENTS

U.S and foreign patents

HOSPITAL PARTNERSHIPS

Mass General Brigham

MANAGEMENT AND SCIENTIFIC ADVISORY BOARD (SAB)

- Alan Lucas, CEO, Co-founder and Director
- Raphael Bueno, M.D., Co-founder, Director, and SAB Chair | Chief, 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, Harvard Medical School
- Giacomo Basadonna M.D. Ph.D., Director and SAB Member | Professor of Surgery, UMass Medical School
- Steve Gullans, Ph.D., Director | Principal at Gullans Advisory, LLC | Experienced biotech executive | Venture investor | Scientist | Entrepreneur | Author
- David Fogel, CPA, CFO
- T. Forcht Dagi, M.D., D.Med.Sc, D.H.C., F.R.C.S.Ed, SAB Member | Neurosurgeon | Investor | Entrepreneur
- David Feller-Kopman, M.D., SAB Member | Chief, Pulmonary and Critical Care Medicine Dartmouth-Hitchcock Medical Center | Professor of Medicine Geisel School of Medicine
- Robert J. McKenna, M.D., SAB Member Professor of Surgery, Saint John's Cancer Institute | Director Minimally Invasive Chest Surgery and Thoracic Surgical Oncology | Professor of Thoracic Surgery, Stanford University

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 and recommend where to excise the tumor. The system is the first to measure surgical margin in real-time, enabling significantly enhanced precision in tissue resection.

Specifically, the system consists of:

- An active fiducial marker (called a J-Bar) is placed next to the tumor to localize and track its position as well as identify the shortest route of entry from the lung surface to the tumor nodule
- A surgical cutting 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 measure tumor margins in real-time

The real-time measurements permit resection with a sufficient margin of lung tissue surrounding the tumor.

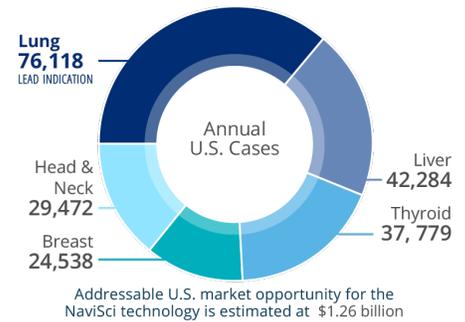
"We are providing a GPS locator for the surgeon to see beyond the tissue surface, to provide real-time the location of the lesion and other relevant structures, determine the margin and identify precisely where to make the resection."

Jayender Jagadeesan, Ph.D., Associate Professor of Radiology, Brigham and Women's Hospital.

Development and Market Access

In Fall 2021, the company began a clinical trial with NaviSci System under an Investigational Device Exemption (IDE) approved by the FDA in patients with early-stage lung cancer. The 25-patient trial, which is being conducted at Brigham & Women's hospital, is evaluating the system's safety, and ability to identify and remove tumors minimally invasively with appropriate margins. The trial will also test the system's economic value proposition of improved surgical workflow.

The study, if successful, will support a 510(k) submission to the U.S. FDA for market clearance. The company has also defined a U.S. reimbursement pathway for the system within existing CPT and DRG ICD-10 codes.



Markets

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

For the company's lead application, lung cancer, there are more than 228,000 U.S. patients diagnosed annually.

There are several other cancers, including liver, breast, 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 margins.

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GPS NAVIGATION FOR PRECISE MARGIN CONTROL

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

