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Surgalign Receives FDA Clearance for HOLO Portal™ System, the World's First AI-driven AR Guidance System for Spine Surgery and Reports Preliminary Fourth Quarter and Full Year 2021 Results

Clearance is for use in the lumbar portion of the \$5 billion instrumented fusion market*

DEERFIELD, Ill., Jan. 18, 2022 (GLOBE NEWSWIRE) -- Surgalign Holdings, Inc., (NASDAQ: SRGA) a global medical technology company focused on elevating the standard of care by driving the evolution of digital health, today announced that it has received U.S. Food & Drug Administration (FDA) 510(k) clearance for its HOLO Portal surgical guidance system for use within lumbar spine procedures. The HOLO Portal system is the world's first artificial intelligence (AI)-driven augmented reality (AR) guidance system for spine and the first clinical application of Surgalign's HOLO™ AI digital health platform.

"Receiving the initial clearance for the HOLO Portal system is a significant milestone and represents a critical step toward building the foundation of the digital surgery of the future. This system is designed to improve patient outcomes by delivering intelligent solutions to our customers, and we believe it is truly revolutionary," said Terry Rich, Surgalign's president and chief executive officer. "With clearance in hand for our guidance application, our near-term focus is getting the platform into the hands of surgeons as we work towards a market release. While the current capabilities of the HOLO Portal system have the potential to offer a quantum leap in the way surgical procedures are performed, we have a much larger vision for our HOLO AI digital health platform across a variety of healthcare specialties and throughout the care continuum."

The HOLO Portal system combines machine learning-based image guidance technology with AR, automated spine segmentation (i.e., anatomy recognition), and automated surgical planning utilizing proprietary AI software. Intraoperative images are autonomously processed by the AI system to create a patient-specific plan that is presented to the surgeon using the AR display.

"HOLO Portal is the first substantial innovation I've seen in the years of utilizing digital technology in my practice," said Dr. D. Greg Anderson, MD, PhD, and Professor in the Departments of Orthopaedic and Neurological Surgery at Thomas Jefferson University and Clinical Director of the Spine Section of the Orthopaedic Research Laboratory at the Rothman Institute. "The system's groundbreaking combination of AR and AI will better

inform surgical decisions for my patients and ultimately deliver more accurate and efficient care in the surgical environment. It is truly transformative.”

HOLO Portal is the result of six years of development and testing at Holo Surgical Inc., by virtual and augmented reality expert Prof. Cristian Luciano, PhD; spine surgeon Dr. Kris Siemionow, MD, PhD; and Prof. Paul Lewicki, PhD, a pioneer in AI and predictive analytics and founder of one of the leading and earliest companies in predictive data mining. Surgalign acquired Holo Surgical in October of 2020.

Professor Lewicki, “I recognize the power associated with HOLO technology, specifically the machine learning and AI algorithms and their ability to revolutionize healthcare. We spent years developing machine learning based neural networks to teach the computer anatomy and address specific surgical needs. The result is displayed in 3D directly in the surgeon’s field of vision using the AR display, allowing for an elegant flow of information between the system and the physician.”

“I believe our technology has the potential for improved patient outcomes and reduced operative time due to autonomous surgical planning and intraoperative guidance. The system displays the anatomy in 3D, which allows for less tissue damage during the surgical procedure, due to improved visualization,” added Dr. Siemionow. “When physicians use HOLO, they will realize that the system provides them with information they may currently be missing—surgeons will quickly see how they can leverage the technology in the operating room and beyond to deliver better care.”

Preliminary Fourth Quarter and Full Year 2021 Results

Preliminary global revenue for the quarter ended December 31, 2021, is expected to be within a range of \$21.5 - \$21.9 million.

Preliminary global revenue for the full year ended December 31, 2021, is expected to be within a range of \$90.2 - \$90.6 million.

As of December 31, 2021, preliminary cash and cash equivalents is expected not to be below \$51.0 million after taking into account the cash consideration paid for Inteneural Networks Inc. (“INN”).

About Surgalign Holdings, Inc.

