Q3 | 2024 Newsletter

Dear Friend of Navigation Sciences,

I hope you had a pleasant summer and are off to a productive start to the fall. We have continued our software and product development activities and fundraising towards an FDA submission for the NaviSci™ System next year. Recently, the NaviSci System was selected as a candidate by The Galien Foundation for its annual 'Best Start Up' award, and we look forward to attending the Forum in early November.

At this point in the company's journey, I thought reflecting on the Navigation Sciences' origins, our progress, and the evolution of the lung cancer diagnostic and surgical landscape would be helpful. The changing dynamics in lung cancer treatment drive the opportunity for the NaviSci System and the company.

The Company's Origins

Navigation Sciences emerged from a collaboration between the company's scientific founders, Raphael Bueno, MD, Chief of Thoracic Surgery at Brigham and Women's Hospital, and Jayender Jagadeesan, PhD, Associate Professor of Radiology at the hospital. Dr. Bueno and his colleagues have been leaders in defining surgical margins and resections in lung cancer surgery. Dr. Jagadeesan is an expert in image-guided therapy, surgical navigation, and minimally invasive surgical devices. Early on, they understood more lung tumors were beginning to be diagnosed earlier, when they are small and treatable, with minimally invasive surgery.

"Margins have always been important in cancer surgery," says Dr. Bueno. "In lung cancer, now that we are removing smaller portions of the lung with wedge resections and segmentectomies, margins become critical to reducing the risks of local recurrence and thus improving patient survival."

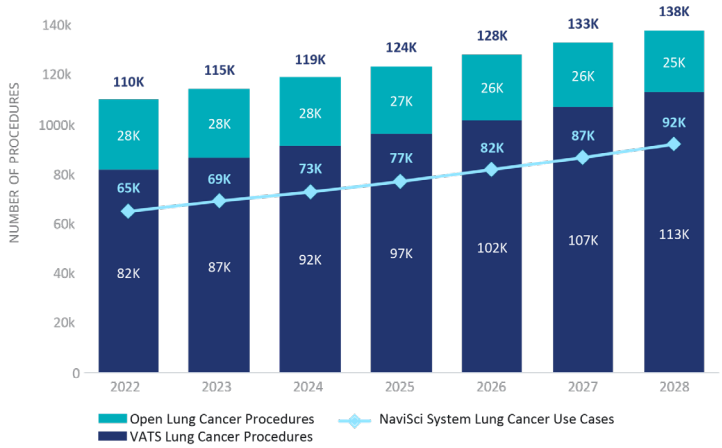
With non-dilutive funding at Brigham and Women's Hospital, they developed and tested a prototype system based on an image-guided video-assisted thoracic surgery (iVATS) approach in preclinical and then in a successful Phase I-II clinical trial.

Their work led to several patents, which provided the basis for the founding of Navigation Sciences. The company licensed the patents from Brigham & Women's Hospital and has since expanded its intellectual property portfolio. The company has four issued patents in the U.S. and key overseas markets, with additional patents pending.

The Changing Lung Cancer Surgery Landscape

When Drs. Bueno and Jagadeesan began their collaboration, Stage 1 and Stage 2 nodules accounted for less than 40 percent of lung cancer diagnoses. With increased screening, by 2028, Stage 1 nodules will account for 60 percent of diagnoses.

