



LENSAR Announces Certification for the ALLY[®] Adaptive Cataract Treatment System in the European Union

First EU ALLY Commercial Installation Planned for August 2024

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ORLANDO, Fla.--(BUSINESS WIRE)--LENSAR, Inc. (Nasdaq: LNSR) ("LENSAR" or "the Company"), a global medical technology company focused on advanced laser solutions for the treatment of cataracts, today announced that the ALLY Adaptive Cataract Treatment System ("ALLY" or "ALLY System") has received certification under the European Union's ("EU") Medical Device Regulation ("MDR").

"We are thrilled to receive EU MDR certification for ALLY, which marks a significant milestone for LENSAR. We believe ALLY's commercial availability in the EU creates a significant growth opportunity for us, through the ability to provide new capabilities and advanced next-generation laser technology to European surgeons," said Nick Curtis, President and CEO of LENSAR. "European cataract surgeons now have access to a technology that has demonstrated to not only enhance the precision, efficiency and patient satisfaction associated with the procedure, but also to significantly improve practice workflow and economics."

Receiving MDR certification enables LENSAR to begin providing EU surgeons a transformative technology solution for cataract procedures. ALLY is the first platform to enable surgeons to perform a laser cataract procedure seamlessly in a single, sterile environment. Due to its highly ergonomic design, enhanced speed and features, ALLY increases both patient and practice efficiencies. The Company is commercializing ALLY through its distributor network in the EU and expects to place the first ALLY Systems with European surgeons in the third quarter of 2024.

The ALLY System is designed to address the performance limitations of aging, first-generation technologies while simultaneously enabling physicians to maximize efficiency in the operating room, as supported by recently published time and motion studies. These studies have shown significant procedure time savings resulting in increased revenue opportunities for both surgeons and ambulatory surgery centers, as well as less throughput time for patients, beginning with the time they enter the facility until they leave post-procedure.

ALLY's small footprint and enhanced ergonomics provide surgeons a unique opportunity to improve efficiencies in any operating room or in-office surgical suite. ALLY is the first and only cataract laser to use artificial intelligence in the iris registration and surface identification of astigmatism management, as well as to automatically determine cataract density, optimize fragmentation patterns and energy settings, with the goal of minimizing the overall energy delivered to complete the cataract procedure more efficiently and help contribute to quicker visual recovery and better patient outcomes. These proprietary features provide new opportunities for surgeons in laser cataract surgery procedures.

About LENSAR

LENSAR is a commercial-stage medical device company focused on designing, developing, and marketing advanced systems for the treatment of cataracts and the management of astigmatism as an integral aspect of the cataract procedure. LENSAR has developed its ALLY® Adaptive Cataract Treatment System as a compact, highly ergonomic system utilizing an extremely fast dual-pulse laser and integrating AI into proprietary imaging and software. ALLY is designed to transform premium cataract surgery by utilizing LENSAR's advanced technologies with the ability to perform the entire procedure in a sterile operating room or in-office surgical suite, delivering operational efficiencies and reducing overhead. ALLY includes LENSAR's proprietary Streamline® software technology, which is designed to guide surgeons to achieve better outcomes.

Forward-looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the Company's business strategies, expected growth, commercialization of the ALLY® Adaptive Cataract Treatment System in the EU, and the ALLY System's performance and market adoptions and usage. In some cases, you can identify forward-looking statements by terms such as “aim,” “anticipate,” “approach,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “goal,” “intend,” “look,” “may,” “mission,” “plan,” “possible,” “potential,” “predict,” “project,” “pursue,” “should,” “target,” “will,” “would,” or the negative thereof and similar words and expressions.

Forward-looking statements are based on management's current expectations, beliefs and assumptions and on information currently available to us. Such statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to, the important factors that are disclosed under the heading “Risk Factors” contained in the Company's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024 filed with the Securities and Exchange Commission (“SEC”), as such factors may be updated from time to time in the Company's other filings with the SEC. All forward-looking statements are expressly qualified in their entirety by such factors. Except as required by law, the Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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