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): August 16, 2021

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	**02472**
(Address of principal executive offices)	**(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 August 16, 2021, Eloxx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the second fiscal quarter ended June 30, 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
99.1	Press Release, dated August 16, 2021

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
and General Counsel

Date: August 16, 2021

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

Added Additional Treatment Arm and Provided Enrollment Update for Ongoing ELX-02 Phase 2 Clinical Trials for Cystic Fibrosis (CF)

Nominated ZKN-013 as Lead Candidate for Recessive Dystrophic Epidermolysis Bullosa (RDEB) and Junctional Epidermolysis Bullosa (JEB) Programs

Advanced Multiple Preclinical Rare Inherited and Targeted Oncology Programs

Received Funding Award from Cystic Fibrosis Foundation to Develop Ribosome Modulating Agents (RMAs) with TURBO-ZM™ Platform

Raised Approximately $52M in Gross Proceeds Through Public Offering

WATERTOWN, MA – Aug 16, 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 June 30, 2021, and provided a business update.

“Since the acquisition of Zikani Therapeutics in early April, we have made tremendous progress across our portfolio of novel therapeutic programs,” said Sumit Aggarwal, President and Chief Executive Officer of Eloxx. “In CF, we remain on track to report data from the ongoing Phase 2 clinical trials for ELX-02 , while we are also preparing for combination studies of ELX-02 and ivacaftor and commencing efforts to evaluate inhaled delivery of ELX-02. Beyond CF, we continue to advance our preclinical programs to demonstrate the potential of our oral RMAs. We intend to provide additional insight into these programs in the coming quarters.”

Second Quarter 2021 and Subsequent Highlights

Class 1 Cystic Fibrosis

- Ongoing ELX-02 Phase 2 clinical trials in CF patients affected by nonsense mutations in the CFTR (CF transmembrane conductance regulator) gene are designed to evaluate the safety of ELX-02 and assess short-term biological activity in patients.
    - As previously announced, based on enrollment as of the end of June 2021, we remain on track to report data from the monotherapy arms of the ELX-02 clinical trials in the fourth quarter of 2021. We are continuing to enroll additional patients to support Phase 3 clinical trial planning

- Biological activity is being assessed by changes in sweat chloride, a surrogate marker for restoring CFTR activity. For comparison, Orkambi, an FDA-approved CF agent, demonstrated mid-single digit reductions in sweat chloride over one- to two-week study durations in a similar trial setting.

- Patient dosing in the expansion arm, which includes a combination of ELX-02 and the CFTR protein potentiator, Kalydeco (ivacaftor), is expected to begin by the end of 2021. Previously disclosed preclinical organoid experiments have demonstrated that the addition of Kalydeco to ELX-02 can enhance activity up to three-fold.

- Safety Review Committee has approved advancement to highest dose level to be studied.

· Began evaluation of inhaled (nebulizer-based) delivery of the current subcutaneous formulation of ELX-02. Preclinical rodent studies of ELX-02 and other aminoglycosides have demonstrated 30- to 100-fold higher drug concentration in the lung versus plasma. This has the potential to further improve the activity of ELX-02 as both a single agent and in combination with other drugs.

· Received an award of up to $2.6M from the Cystic Fibrosis Foundation to identify optimized oral Ribosome Modulating Agents (RMAs) with our TURBO-ZM™ Platform for further development for the treatment of CF patients with nonsense mutations.

Recessive Dystrophic Epidermolysis Bullosa (RDEB) and Junctional Epidermolysis Bullosa (JEB)

· Nominated ZKN-013 as the drug candidate to move into IND-enabling studies for the treatment of RDEB and JEB. Good Laboratory Practice (GLP) safety studies are expected to begin by the end of 2021. We remain on track to file an IND submission in 2022.

- In preclinical experiments, treating RDEB patient-derived fibroblasts and keratinocytes with ZKN-013 showed clinically relevant restoration of full-length Collagen 7A (COL7A) across multiple genotypes in a dose dependent manner.

- In a non-GLP animal toxicity study, ZKN-013 demonstrated a substantial safety margin with therapeutically sufficient drug levels in skin with chronic dosing.

Rare Inherited and Targeted Oncology

· Continued to advance our preclincial oncology pipeline, which is focused on rare inherited cancers with driver nonsense mutations and cancers with driver mutations in the ribosome.

· Our lead program is for the treatment of patients with Familial Adenomatous Polyposis (FAP).

