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 9, 2022

LENSAR, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39473**	**32-0125724**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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 7.01 Regulation FD Disclosure

On June 13, 2022, LENSAR, Inc. (the "Company") issued a press release announcing that the Company received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for the Company's next-generation ALLY Adaptive Cataract Treatment System ("ALLY" or "ALLY System") as discussed in Item 8.01 of this Current Report on Form 8-K. 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 June 9, 2022, the Company received FDA 510(k) clearance for its ALLY System. ALLY is the first FDA-cleared platform to enable cataract surgeons to complete the femtosecond-laser-assisted cataract surgery procedure seamlessly in a single, sterile environment.

The Company plans to deliver the first ALLY Systems to surgeons in the third quarter of this year through a controlled and targeted initial launch. Following this launch, the Company plans to make ALLY widely available to cataract surgeons in 2023.

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 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

Exhibit No.	Description
99.1	Press Release of LENSAR, Inc., dated June 13, 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 hereunto duly authorized.

LENSAR, INC.

Date: June 13, 2022

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

2800 DISCOVERY DRIVE
ORLANDO, FL 32826

LENSAR® Receives U.S. FDA Clearance of ALLY™ Adaptive Cataract Treatment System

June 13, 2022, ORLANDO, Fla. 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 U.S. Food and Drug Administration ("FDA") 510(k) clearance for its next-generation ALLY Adaptive Cataract Treatment System ("ALLY" or "ALLY System"). ALLY is the first FDA-cleared platform to enable cataract surgeons to complete the femtosecond-laser-assisted cataract surgery ("FLACS") procedure seamlessly in a single, sterile environment. The Company plans to deliver the first ALLY Systems to surgeons in the third quarter of this year through a controlled and targeted initial launch. Following this launch, the Company plans to make ALLY widely available to cataract surgeons in 2023.

"We are elated to bring this proprietary technology to cataract surgeons. Our mission has been to develop a platform where surgeons can seamlessly perform the entire FLACS procedure in a single setting, improve workflow efficiencies, and most importantly, help surgeons deliver better outcomes through the advanced technologies in the ALLY System. We are seeing an overwhelmingly positive response to the ALLY system. Over 125 surgeons have experienced ALLY firsthand, during demonstrations performed at the American Society of Cataract and Refractive Surgery Annual Meeting in April, and more recently at our home office," said Nick Curtis, Chief Executive Officer of LENSAR.

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 cataract surgery platform to provide Adaptive Intelligence to automatically determine cataract density, optimize fragmentation patterns, and energy settings, with the goal of minimizing overall energy delivered to complete the cataract procedure more efficiently and help contribute to quicker visual recovery, and better patient outcomes. These proprietary features, combined with advanced astigmatism management technology, have the potential to establish new standards for femtosecond laser cataract surgery procedures. The ability to automate surgeons' treatment plan, while improving time and workflow is a benefit to surgeons, patients, and operating room staff.

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.

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 Company's development and commercialization of the ALLY™ Adaptive Cataract Treatment System and the potential clearance of future 510(k) filings related to ALLY. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "expect," "should," "plan," "intend," "estimate," "target," "mission," "may," "will," "would," "should," "could," "target," "potential," "project," "predict," "contemplate," "potential," 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; 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 Adaptive Cataract Treatment 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 the LENSAR Laser Systems; 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 March 31, 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.

Contacts:
Thomas R. Staab, II, CFO
ir.contact@lensar.com

Lee Roth / Cameron Radinovic
Burns McClellan for LENSAR
lroth@burnsmc.com / cradinovic@burnsmc.com

Media:
Lauren Gyoerkoe, VP Marketing
lauren.gyoerkoe@lensar.com