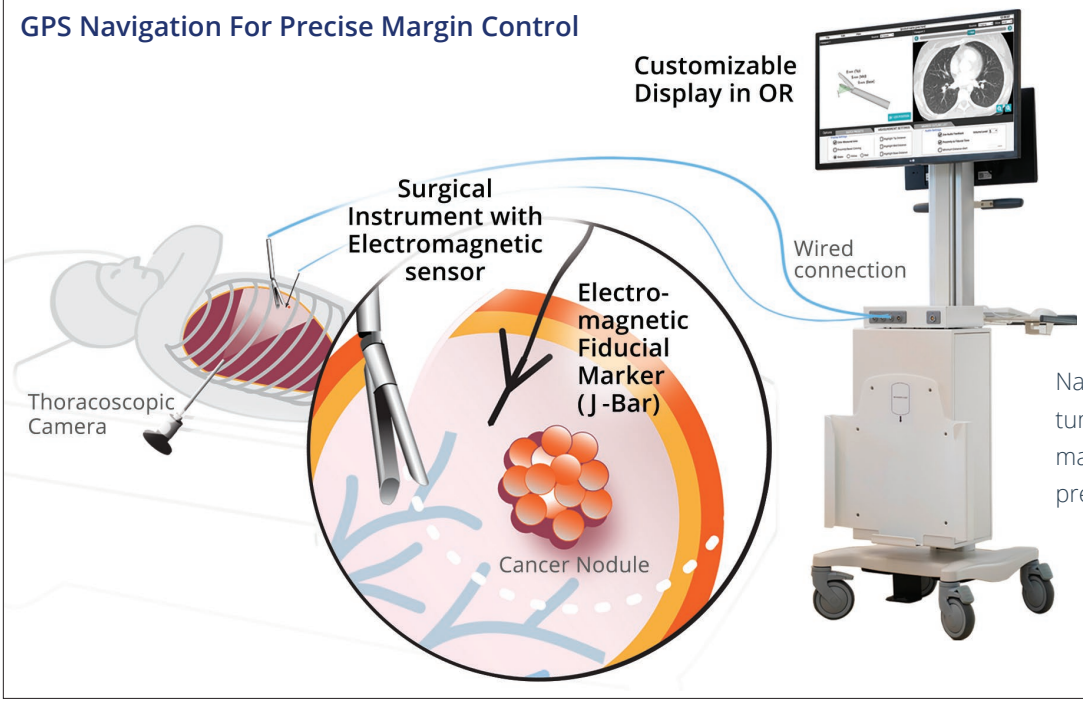
US Lung Cancer Surgical Procedure Breakdown with Addressable Uses for NaviSci System



"The anticipated growth is being driven by expanded use of CT-Xray screening and favorable CMS reimbursement," said Alan Lucas, Navigation's CEO. The number of individuals eligible for reimbursement for annual screening is now 14.2 million. "At the same time, tissue-sparing surgery for early-stage lung cancer patients is becoming the standard of care," he said, noting that two large prospective clinical trials have found long-term survival in patients who underwent tissue-sparing wedge resections or segmentectomies was comparable to patients who received full lobectomies.

The findings suggest that segmentectomy should be the standard surgical procedure for this population of patients. However, although survival in the two groups was comparable, the local recurrence rate was twice as high for segmentectomy (10.5%) compared to lobectomy (5.4%). The market driver of the NaviSci System is its ability to provide real-time intraoperative measurements to guide surgical resection with appropriate margins and reduce recurrence rates..

GPS Navigation For Precise Margin Control



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

NaviSci System's key innovation

The NaviSci System is the first to provide real-time intraoperative measurements during surgery. The System offers "a GPS locator for the surgeon to see beyond the tissue surface, determine the margin, and identify precisely where to make the resection," says Dr. Jagadeesan. "This technology addresses one of the central challenges of precision lung and other soft tissue surgeries."

Among the NaviSci System's key innovations is software for tracking soft tissue and creating a real-time 3D model of the tumor and surrounding tissue. This enables the physician to know precisely where the target tumor and surrounding tissue are in relation to the surgical instrumentation in real-time and to guide the surgeon in excising the nodule.

The critical components of the System, in addition to the software, include:

- An active, fiducial marker with an electromagnetic sensor (called a J-Bar) is placed next to the tumor to localize and track its position and,
- A surgical instrument with a second electromagnetic position sensor. The software links the sensors on the J-Bar with the instrument to provide visual and quantitative measurement information in real-time.

Navigation is also developing a bronchoscope-based tissue marker (NaviSci EndoMarker™), designed to be used before surgery and simplify workflow.

Progress and Milestones

The NaviSci System has undergone hardware development, preclinical testing, and a successful 25-patient clinical trial at Brigham & Women's Hospital. The trial results confirmed that the System is useful in providing real-time measurement for surgical resection of lung nodules, that it is safe and effective, and that the System's distance measurements correlate with the pathology lab. The company is working to complete development in preparation for an FDA submission in 2025.

To support the NaviSci System's development, the company has raised $5.5 million. In addition, the company was awarded a $400,000 National Cancer Institute (NCI) SBIR grant to support the development of the NaviSci EndoMarker.

I hope this provides a perspective on our excellent progress in developing the NaviSci System. When commercialized, it will fill an important, growing need in precision lung cancer surgery.

Please let me know if you want to participate in the Series B round.

As always, thank you for your support.

Sincerely,

Alan Lucas, CEO, Navigation Sciences, Inc.
Alan.lucas@navigationsci.com +1-617-834-2829

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