

## FDA Clears superDimension/Bronchus

First FDA-clears device for real-time navigation of bronchoscopic tools expected to be key to success in diagnosis and treatment of lung disease

Tel-Aviv, Israel, November 15, 2004 - superDimension, Ltd, an emerging leader in guided bronchoscopy, today announced that the U.S. Food and Drug Administration has cleared its superDimension/Bronchus™ for marketing and distribution in the United States. superDimension/Bronchus, the only FDA-cleared navigation system for guiding endoscopic instruments in the pulmonary tract, is expected to become a key tool in the minimally-invasive diagnosis and treatment of lung disease, including lung cancer, emphysema, asthma and tuberculosis. The potential market for superDimension/Bronchus exceeds 4,000,000 applicable procedures per year, with an annual growth rate of approximately 8%.

Currently bronchoscopy is performed rather blindly in the peripheral areas of the lungs, where most lesions are situated but where the bronchoscope itself cannot reach. Most bronchoscopies are therefore performed without endoscopic vision of the targeted area. Consequently, success rates in peripheral bronchoscopy are low and unreliable results are common, necessitating higher risk, costlier, more invasive procedures. Similar difficulties hinder access to lymph nodes, where proper biopsy is critical for the staging of lung cancer.

superDimension/Bronchus transforms traditional bronchoscopy into one that is guided in real time on a 3D CT roadmap of the entire lungs, including those areas that are beyond the bronchoscope's own reach. Yet the procedure is performed in a regular bronchoscopy suite and makes use of any standard bronchoscope and any standard diagnostic or therapeutic bronchoscopic tool from any vendor.

superDimension/Bronchus is based on over 100 man-years of research and development and is already covered by 10 granted US patents. Earlier this year, it was selected by MIT's Technology Review as one of the five most outstanding patents in the world for 2004 and the only healthcare one among those five.

"This FDA approval is the first in a series of products that we plan to introduce in coming years in the field of interventional pulmonology", said David Tolkowsky, President and CEO of superDimension. "Following our successful commercial launch in Europe earlier this year, we are now entering the world's largest single market."

"We are already encountering huge demand and are therefore expediting the establishment of our North American headquarters in Minneapolis", added John Schorgl, Vice President and General Manager of superDimension, Inc, superDimension's wholly-owned North American subsidiary. "

Successful clinical trials in the biopsy of peripheral lung lesions were conducted in Europe and Israel in 2003-4. Additional trials in the field of therapeutics and lymph node aspiration are planned for 2005 in the United States and Europe.

### About superDimension

superDimension is an emerging leader in the minimally-invasive diagnosis and treatment of lung disease via CT-guided bronchoscopy. The superDimension/Bronchus system answers one of the most critical needs in the field: the accurate, minimally-invasive access to lung locations that are far beyond the bronchoscope's own field of vision. The majority of lung procedures carried out today target these locations, which include peripheral lesions and lymph nodes.

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