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): November 8, 2018

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)**	**(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 November 8, 2018, Eloxx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the third fiscal quarter ended September 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

Exhibit No.	Description
99.1	Press Release of the Company dated November 8, 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: November 8, 2018

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

Exhibit 99.1

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

ELX-02 has been granted an orphan drug designation by the European Medicines Agency (EMA) for Cystic Fibrosis

Advancing several investigational drug candidates from our library in IND enabling studies for rare inherited retinal diseases

Announced scientific partnership with the Foundation Fighting Blindness to support ocular portfolio development

On track for top line data from two Phase 2 clinical trials in cystic fibrosis and cystinosis in 2019

Company to host webcast and conference call on Thursday, November 8, 2018 at 8:30 am ET

Waltham, MA. – November 8, 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 nine months ended September 30, 2018 and provided a business update.

"We are very pleased that ELX-02 has been granted orphan drug designations from the European Medicines Agency for cystic fibrosis, and the Food and Drug Administration in the US for cystinosis, and we look forward to reporting top line data from our Phase 2 clinical trials in both indications in 2019. New positive data recently presented at the North American Cystic Fibrosis Conference demonstrated that ELX-02 is the first read-through agent to show dose responsive increases in CFTR function that was found to correlate with *CFTR*mRNA elevations to levels at or above wild-type," said Robert E. Ward, Chairman and CEO of Eloxx Pharmaceuticals. "We are also advancing several new investigational product candidates from our library in IND enabling studies in rare inherited retinal diseases, and we are very pleased to announce our strategic broad partnership with the Foundation Fighting Blindness as we identify a lead candidate later this year to move into clinical development."

Recent Accomplishments

- Eloxx today announced that ELX-02 has been granted an orphan drug designation by the European Medicines Agency. Earlier this year, the U.S. Food and Drug Administration had granted ELX-02 an orphan drug designation for cystinosis.

    - 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 given a Phase 2 clinical trial of ELX-02 in cystic fibrosis patients with a G542X mutation "high priority" status. We expect to enroll no more than 24 patients in this trial and to report top line data in 2019.

    - 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 expect to report top line data from this study in 2019.

- Eloxx has several compounds from our library of eukaryotic ribosomal selective glycosides in IND enabling studies that have demonstrated positive activity on nonsense mutations in inherited retinal disorders and a favorable tolerability profile. We believe that these data are very supportive of continued development and are on track to take one of these candidates into the clinic in a rare ocular genetic disease.

- Eloxx has entered into a wide-ranging partnership with the Foundation Fighting Blindness, whose urgent mission is to drive the research that will provide preventions, treatments and cures for a spectrum of retinal degenerative diseases. We are proud to support the My Retinal Tracker®, a registry of patients affected by inherited retinal degenerative diseases which is designed to accelerate the discovery of treatments and cures. As a National Partner, we are also excited to support the Foundation's programs for educating people affected by retinal degenerative diseases.

- Eloxx presented new positive data for ELX-02 at the North American Cystic Fibrosis Conference on October 18th, 2018 in Denver, Colorado in a Poster presentation titled **"Measuring mRNA levels in cystic fibrosis organoids with nonsense mutations following treatment with ELX-02,"** presented by Neal Sharpe, Ph.D., V.P. Translational Science. ELX-02 demonstrated significant increases in CFTR functional assay ($P<0.0001$) and mRNA levels ($P<0.05$) across multiple CFTR nonsense mutations in cystic fibrosis patient-derived organoids. ELX-02 demonstrated significant forskolin-induced swelling (FIS) in cystic fibrosis patient-derived organoids carrying homozygous and compound heterozygous CFTR nonsense mutations. Eloxx reported that:

- ELX-02 demonstrated dose responsive increases in CFTR function and mRNA expression when tested in a correlative assay using organoids from cystic fibrosis patients with homozygous and heterozygous nonsense mutations. The FIS swelling was consistent across a range of concentrations of the swelling inducing agent, forskolin, and did not saturate in the timeframe of the assay. Additionally, the swelling response was demonstrated to be dependent on CFTR activity and the presence of a nonsense mutation. The response demonstrated is consistent with levels potentially predictive of clinical efficacy.

