

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

Eloxx Pharmaceuticals, Inc.

Form: 8-K

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**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 7, 2018

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
(IRS 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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations 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.

Item 2.02 Results of Operations and Financial Condition.

On August 7, 2018, Eloxx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the second fiscal quarter ended June 30, 2018. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated August 7, 2018

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.

ELOXX PHARMACEUTICALS, INC.

Date: August 7, 2018

By: /s/ Gregory Weaver
Gregory Weaver
Chief Financial Officer



Eloxx Pharmaceuticals Reports Second Quarter 2018 Financial and Operating Results and Provides Business Update

CTA approved in Belgium and IND open in the U.S. for investigational drug candidate, ELX-02

On track to initiate Phase 2 clinical trials in cystic fibrosis and cystinosis in 2018

Expanded Leadership Team with Global Pharmaceutical Executives to Accelerate Growth

Company to host webcast and conference call on Tuesday, August 7, 2018 at 4:30 pm ET

Waltham, MA. – August 7, 2018 – Eloxx Pharmaceuticals, Inc., (NASDAQ: ELOX) a clinical-stage biopharmaceutical company dedicated to the discovery and development of novel therapeutics to treat cystic fibrosis, cystinosis and other diseases caused by nonsense mutations limiting production of functional proteins, today reported its financial results for the three and six months ended June 30, 2018 and provided a business update.

“We are pleased to have achieved important regulatory milestones in Europe and the U.S. gaining clearance to initiate two Phase 2 clinical trials for our lead investigational product candidate, ELX-02, in cystic fibrosis and cystinosis, respectively. We are on track to initiate these this year and we are funded through data readouts,” said Robert E. Ward, Chairman and CEO of Eloxx Pharmaceuticals. “I am very gratified to have been successful in attracting experienced pharmaceutical executives to our leadership team who I am confident will add significant value as we build a high-performance culture committed to maximizing the value of ELX-02 and our library of novel compounds and pursue global collaborations.”

Recent Accomplishments

- Eloxx’s CTA for ELX-02 in cystic fibrosis has been approved by the Federal Agency for Medicines and Health Products (the “FAMHP”) in Brussels, Belgium. The European Cystic Fibrosis Society Clinical Trial Network (ECFS-CTN) has reviewed and approved our protocol for a Phase 2 clinical trial of ELX-02 in cystic fibrosis patients with a G542X mutation and has given it “high priority” status. We expect to initiate this trial in the fourth quarter of 2018.
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- Our IND in the U.S. for ELX-02 in cystinosis is open and we have gained alignment with the U.S. Food and Drug Administration (FDA) on a focused Phase 2 clinical trial enrolling 6 patients. We plan to initiate this Phase 2 clinical trial in the fourth quarter of 2018.
- We have successfully manufactured a lyophilized dosage form of ELX-02 which is convenient for patients and physicians and can be stored at room temperature. This is a significant milestone towards a final commercial drug product.
- We have completed the first four cohorts of the MAD study for ELX-02 and we look forward to dosing in the fifth and final cohort. We anticipate that this study will be completed in 2018.
- Eloxx substantially expanded its Leadership Team with highly experienced biopharmaceutical executives who will be instrumental in accelerating the company's growth and advancing our clinical programs on time and on budget. We plan to continue to add key talent to help us deliver on our mission of bringing safe and effective medicines to patients who need them as rapidly as possible.
 - Dr. Greg Williams joined Eloxx as Chief Operating Officer. Dr. Williams has a long tenured career leading clinical and regulatory teams responsible for the development and approval of many leading brands in multiple indications across a variety of large and small biopharmaceutical companies, including the Medicines Company, NPS and most recently, Radius Health.
 - David Snow joined Eloxx as Chief Business Officer with over 25 years of experience in the pharmaceutical industry developing global brands, leading large commercial organizations across major markets, driving transformational growth, and delivering on business development.
 - Neil Belloff joined Eloxx as General Counsel from Celgene Corporation and has more than 30 years of legal and business experience. In addition to his corporate governance and compliance expertise, Neil was also an Executive Vice President at Deutsche Telecom, and previously served as Senior Attorney-Advisor at the Securities and Exchange Commission in Washington.

Eloxx presented two abstracts at the 41st European Cystic Fibrosis Conference (ECFS) in Belgrade Serbia; a Late Breaker titled "*Evaluation of ELX-02 in Cystic Fibrosis Patient Organoids with Non-Sense Mutations*", and an oral presentation titled "Translational Read-Through of CFTR Non-Sense Mutations and Inducement of Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) Function by ELX-02 Treatment".

Second Quarter 2018 Financial Results

As of June 30, 2018, we had cash and cash equivalents of \$63.4 million. As a result of our equity capital raise in April 2018, which provided net proceeds of approximately \$53.6 million, we expect that our current cash and cash equivalents will be sufficient to fund our current operations to 2020 and through data readouts for our Phase 2 clinical trials for our investigational product, ELX-02, in cystic fibrosis and cystinosis.

