



# 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 feasibility study, initiated in Spring 2021, for treating early-stage lung cancer. The feasibility 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 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 (\$'000'S OMITTED)

YEAR	2021	2022	2023	2024	2025
REVENUE	\$ –	\$ –	\$4,409	\$16,793	\$32,985
EBITDA	(1,823)	(4,617)	(2,275)	1,784	13,236

## COMPANY PROFILE

**INDUSTRY** Surgical Technology

**FOUNDED:** 2017 \$2.5M capital raised

### BUSINESS MODEL

Minimally invasive surgical instruments and software

### ADDRESSABLE MARKET

U.S. \$1.26B | ~450K procedures

**PATENTS** U.S and foreign patents pending

### HOSPITAL PARTNERSHIPS

Mass General Brigham

### MANAGEMENT AND SCIENTIFIC ADVISORY BOARD

- Alan Lucas, CEO, Co-founder and Director
- Raphael Bueno, M.D., Co-founder, Director, and Scientific Advisory Board (SAB) Chair | Chief of Thoracic Surgery, Brigham and Women's Hospital
- Giacomo Basadonna M.D. Ph.D., Director and SAB Member | Professor of Surgery, UMass Medical School
- Jayender Jagadeesan, Ph.D., Co-founder and SAB Member | Associate Professor of Radiology, Brigham and Women's Hospital
- David Fogel, CPA, CFO
- T. Forcht Dagi, M.D., D.Med.Sc, D.H.C., F.R.C.S.Ed, SAB Member | Professor, Queen's University Belfast | Senior Consultant, Mayo Clinic College of Medicine and Science | Senior Managing Partner, ROSC Global LLC
- David Feller-Kopman, M.D., FCCP, SAB Member | Chief, Pulmonary and Critical Care Medicine Dartmouth-Hitchcock Medical Center, Professor of Medicine Geisel School of Medicine

### CONTACT INFORMATION

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## 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.

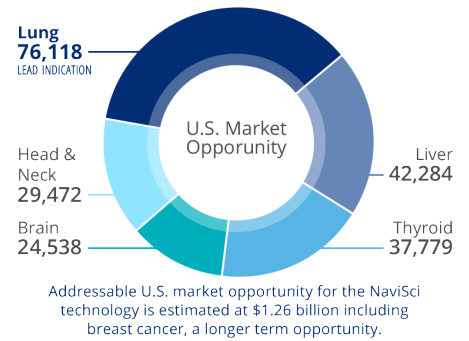
*"We are providing a GPS locator for the surgeon to see beyond the tissue surface, to provide real-time the location of the lesion and other relevant structures, determine the margin and identify precisely where to make the resection."*

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

## Development and Market Access

In Spring 2021, the company began a clinical feasibility study with NaviSci System under an Investigational Device Exemption (IDE) approved by the FDA in patients with early-stage lung cancer. The 25-patient feasibility 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.



There are approximately 450,000 surgeries per year in the U.S. for soft tissue cancer, where Navigation's technology may provide benefit. These tumors include lung, liver, thyroid, head and neck, brain and a longer-term opportunity in breast cancer.

For the company's lead application, early-stage lung cancer, there are more than 76,000 U.S. patients diagnosed annually. That number is growing due to expanded use of CT X-ray screening and favorable reimbursement and is expected to increase dramatically, following the recommendation by the U.S. Preventative Services Task Force that the annual population for screening be increased by 6.4 million to 14.5 million people.

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## GPS NAVIGATION FOR PRECISE MARGIN CONTROL

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

