



Real-Time Margin Measurement for Precision Cancer Surgery

Navigation Sciences™ is a clinical stage company developing the NaviSci™ Intelligent Surgical 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 completed a 25-patient prospective clinical trial for treating early-stage lung cancer. The study is designed to support a 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. By 2028, an estimated 60 percent of diagnosed lung nodules will be Stage 1. Recent clinical data published in the New England Journal of Medicine (NEJM, Feb. 9, 2023) support the use of tissue sparing surgical approaches in many early stage lung cancer patients.

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

COMPANY PROFILE

INDUSTRY: Surgical Technology

FOUNDED: 2017 | \$4.5M capital raised \$400K NCI SBIR/STTR program grant

BUSINESS MODEL: Minimally invasive surgical instruments and software

ADDRESSABLE MARKET: \$980M | ~500K procedures

PATENTS: 3 US and foreign patents pending

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 of Thoracic and Cardiac Surgery, Brigham and Women's Hospital
- Jayender Jagadeesan, Ph.D., Co-founder and SAB Member | Associate Professor of Radiology Brigham and Women's Hospital
- 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 | Venture Investor | Scientist | Entrepreneur | Author
- Cynthia Ekberg Tsai, Director | CEO Healthquest, CEO Tana Systems | Director, Certus Critical Care
- 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 MIS Thoracic Surgical Oncology | Professor of Thoracic Surgery, Stanford University

FINANCIAL PROJECTIONS TABLE 2022—2026 (\$000'S OMITTED)

YEAR	2022	2023	2024	2025	2026
REVENUE	\$305	\$61	\$ –	\$2,456	\$13,197
EBITDA	(1,180)	(787)	(6,360)	(3,963)	7,379
FUNDING	\$170	\$ –	\$ 11,000	\$ –	\$ –

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.

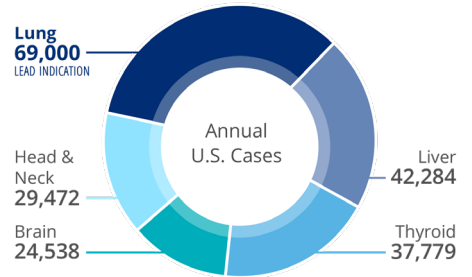
Development and Market Access

In the Spring of 2022, the company completed a 25-patient clinical feasibility trial with the NaviSci System. The trial, conducted at Brigham & Women’s hospital, confirmed that the NaviSci™ navigation system is useful in providing real-time margin assessment for surgical resection of lung nodules, that it is safe and effective, and the system’s distance measurements strongly correlate with the pathology lab. The study was presented at a poster session in early May 2023 at the American Association for Thoracic Surgery.

The study will support a 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. 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.

Markets

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

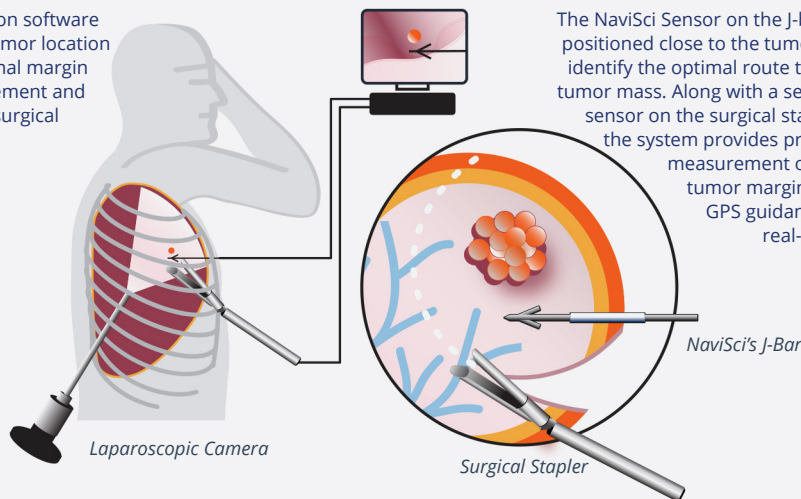


Addressable U.S. market opportunity for the NaviSci technology is estimated at \$1.26 billion including breast cancer, a longer term opportunity.

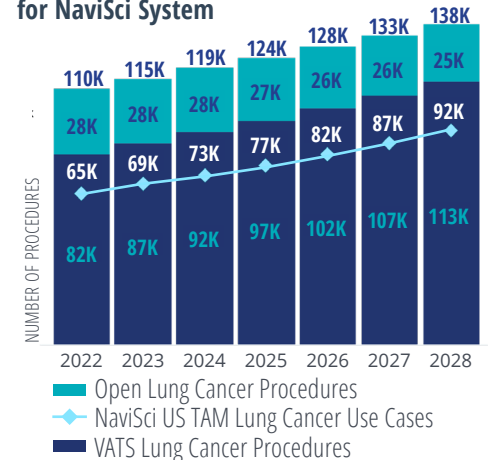
The addressable market for the NaviSci system in early stage lung cancer is expected to grow from 69K in 2023 to 92K in 2028. There are several other cancers, including liver, breast, thyroid, and head and neck tumors, where there is a significant need for improving soft tissue surgery through minimally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

GPS NAVIGATION FOR PRECISE MARGIN CONTROL

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



US Lung Cancer Surgical Procedure Breakdown with Addressable Uses for NaviSci System



CONTACT:

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

Copyright © 2023 Navigation Sciences, Inc. Navigation Sciences™, iVATS™, NaviSci™, NaviSci EndoMarker™, and J-Bar™ are Trademarks of Navigation Sciences, Inc. All rights reserved. U.S. and Foreign patents pending