

**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 6, 2021

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))

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

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 2.02. Results of Operations and Financial Condition.

On May 6, 2021, Eloxx Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the first fiscal quarter ended March 31, 2021 and providing a business update. A copy of the Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including the information contained in the press release furnished as Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or otherwise subject to the liabilities of that section, and shall not be deemed incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

**Exhibit
No.**

Description

<u>99.1</u>	<u>Press Release, dated May 6, 2021</u>
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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/ Neil S. Belloff

Name: Neil S. Belloff

Title: Chief Operating Officer, General Counsel and
Corporate Secretary

Date: May 6, 2021



Eloxx Pharmaceuticals Reports First Quarter 2021 Financial and Operating Results and Provides Business Update

Acquisition of Zikani Therapeutics, Ribosomal Modulation Company; Combined Company Advancing Ribosomal RNA-Targeted Genetic Therapies

Additional Treatment Arm Added to Ongoing Phase 2 Clinical Studies for Cystic Fibrosis (CF)

Cystic Fibrosis Foundation (CF Foundation) Increases Clinical Trial Funding to Include Europe and Israel

ELX-02 Phase 1 Results Published in Multiple Scientific Journals

WALTHAM, MA – May 6, 2021 – Eloxx Pharmaceuticals, Inc. (NASDAQ: ELOX), a leader in ribosomal RNA-targeted genetic therapies for rare diseases, today reported its financial results for the three months ended March 31, 2021 and provided a business update.

“The beginning of 2021 has been transformative for Eloxx and was extremely important in laying the groundwork for the future success of ELX-02, our candidate for cystic fibrosis, and in amplifying the potential of Eloxx’s innovative science and be a leader in RNA-targeted genetic therapies. Our enthusiasm has only increased in the short period since the acquisition,” said Sumit Aggarwal, President and Chief Executive Officer of Eloxx. “We remain incredibly excited by the potential of ELX-02 to help treat CF patients affected by nonsense mutations and look forward to completing enrollment in the first four treatment arms by mid-year, and expect to report data in the second half of 2021.”

First Quarter 2021 and Subsequent Highlights

- We acquired Zikani Therapeutics, Inc., a ribosomal modulation company, in an all stock transaction on April 1, 2021. We believe the acquisition maximizes the potential for ELX-02 for CF, which is currently in Phase 2 development. The acquisition also adds a preclinical stage pipeline in rare diseases and oncology targeting RNA and ribosomal mutations. Eloxx expects to file an Investigational New Drug application for the first oral drug to treat patients with Recessive Dystrophic and Junctional Epidermolysis Bullosa (RDEB and JEB) in 2022. Sumit Aggarwal, former Zikani President and CEO, was appointed President and CEO of Eloxx.
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- As previously announced, the new study arm was added to our global Phase 2 clinical program for ELX-02 for the treatment of CF in patients with at least one G542X allele. The Phase 2 clinical program now includes a fifth treatment arm to evaluate safety of ELX-02 in combination with Kalydeco® (ivacaftor), a FDA-approved CF transmembrane conductance regulator (CFTR) potentiator for the treatment of CF in patients who have at least one mutation in their CF gene amenable to ivacaftor. The Phase 2 trials are designed to evaluate the safety of ELX-02 and assess its biological activity. We remain on track to present data from the first four treatment arms in the second half of this year.
- The CF Foundation extended its funding of our clinical trial program to include Europe and Israel.
- Phase 1 results for ELX-02 were published in multiple medical journals, including:
 - o “Targeting G542X CFTR Nonsense Alleles with ELX-02 Restores CFTR Function in Human-Derived Intestinal Organoids” in the *Journal of Cystic Fibrosis*;
 - o “A Randomized, Double-Blind, Placebo-Controlled, Multiple Dose Escalation Study to Evaluate the Safety and Pharmacokinetics of ELX-02 in Healthy Subjects” in the journal *Clinical Pharmacology in Drug Development*; and
 - o “Phase 1 Renal Impairment Trial Results Enable Targeted Individualized Dosing of ELX-02 in Nephropathic Cystinosis Patients” in the *Journal of Clinical Pharmacology*.

