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 14, 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

On June 14, 2023, Eloxx Pharmaceuticals, Inc. (the "Company" or "our") announced the final data assessment from the Phase 2 clinical trial of ELX-02 in combination with ivacaftor in Class 1 Cystic Fibrosis ("CF") patients with at least one nonsense mutation. The Phase 2 combination clinical trial of ELX-02 was designed to evaluate safety and assess biological activity in G542X nonsense mutation Class 1 CF patients as monotherapy and in combination with ivacaftor after 5 weeks of treatment. Interim topline results from 11 evaluable patients were reported in September 2022. In the final assessment of 13 evaluable patients, ELX-02 demonstrated clinically relevant improvement in ppFEV1. The final data assessment includes a reanalysis using change in ppFEV1 from Day 1 instead of baseline, as multiple patients experienced disease progression between screening and dosing. The clinical improvement of ELX-02 in CF study bolsters the Company's recently announced results in Phase 2 Alport syndrome trial, further supporting the decision to advance into a pivotal trial in Alport syndrome.

- 6 of 13 patients entered trial from monotherapy arm (after average 463 days) and had a decrease in lung function (annualized -4.26% reduction in ppFEV1) due to disease progression.

- Treatment with ELX-02 stabilized disease overall and resulted in a clinically relevant increase in ppFEV1 in 6 of 13 patients (which we refer to as Responders) based on change in ppFEV1 at the end of treatment at Day 35 compared to the start of treatment at Day 1.

- At the safety follow up evaluation, done 28 days following the end of treatment, a decrease in ppFEV1 was observed on average across the 13 patients compared to the end of treatment at day 35. All patients that had an increase in ppFEV1 at the end of treatment on day 35 had a decline in their ppFEV1 at the 28 day safety follow up.

Number of patients	**Change in ppFEV1 (%) at end of treatment at Day 35 vs Day 1**	**Change in ppFEV1 (%) at 28-day Safety follow up vs end of treatment at Day 35**
Overall, n=13	-0.31%	-2.69%
Responders, n=6	+2.83%	-5.83%

- Previously reported topline data from 11 patients showed evidence of activity, as patients with higher baseline sweat chloride levels demonstrated increased responses as indicated by SCC (p=0.00013 at Day 35).

- ELX-02 was generally well tolerated in the trial, with no treatment-related serious adverse events noted.

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: June 15, 2023

ELOXX PHARMACEUTICALS, INC.

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