We incurred a loss for the three months ended June 30, 2018, of \$13.4 million or \$0.42 per share, which includes \$6.2 million non-cash expense related to stock-based compensation. The Company incurred a net loss for the three months ended June 30, 2017, of \$3.9 million, or \$1.04 per share. For the three months ended June 30, 2018, the net cash used in operating activities was \$8.5 million. For the three months ended June 30, 2017, the net cash used in operating activities was \$3.2 million driven primarily by our net loss.

Our research and development expenses were \$4.2 million for the three months ended June 30, 2018, compared to \$2.6 million for the three months ended June 30, 2017, an increase of \$1.6 million due to increased fees and salaries and growth in clinical development.

Our general and administrative expenses were approximately \$9.6 million for the three months ended June 30, 2018 compared to approximately \$0.6 million for the three months ended June 30, 2017, an increase of approximately \$9.0 million. The increase in our general and administrative expenses was primarily related to an increase in our headcount and related salaries, non-cash stock-based compensation, and professional service fees.

Year to Date 2018 Financial Results

We incurred a loss for the six months ended June 30, 2018, of \$22.0 million or 0.74 per share, which includes \$6.9 million non-cash expenses related to stock-based compensation. The Company incurred a net loss for the six months ended June 30, 2017, of \$6.6 million, or \$1.77 per share. For the six months ended June 30, 2018, the net cash used in operating activities was \$14.2 million. For the six months ended June 30, 2017, the net cash used in operating activities was 5.9 million, driven primarily by our net loss.

Our research and development expenses were \$8.5 million for the six months ended June 30, 2018, compared to \$5.0 million for the six months ended June 30, 2017, an increase of \$3.5 million due to increased fees and salaries and growth in clinical development.

Our general and administrative expenses were approximately \$13.0 million for the six months ended June 30, 2018 compared to approximately \$0.9 million for the six months ended June 30, 2017, an increase of approximately \$12.1 million. The increase in our general and administrative expenses was primarily related to an increase in our headcount and related salaries, non-cash stock-based compensation, as well as other personnel and professional service fees.

Conference Call Information:**Date:** Tuesday, August 7, 2018**Time:** 4:30 p.m. ET**Domestic Dial-in Number:** (866) 913-8546**International Dial-in Number:** (210) 874-7715**Conference ID:** 7858608**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/m6/p/n7s8dtg6>. A replay will be available on the Company's website approximately two hours after the call.**Conference Call Replay Information:****Domestic Dial-in Number:** (855) 859-2056**International Dial-in Number:** (404) 537-3406**Conference ID:** 7858608**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 designed 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. 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. 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 is headquartered in Waltham, MA, with R&D operations in Rehovot, Israel.

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:

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ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES
UNAUDITED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 63,412	\$ 24,049
Restricted bank deposit	100	102
Prepaid expenses and other current assets	458	355
Total current assets	63,970	24,506
Property and equipment, net	302	278
Total	\$ 64,272	\$ 24,784
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,098	\$ 1,530
Accrued expenses	2,258	1,893
Total current liabilities	4,356	3,423
Stockholders' equity:		
Series A, B-1, B-2 and C Preferred Stock; Preferred stock, \$0.01 par value per share, 5,000,000 shares authorized, no shares issued and outstanding at June 30, 2018 and December 31, 2017	—	—
Common stock, \$0.01 par value per share, 500,000,000 shares authorized, 34,728,061 and 27,527,738 shares issued at June 30, 2018 and December 31, 2017, respectively	349	274
Common stock in treasury, at cost, 8,385 and 0 shares at June 30, 2018 and December 31, 2017, respectively	(31)	—
Additional paid in capital	120,555	60,047
Accumulated deficit	(60,957)	(38,960)
Total stockholders' equity	59,916	21,361
Total	\$ 64,272	\$ 24,784

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	\$ 4,150	\$ 2,595	\$ 8,544	\$ 4,950
General and administrative	9,560	584	12,953	861
Reverse merger related expenses	(167)	—	594	—
Total operating expenses	<u>13,543</u>	<u>3,179</u>	<u>22,091</u>	<u>5,811</u>
Loss from operations	(13,543)	(3,179)	(22,091)	(5,811)
Other (income) expense, net	(137)	699	(94)	745
Net loss	<u>\$ (13,406)</u>	<u>\$ (3,878)</u>	<u>\$ (21,997)</u>	<u>\$ (6,556)</u>
Basic and diluted net loss per share	<u>\$ (0.42)</u>	<u>\$ (1.04)</u>	<u>\$ (0.74)</u>	<u>\$ (1.77)</u>
Weighted average number of common shares in computing basic and diluted net loss per share	31,823,766	4,205,277	29,687,619	4,205,277