First Quarter 2021 Financial Results

For the three months ended March 31, 2021, we incurred a net loss of \$8.7 million or \$0.22 per share, which includes \$1.3 million in stock-based compensation. For the same period in the prior year, we incurred a net loss of \$13.9 million, or \$0.35 per share.

Our research and development expenses (R&D) were \$4.1 million for the three months ended March 31, 2021, which includes \$0.2 million in stock-based compensation. For the same period in the prior year, R&D expenses were \$4.8 million. The decrease in R&D expenses was driven by reduced expenses related to the development of ELX-02 due to the impact of the COVID-19 and realignment actions taken in February 2020 that included reductions in R&D headcount and external spending.

Our general and administrative (G&A) expenses were \$4.3 million for the three months ended March 31, 2021, which includes \$1.1 million in stock-based compensation. For the same period in the prior year, G&A expenses were \$5.0 million. The decrease was primarily driven by realignment actions taken in February 2020 that included reductions in general and administrative headcount and external spending.



As of March 31, 2021, we had cash and cash equivalents of \$18.2 million, which we expect will be sufficient to fund our operations into the third quarter of 2021.

About Eloxx Pharmaceuticals

Eloxx Pharmaceuticals, Inc. is engaged in the science of ribosome modulation, leveraging its innovative TURBO-ZM™ chemistry technology platform in an effort to develop novel Ribosome Modulating Agents (RMAs) and its library of Eukaryotic Ribosome Selective Glycosides (ERSGs). 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 clinical development, focusing on cystic fibrosis. Eloxx also has preclinical programs focused on select rare diseases, including inherited diseases, cancer caused by nonsense mutations, kidney diseases, including autosomal dominant polycystic kidney disease, as well as rare ocular genetic disorders.

For more information, please visit www.eloxxpharma.com.

Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of present and historical facts contained in this press release, including without limitation, statements regarding the expected timing of trials and results from clinical studies of our product candidate, the expansion of our clinical trial sites and the potential of our product candidate to treat nonsense mutations 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: our 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 our 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 our clinical trials, operations, vendors, suppliers, and employees; our ability to obtain the capital necessary to fund our operations; the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; our ability to obtain financial in the future through product licensing, public or private equity or debt financing or otherwise; general business conditions, regulatory environment, competition and market for our 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as any such factors may be updated from time to time in our other filings with the SEC, including our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2021, accessible on the SEC's website at www.sec.gov and the "Financials & Filings" page of our website at <https://investors.eloxxpharma.com/financial-information/sec-filings>



All forward-looking statements speak only as of the date of this press release and, except as required by applicable law, we have 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.

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ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 18,247	\$ 24,668
Restricted cash	54	56
Prepaid expenses and other current assets	1,659	1,169
Total current assets	19,960	25,893
Property and equipment, net	117	133
Operating lease right-of-use asset	289	421
Other long-term assets	-	30
Total assets	\$ 20,366	\$ 26,477
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 485	\$ 481
Accrued expenses	2,917	2,886
Current portion of long-term debt	5,562	5,239
Advances from collaboration partners	3,411	805
Current portion of operating lease liability	280	389
Taxes payable	38	38
Total current liabilities	12,693	9,838
Long-term debt	4,913	6,376
Operating lease liability	10	33
Total liabilities	17,616	16,247
Total stockholders' equity	2,750	10,230
Total liabilities and stockholders' equity	\$ 20,366	\$ 26,477

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 4,073	\$ 4,767
General and administrative	4,341	5,006
Restructuring charges	—	3,994
Total operating expenses	8,414	13,767
Loss from operations	(8,414)	(13,767)
Other expense, net	280	179
Net loss	<u>\$ (8,694)</u>	<u>\$ (13,946)</u>
Net loss per share, basic and diluted	<u>\$ (0.22)</u>	<u>\$ (0.35)</u>
Weighted average number of shares of common stock used in computing net loss per share, basic and diluted	40,180,131	40,074,275