

**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): June 27, 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 Number)

**2800 Discovery Drive,  
Orlando, Florida 32826**

(Address of principal executive offices)

Registrant's telephone number, including area code:  
**(888) 536-7271**

**Not Applicable**

(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 registrants under any of the following provisions (*see* General Instruction A.2. below):

- 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 8.01 Other Events

LENSAR® Inc. (“LENSAR” or the “Company”) is holding its commercial launch meeting the week of June 27, 2022 for its ALLY™ Adaptive Cataract Treatment System (“ALLY” or “ALLY System”), after receiving U.S. Food and Drug Administration (“FDA”) clearance in June 2022, as previously announced. This meeting is a precursor to commercialization of the ALLY System to cataract surgeons in the United States. The meeting is being attended by the Sales, Marketing, Clinical Applications, Customer Service, Field Service and Technical Support teams. The objective is to inform and collectively prepare these teams for ALLY’s commercial introduction.

The Company expects to place between 8 and 12 systems in a controlled and targeted initial launch, with the first ALLY Systems being placed in the third quarter and continuing throughout the remainder of 2022. ALLY is expected to be made widely available to U.S. cataract surgeons in 2023. The Company’s ability to place systems in 2022 has been limited by supply chain constraints that have delayed the delivery of certain ALLY raw materials and the completion and testing of ALLY Systems for use as launch-stock inventory.

The Company will deliver the ALLY System to U.S. surgeons with the phacoemulsification features disabled. As previously announced, LENSAR received FDA clearance for the femtosecond laser functionality within the ALLY System and plans to seek additional 510(k) clearance for the phacoemulsification features in a subsequent 510(k) filing subject to a third party’s phacoemulsification device receiving clearance and serving as the predicate device. LENSAR was recently informed by the third-party manufacturer of the phacoemulsification technology that it has withdrawn its 510(k) submission for its standalone device and plans to resubmit the application at a later date. As this device will be considered the predicate device for purposes of evaluating ALLY’s phacoemulsification functionality, LENSAR is unable to submit its second 510(k) submission seeking clearance of the phacoemulsification features within ALLY until the predicate device receives FDA clearance.

The shift in the second 510(k) submission timeline will have no effect on the plans for the upcoming U.S. launch of ALLY as the launch was previously planned with the phacoemulsification features disabled. The Company has prioritized filing a CE Mark application in 2022 to commercialize the ALLY System in the European Union.

## 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 Company’s development and commercialization of the ALLY Adaptive Cataract Treatment System (“ALLY”) and the potential clearance of future 510(k) filings related to ALLY. 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 March 31, 2022, as such factors may be updated from time to time in the Company’s other filings with the Securities and Exchange Commission (“SEC”), which filings are accessible on the SEC’s website at [www.sec.gov](http://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.

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**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 hereunto duly authorized.

LENSAR, INC.

Date: June 30, 2022

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