

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 08, 2022

LENSAR, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39473
(Commission File Number)

32-0125724
(IRS Employer
Identification No.)

2800 Discovery Drive
Orlando, Florida
(Address of Principal Executive Offices)

32826
(Zip Code)

Registrant's Telephone Number, Including Area Code: 888 536-7271

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.01 per share	LNSR	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On September 8, 2022, LENSAR, Inc. (the “Company”) issued a press release announcing its application for certification of the ALLY™ Adaptive Cataract Treatment System (“ALLY” or the “ALLY System”) in the European Union. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated into this Item 7.01 by reference.

The information contained in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 8.01 Other Events.

On September 8, 2022, the Company announced its application for certification of ALLY in the European Union. The CE Mark, if affixed following successful completion of the certification process, allows for commercialization of ALLY in the European Union. The application for certification in the European Union follows U.S. FDA clearance of ALLY in June 2022. If ALLY is certified and CE marked, the Company plans to make the system commercially available to European surgeons through a distributor network, similar to the approach taken for its first-generation LENSAR Laser System.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding management’s future expectations, beliefs, intentions, goals, strategies, plans or prospects are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the potential regulatory approval and commercialization of ALLY in jurisdictions outside the U.S. Forward-looking statements may be identified by words such as “anticipates,” “believe,” “continue,” “expect,” “intend,” “may,” “plan to,” “potential,” “projects,” “will,” and other similar words or expressions, or the negative of these words or similar words or expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors, including, without limitation, the risks referred to under the section “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2022, as such factors may be updated from time to time in the Company’s other filings with the SEC, which filings are accessible on the SEC’s website at www.sec.gov and the Investors & Media page of the Company’s website at <https://ir.lensar.com>. All forward-looking statements speak only as of the date of this Current Report on Form 8-K and, except as required by applicable law, the Company has no obligation to update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of LENSAR, Inc., dated September 8, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

LENSAR, Inc.

Date: September 8, 2022

By: /s/ Nicholas T. Curtis
Name: Nicholas T. Curtis
Title: Chief Executive Officer



LENSAR Announces Application for Certification of the ALLY™ Adaptive Cataract Treatment System in the EU

ORLANDO, Fla. (September 8, 2022) – LENSAR, Inc. (Nasdaq: LNSR) (“LENSAR” or “the Company”), a global medical technology company focused on advanced femtosecond laser surgical solutions for the treatment of cataracts, today announced the application for certification of the ALLY™ Adaptive Cataract Treatment System (“ALLY” or the “ALLY System”) in the European Union.

“Following the FDA clearance of ALLY in June 2022 and recent U.S. commercial launch, this is another important step in our effort to bring ALLY to cataract surgeons in key global markets. Our mission has always been to create a platform that optimizes the way premium cataract surgeries are performed, and we believe that ALLY addresses all limitations of current competitive technologies.” said Nick Curtis, Chief Executive Officer of LENSAR. “Following successful completion of the certification process, we are prepared to launch ALLY in the EU. This application marks yet another major milestone met for LENSAR in 2022.”

ALLY enables surgeons to complete a femtosecond-laser-assisted cataract surgery (“FLACS”) procedure seamlessly in a single, sterile environment and provide Adaptive Intelligence™ to automatically determine cataract density, optimize fragmentation patterns, and energy settings. The CE Mark, if affixed following successful completion of the certification process, allows for commercialization of ALLY in the European Union. The application for certification in the European Union follows U.S. FDA clearance of ALLY in June 2022. If ALLY is certified and CE marked, LENSAR plans to make the system commercially available to European surgeons through a distributor network, similar to the approach taken for its first-generation LENSAR Laser System.

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 visually significant astigmatism as an integral aspect of the cataract procedure. LENSAR has developed its next-generation ALLY™ Adaptive Cataract Treatment System, its first platform to integrate its proprietary imaging with an optimized femtosecond laser in a compact system. ALLY is designed to transform cataract surgery by utilizing LENSAR’s advanced technologies with the ability to perform the entire procedure in an operating room or in-office surgical suite, delivering operational efficiencies and reduced overhead. ALLY includes LENSAR’s proprietary Streamline® software technology, designed to guide surgeons to achieve better outcomes.



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CATARACT LASER WITH AUGMENTED REALITY

Forward-looking Statements

This press release contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 potential EU regulatory approval and the commercialization of the ALLY™ Adaptive Cataract Treatment System, including in jurisdictions outside the United States. In some cases, you can identify forward-looking statements by terms such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “may,” “mission,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or the negative thereof and similar words and expressions.

Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from those, express or implied, in these forward-looking statements. Important factors that could impair the value of the Company’s assets and business include, without limitation, its history of operating losses and ability to generate revenue; its ability to maintain, grow market acceptance of and enhance its LENSAR Laser System and to develop, receive regulatory clearance or certification of and successfully commercialize the ALLY System; the impact of the COVID-19 pandemic and the Company’s ability to grow revenues; the Company’s ability to obtain any additional necessary clearances or approvals for the ALLY System; the willingness of patients to pay the price difference for LENSAR products; its ability to grow a U.S. sales and marketing organization; its ability to meet its future capital needs; the impact of any material disruption to the supply or manufacture of ALLY Systems and its recurring revenue products; the ability of the Company to compete against competitors that have longer operating histories and more established products than the Company; the Company’s ability to address numerous international business risks; and the other 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 June 30, 2022, filed with the Securities and Exchange Commission (“SEC”), as such factors may be updated from time to time in its other filings with the SEC, each accessible on the SEC’s website at www.sec.gov and the Investor Relations section of the Company’s website at <https://ir.lensar.com>. 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 LENSAR’s views as of any date subsequent to the date of this press release.



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