

**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): July 31, 2019

Eloxx Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-31326
(Commission
File Number)

84-1368850
(I.R.S. Employer
Identification No.)

950 Winter Street
Waltham, MA
(Address of principal executive offices)

02451
(Zip Code)

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

(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))

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. ☐

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 Global Market

Item 8.01 Other Events

On July 31, 2019, Eloxx Pharmaceuticals, Inc. issued a press release announcing, among other things, the opening of its investigational new drug application in the U.S. for a phase 2 clinical trial of ELX-02 in cystic fibrosis patients with the G542X mutation and protocol endorsement from the Cystic Fibrosis Foundation, as well as information regarding the Company's webcast and conference call on August 7, 2019 at 8:30 am ET to report second quarter 2019 financial results and provide a business update. A copy of the press release is filed herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
<u>99.1</u>	<u>Press Release, dated July 31, 2019.</u>

SIGNATURE

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.

ELOXX PHARMACEUTICALS, INC.

By: /s/ Gregory Weaver

Name: Gregory Weaver

Title: Chief Financial Officer

Date: July 31, 2019



Eloxx Pharmaceuticals Announces Open Investigational New Drug Application (IND) for a Phase 2 Clinical Trial of ELX-02 in Cystic Fibrosis Patients with the G542X Mutation in the US and Protocol Endorsement from the Cystic Fibrosis Foundation (CFF)

On track to report top line data from Phase 2 clinical trials for ELX-02 in cystic fibrosis and cystinosis in the U.S., Europe, Israel, and Canada in 2019

Company to host webcast and conference call on August 7, 2019 at 8:30 am ET to report second quarter 2019 financial results and provide a business update

Waltham, MA. – July 31, 2019 – Eloxx Pharmaceuticals, Inc., (NASDAQ: ELOX) a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel therapeutics to treat cystic fibrosis, cystinosis, inherited retinal disorders, and other diseases caused by nonsense mutations limiting production of functional proteins, today announced that an IND for ELX-02 in cystic fibrosis is now open in the U.S. and the Phase 2 clinical trial has been endorsed by the CFF.

“We are very pleased that our IND is open in the U.S. and the protocol for our Phase 2 clinical trial in cystic fibrosis has been endorsed by the Cystic Fibrosis Foundation (CFF) in the U.S. Dr. Ahmet Uluer, Director of the Adult Cystic Fibrosis Program at the Boston Children’s Hospital/Brigham and Women’s Hospital CF Center, has agreed to be the lead study investigator in the U.S., and Professor Kerem Eitan, M.D., Head of the Division of Pediatrics, Children’s Hospital, Hadassah Medical Center, will serve as the Global Lead Investigator. We are gratified by the participation of these two leading experts and we look forward to reporting top line data later this year,” said Robert E. Ward, Chairman and CEO of Eloxx Pharmaceuticals. “We believe that the positive data we have generated for ELX-02 in cystic fibrosis patient-derived organoids substantially de-risk our Phase 2 program.”

“I am very pleased to be leading the Phase 2 clinical trial of ELX-02 in cystic fibrosis patients with the G542X mutation on one or both alleles in the U.S. These patients have a high unmet medical need and few if any targeted treatment options. ELX-02 is the only therapy to have demonstrated positive results in organoids derived from cystic fibrosis patients across the majority of nonsense mutations and studies have shown the organoid model to be highly predictive of clinical benefit,” said Ahmet Uluer, DO, MPH, Director, Adult Cystic Fibrosis Program, Boston Children’s Hospital, Division of Pulmonary Medicine, and Brigham and Women’s Hospital, Division of Pulmonary and Critical Care Medicine. “While important progress has been made in the development of disease modifying treatments for patients with cystic fibrosis, patients with nonsense mutations represent the most severe phenotypes and often do not respond to currently available therapies,” said Dr. Kerem Eitan, Head of the Division of Pediatrics, Children’s Hospital, Hadassah Medical Center. “I am excited to lead this clinical trial of ELX-02 which may provide a new therapeutic approach for these patients.”

Conference Call Information:**Date:** Wednesday, August 7, 2019**Time:** 8:30 a.m. ET**Domestic Dial-in Number:** (866) 913-8546**International Dial-in Number:** (210) 874-7715**Conference ID:** 1754316**Live Webcast:** accessible from the Company's website at www.eloxxpharma.com under Events and Presentations or with this link: <https://edge.media-server.com/mmc/p/9axiqnvt>**About Eloxx Pharmaceuticals**

Eloxx Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel RNA-modulating drug candidates (designed to be eukaryotic ribosomal selective glycosides) that are formulated to treat rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt protein synthesis from messenger RNA. As a consequence, patients with premature stop codon diseases have reduced or eliminated protein production from the mutation bearing allele accounting for some of the most severe phenotypes in these genetic diseases. These premature stop codons have been identified in over 1,800 rare and ultra-rare diseases. Read-through therapeutic development is focused on extending mRNA half-life and increasing protein synthesis by enabling the cytoplasmic ribosome to read through premature stop codons to produce full-length proteins. Eloxx's lead investigational product candidate, ELX-02, is a small molecule drug candidate designed to restore production of full-length functional proteins. ELX-02 is in the early stages of clinical development focusing on cystic fibrosis and cystinosis. ELX-02 is an investigational drug that has not been approved by any global regulatory body. Eloxx's preclinical candidate pool consists of a library of novel drug candidates designed to be eukaryotic ribosomal selective glycosides identified based on read-through potential. Eloxx recently announced a new program focused on rare ocular genetic disorders. Eloxx is headquartered in Waltham, MA, with operations in Rehovot, Israel. For more information, please visit www.eloxxpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, including: the development of the Company's read-through technology; the approval of the Company's patent applications; the Company's ability to successfully defend its intellectual property or obtain necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the Company's ability to obtain applicable regulatory approvals for its current and future product candidates; the acceptance by the market of the Company's products should they receive regulatory approval; the timing and success of the Company's preliminary studies, preclinical research, clinical trials, and related regulatory filings; the ability of the Company to consummate additional financings as needed; as well as those discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

Contact:

Barbara Ryan

203-274-2825

barbarar@eloxxpharma.com
