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 18, 2023

Eloxx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-31326**	**84-1368850**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**
480 Arsenal Way, Suite 130, Watertown, MA		**02451**
(Address of principal executive offices)		**(Zip Code)**

(Registrant's telephone number, including area code): (781) 577-5300

N/A
(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, $0.01 par value per share	ELOX	The Nasdaq Capital Market

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

Eloxx Pharmaceuticals, Inc. (the "Company") is providing the following business update.

Recent Developments

On September 18, 2023, the Company reported an independent qualitative evaluation by a board-certified anatomic pathologist with diagnostic expertise in medical kidney biopsies of transmission electron microscopy ("TEM") kidney biopsy results from the Company's proof-of-concept Phase 2 open-label clinical trial of ELX-02 for the potential treatment of Alport syndrome with nonsense mutations after eight weeks of treatment. Visual assessment of TEM images from kidney biopsies showed an improvement in foot process effacement in the three treated patients consistent with disease regression.

The qualitative visual assessment of images of pre- and post-treatment kidney biopsies from the three patients in the Company's Phase 2 clinical trial noted:

- Patient 4401-01 and Patient 4401-02: All images showed more regions of glomerular basement membranes in post-treatment biopsies covered by intact foot processes, consistent with partial improvement of podocyte injury in those biopsies. As previously reported by the Company, Patient 4401-02 achieved remission based on Urine-Protein Creatine Ratio.
- Patient 4402-01: Post-treatment images showed wider areas of intact foot processes compared with either pre- or post-treatment images for Patient 4401-01 and Patient 4401-02, suggesting improvement, though a reliable qualitative comparison between 4402-01 pre-treatment and post-treatment scans was not feasible.

Based on the results from the Phase 2 trial, the Company intends to gain alignment with the FDA on the design of a pivotal trial for ELX-02 for the potential treatment of Alport syndrome with nonsense mutations and the potential for seeking Breakthrough Therapy Designation.

Forward-looking Statements

This Current Report on Form 8-K (the "Form 8-K") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Form 8-K, including without limitation, statements regarding the Company's intentions regarding communications with FDA for alignment on a potential pivotal trial and a Breakthrough Therapy Designation submission are forward-looking statements. Forward-looking statements can be identified by the words "aim," "may," "will," "would," "should," "expect," "explore," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "seeks," or "continue" or the negative of these terms similar expressions, although not all forward-looking statements contain these words. Forward-looking statements are based on management's current plans, estimates, assumptions and projections based on information currently available to us. Forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and actual results or outcomes may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to: the Company's ability to progress any product candidates in preclinical or clinical trials; the uncertainty of clinical trial results and the fact that positive results from preclinical studies are not always indicative of positive clinical results; the scope, rate and progress of the Company's preclinical studies and clinical trials and other research and development activities; the competition for patient enrollment from drug candidates in development; the impact of the global COVID-19 pandemic on the Company's clinical trials, operations, vendors, suppliers, and employees; the Company's ability to obtain the capital necessary to fund the Company's operations; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; the Company's ability to obtain financial in the future through product licensing, public or private equity or debt financing or otherwise; the Company's ability to meet the continued listing requirements of the Nasdaq Capital Market; general business conditions, regulatory environment, competition and market for the Company's products; and business ability and judgment of personnel, and the availability of qualified personnel and other important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, as any such factors may be updated from time to time in the Company's other filings with the SEC, accessible on the SEC's website at www.sec.gov and the "Financials & Filings" page of the Company's website at https://investors.eloxxpharma.com/financials-filings.

All forward-looking statements speak only as of the date of this 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.

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.

Date: September 18, 2023

ELOXX PHARMACEUTICALS, INC.

By: /s/ Sumit Aggarwal
Name: Sumit Aggarwal
Title: President and Chief Executive Officer