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): May 20, 2021

OMEROS CORPORATION
(Exact name of Registrant as Specified in Its Charter)

Washington	**001-34475**	**91-1663741**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
201 Elliott Avenue West Seattle, WA		**98119**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (206) 676-5000

(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 (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, $0.01 par value per share	OMER	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 under the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 under the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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.

On May 20, 2021, Omeros Corporation (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has extended the review period for the biologics license application ("BLA") for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy ("HSCT-TMA"). In a notice received from the FDA on May 19, 2021, the Company was informed that the new Prescription Drug User Fee Act ("PDUFA") target action date for its Priority Review of narsoplimab is October 17, 2021.

As part of the ongoing BLA Priority Review, the Company recently submitted a response to an FDA information request. FDA has classified the response as a major amendment, which requires additional time to review.

The Company's press release, dated May 20, 2021, announcing the extension in the PDUFA target action date is filed with this Form 8-K as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press Release dated May 20, 2021.
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.

OMEROS CORPORATION

Date: May 20, 2021

By: /s/ Gregory A. Demopulos
Gregory A. Demopulos, M.D.
President, Chief Executive Officer and
Chairman of the Board of Directors

OMEROS ANNOUNCES EXTENSION OF FDA REVIEW PERIOD FOR NARSOPLIMAB IN HSCT-TMA

-- PDUFA Date is October 17, 2021 –

SEATTLE – May 20, 2021 -- Omeros Corporation (Nasdaq: OMER), a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market as well as orphan indications targeting inflammation, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders, today reported that the U.S. Food and Drug Administration (FDA) will require additional time to review the Biologics License Application (BLA) for narsoplimab for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA). The new Prescription Drug User Fee Act (PDUFA) target action date is October 17, 2021.

As part of the ongoing BLA Priority Review, Omeros recently submitted a response to an FDA information request. FDA has classified the response as a major amendment, which requires additional time to review.

“We’re pleased with our ongoing interactions with FDA on the narsoplimab BLA,” said Gregory A. Demopulos, M.D., chairman and chief executive officer of Omeros. “Omeros views the information provided in response to FDA’s information request as further supporting the application, and we look forward to making narsoplimab available to HSCT-TMA patients and their physicians as soon as possible.”

The first drug submitted to FDA for approval in HSCT-TMA, narsoplimab has Breakthrough Therapy and Orphan designations in both HSCT-TMA and IgA nephropathy. The BLA for narsoplimab in HSCT-TMA was accepted for filing in January 2021 under FDA’s Priority Review program.

About Omeros Corporation

Omeros is a commercial-stage biopharmaceutical company committed to discovering, developing and commercializing small-molecule and protein therapeutics for large-market and orphan indications targeting inflammation, immunologic diseases (e.g., complement-mediated diseases and cancers) and central nervous system disorders. Its commercial product OMIDRIA® (phenylephrine and ketorolac intraocular solution) 1%/0.3% continues to gain market share in cataract surgery. Omeros’ lead MASP-2 inhibitor narsoplimab targets the lectin pathway of complement and is the subject of a biologics license application under priority review by FDA for the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy. Narsoplimab is also in multiple late-stage clinical development programs focused on other complement-mediated disorders, including IgA nephropathy, atypical hemolytic uremic syndrome and COVID-19. OMS906, Omeros’ inhibitor of MASP-3, the key activator of the alternative pathway of complement, is in a Phase 1 clinical trial, and the company’s PDE7 inhibitor program OMS527, targeting addiction and movement disorders, has successfully completed a Phase 1 trial. Omeros’ pipeline holds a diverse group of preclinical programs including a proprietary-asset-enabled antibody-generating technology and a proprietary GPCR platform through which it controls 54 GPCR drug targets and their corresponding compounds. One of these novel targets, GPR174, modulates a

new cancer immunity axis recently discovered by Omeros, and the company is advancing GPR174-targeting antibodies and small-molecule inhibitors. For more information about Omeros and its programs, visit www.omeros.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, which are subject to the “safe harbor” created by those sections for such statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “likely,” “look forward to,” “may,” “objective,” “plan,” “potential,” “predict,” “project,” “should,” “slate,” “target,” “will,” “would” and similar expressions and variations thereof. Forward-looking statements are based on management’s beliefs and assumptions and on information available to management only as of the date of this press release. Omeros’ actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with product commercialization and commercial operations, regulatory processes and oversight, and the risks, uncertainties and other factors described under the heading “Risk Factors” in the company’s Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 1, 2021. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and the company assumes no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

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