Surgalign Holdings, Inc. is a global medical technology company committed to the promise of digital health to drive transformation across the surgical landscape. Uniquely aligned and resourced to advance the standard of care, the company is building technologies physicians and other health providers will look to for what is truly possible for their patients. Surgalign is focused on developing solutions that predictably deliver superior clinical and economic outcomes. Surgalign markets products throughout the United States and in more than 50 countries worldwide through an expanding network of top independent distributors. Surgalign is headquartered in Deerfield, IL, with commercial, innovation and design centers in San Diego, CA, Warsaw and Poznan, Poland, and Wurmlingen, Germany. Learn more at www.surgalign.com and connect on LinkedIn and Twitter.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management's current expectations, estimates and projections about our industry, our management's beliefs and certain assumptions made by our management. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," variations of such words and similar expressions are intended to identify such forward-looking statements. The forward-looking statements are not guarantees of future performance and are based on certain assumptions including general economic conditions, as well as those within the Company's industry, and numerous other factors and risks identified in the Company's most recent Form 10-K and other filings with the SEC. Our actual results may differ materially from the anticipated results reflected in these forward-looking statements. Important factors that could cause actual results to differ materially from the anticipated results reflected in these forward-looking statements include risks and uncertainties relating to the following: (i) risks relating to existing or potential litigation or regulatory action arising from the previously announced SEC and internal investigations and their findings; (ii) the identification of control deficiencies, including material weaknesses in internal control over financial reporting and the impact of the same; (iii) potential reputational damage that the Company has or may suffer as a result of the findings of the SEC and internal investigations and related litigation; (iv) general worldwide economic conditions and related uncertainties; (v) the continued impact of the COVID-19 novel coronavirus pandemic and the Company's attempts at mitigation, particularly in international markets served by the Company; (vi) the failure by the Company to identify, develop and successfully implement its strategic initiatives, particularly with respect to its digital surgery strategy; (vii) the reliability of our supply chain; (viii) our ability to meet obligations, including purchase minimums, under our vendor and other agreements; (ix) the duration of decreased demand for our products; (x) whether or when the demand for procedures involving our products will increase; (xi) the Company's access to adequate operating cash flow, trade credit, borrowed funds and equity capital to fund its operations and pay its obligations as they become due, and the terms on which external financing may be available, including the impact of adverse trends or disruption in the global credit and equity markets; (xii) our financial position and results, total revenue, product revenue, gross margin, and operations; (xiii) failure to realize, or unexpected costs in seeking to realize, the expected benefits of the Holo Surgical, Inc. ("Holosurgical") and Inteneural Networks ("INN") acquisitions, including the failure of Holosurgical's and INN's products and services to be satisfactorily developed or achieve applicable regulatory approvals or as a result of the failure to commercialize and distribute their products; (xiv) the failure to effectively integrate Holosurgical's and INN's operations with those of the Company, including: retention of key personnel; the effect on relationships with customers, suppliers, and other third parties; and the diversion of management time and attention to the integration; (xv) the number of shares and amount of cash that will be required in connection with any post-closing milestone payments, including as a result of changes in the trading price of the Company's common stock and their effect on the amount of cash needed by the Company to fund any post-closing milestone payments in connection with the acquisitions; (xvi) the effect of the resignation of our auditor in early 2021 and our ability to successfully transition to our new auditor; (xvii) the continuation of recent quality issues with respect to our global supply chain; (xviii) the effects of resignations from our Board of Directors and executive leadership team in 2021, including our ability to find qualified candidates to fill those vacancies; (xix) the effect and timing of changes in laws or in governmental regulations; and (xx) other risks described in our public filings with the SEC. These factors should be considered carefully, and undue reliance should not be placed on the forward-

looking statements. Each forward-looking statement in this communication speaks only as of the date of the particular statement. Copies of the Company's SEC filings may be obtained by contacting the Company or the SEC or by visiting Surgalign's website at www.surgalign.com or the SEC's website at www.sec.gov. We undertake no obligation to update these forward-looking statements except as may be required by law.

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*Source: SmartTRAK Business Intelligence.



Source: Surgalign Holdings, Inc.