- We have initiated an 8-week study in APC^{Min} (multiple intestinal neoplasia) mice to evaluate the potential of RMAs to treat FAP. The APC^{Min} mouse is a translationally validated model for drug development for FAP.

- Prior studies of erythromycin in APC^{Min} mice showed reductions in colon polyps that successfully translated to demonstrating clinical efficacy.[1]

- This study in APC^{Min} will evaluate polyp number and size in ZKN013 treated mice versus control mice. We expect to report results from this study in the fourth quarter of 2021.

· Initiated cancer cell line and xenograft mouse studies to evaluate the response to treatment with RMAs to advance first-in-class onco-ribosome targeted inhibitors for oncology therapy.

Corporate

· An underwritten public offering of 38,333,334 shares of common stock, including the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $1.35 per share was closed in May 2021. Aggregate gross proceeds from the offering were approximately $51.75 million, before deducting underwriting discounts and commissions and offering expenses.

· Pedro Huertas, M.D., Ph.D., joined Eloxx as a Senior Adviser. Dr. Huertas previously served as CMO of Eloxx. He has also served as CMO of Inozyme Pharma and Sentien Biotechnologies and in various roles at Pfizer, Shire, Massachusetts General Hospital, and Genzyme.

Second Quarter 2021 Financial Results

For the three months ended June 30, 2021, we incurred a net loss of $36.1 million or $0.54 per share, which includes $4.0 million in stock-based compensation. For the same period in the prior year, we incurred a net loss of $7.9 million, or $0.20 per share. Results for the second quarter of 2021 included a $22.7 million acquired in-process research and development expense related to the acquisition of Zikani.

Our research and development expenses (R&D) were $5.7 million for the three months ended June 30, 2021, which includes $0.1 million in stock-based compensation. For the same period in the prior year, R&D expenses were $3.7 million. The increase in R&D expenses was primarily related to an increase in expenses related to the continued development of ELX-02 as a result of the suspension of our clinical trials due to the impact of the COVID-19 pandemic in the prior year period and an increase in salaries and other personnel related costs, partially offset by a decrease in stock-based compensation expense.

Our general and administrative (G&A) expenses were $7.4 million for the three months ended June 30, 2021, which includes $3.9 million in stock-based compensation. For the same period in the prior year, G&A expenses were $3.8 million. The increase was primarily related to an increase in stock-based compensation expense, an increase in salaries and other personnel-related costs associated with the merger with Zikani, as well as an increase in expenses attributable principally to infrastructure related costs including legal, accounting and other professional fees.

As of June 30, 2021, we had cash and cash equivalents of $56.7 million, which we expect will be sufficient to fund our operations into the first quarter of 2023.

[1] *J Mol Med (Berl) 2016 Apr;94(4):469-82) and Int J Cancer 2020 Feb 15;146(4):1064-1074*)

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 Ribsome 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 our expected cash burn and future financial results, the expected timing of trials and results from clinical studies of our product candidates 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, as any such factors may be updated from time to time in our other filings with the SEC, 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, except share and per share data)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,734	$ 24,668
Restricted cash	246	56
Prepaid expenses and other current assets	1,579	1,169
Total current assets	58,559	25,893
Property and equipment, net	185	133
Operating lease right-of-use asset	1,866	421
Other long-term assets	-	30
Total assets	**$ 60,610**	**$ 26,477**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,024	$ 481
Accrued expenses	3,302	2,886
Current portion of long-term debt	5,686	5,239
Advances from collaboration partners	3,411	805
Current portion of operating lease liability	753	389
Taxes payable	34	38
Total current liabilities	15,210	9,838
Long-term debt	3,637	6,376
Operating lease liability	1,120	33
Total liabilities	19,967	16,247
Total stockholders' equity	40,643	10,230
Total liabilities and stockholders' equity	**$ 60,610**	**$ 26,477**

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 5,704	$ 3,738	$ 9,777	$ 8,505
General and administrative	7,355	3,848	11,696	8,854
In process research and development	22,670	—	22,670	—
Restructuring charges	—	—	—	3,994
Total operating expenses	35,729	7,586	44,143	21,353
Loss from operations	(35,729)	(7,586)	(44,143)	(21,353)
Other expense, net	329	301	609	480
Net loss	**$ (36,058)**	**$ (7,887)**	**$ (44,752)**	**$ (21,833)**
Basic and diluted net loss per share	**$ (0.54)**	**$ (0.20)**	**$ (0.84)**	**$ (0.54)**
Weighted average number of common shares used in computing net loss per share, basic and diluted	66,389,865	40,129,304	53,357,401	40,101,789