- Using nanoString™ technology, ELX-02 mediated organoid swelling was found to correlate with increased *CFTR* mRNA, with elevations above wild-type. ELX-02 appears to increase the steady state concentrations of *CFTR* mRNA suggesting that ELX-02 may be modulating nonsense mediated decay.

- The increased CFTR function demonstrated with ELX-02 was further enhanced with the addition of a potentiator and corrector in some organoids derived from patients with heterozygous nonsense mutations.

- These data demonstrate that ELX-02 promotes translation of functional CFTR and support continuing development of ELX-02 in patients with cystic fibrosis.

- The results from our Phase 1a single-ascending dose (SAD) study for ELX-02 have been submitted to a scientific journal for publication.

- We have begun the fifth cohort of our multiple-ascending dose (MAD) study for ELX-02.

ELX-02 is an investigational agent not approved by any regulatory agency for therapeutic use.

Third Quarter 2018 Financial Results

As of September 30, 2018, we had cash and cash equivalents of $55.3 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 September 30, 2018, of $11.2 million or $0.32 per share, which includes $2.7 million non-cash expense related to stock-based compensation. We incurred a net loss for the three months ended September 30, 2017, of $4.0 million, or $1.15 per share. For the three months ended September 30, 2018, the net cash used in operating activities was $8.1 million. For the three months ended September 30, 2017, the net cash used in operating activities was $3.8 million driven primarily by our net loss.

Our research and development expenses were $5.4 million for the three months ended September 30, 2018, compared to $3.3 million for the three months ended September 30, 2017, an increase of $2.1 million due to increased fees and salaries and growth in clinical development.

Our general and administrative expenses were approximately $5.9 million for the three months ended September 30, 2018 compared to approximately $0.7 million for the three months ended September 30, 2017, an increase of approximately $5.2 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 nine months ended September 30, 2018, of $33.2 million or $1.05 per share, which includes $9.6 million non-cash expenses related to stock-based compensation. The Company incurred a net loss for the nine months ended September 30, 2017, of $10.6 million, or $2.92 per share. For the nine months ended September 30, 2018, the net cash used in operating activities was $22.3 million. For the nine months ended September 30, 2017, the net cash used in operating activities was $9.7 million, driven primarily by our net loss.

Our research and development expenses were $14.0 million for the nine months ended September 30, 2018, compared to $8.2 million for the nine months ended September 30, 2017, an increase of $5.8 million due to increased fees and salaries and growth in clinical development.

Our general and administrative expenses were approximately $18.9 million for the nine months ended September 30, 2018 compared to approximately $1.6 million for the nine months ended September 30, 2017, an increase of approximately $17.3 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: Thursday, November 8, 2018

Time: 8:30 a.m. ET

Domestic Dial-in Number: (866) 913-8546
International Dial-in Number: (210) 874-7715

Conference ID: 4287229

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/adeeqo7a

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 fromulated 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 R&D 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:

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

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 55,336	$ 24,049
Restricted bank deposit	46	102
Prepaid expenses and other current assets	756	355
Total current assets	56,138	24,506
Property and equipment, net	345	278
Other long-term assets	52	—
Total	$ 56,535	$ 24,784
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,352	$ 1,530
Accrued expenses	3,727	1,893
Total current liabilities	5,079	3,423
Stockholders' equity:		
Preferred stock, $0.01 par value per share, 5,000,000 shares authorized, no shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock, $0.01 par value per share, 500,000,000 shares authorized, 35,124,844 and 27,527,738 shares issued at September 30, 2018 and December 31, 2017, respectively	351	274
Common stock in treasury, at cost, 8,385 and 0 shares at September 30, 2018 and December 31, 2017, respectively	(83)	—
Additional paid in capital	123,306	60,047
Accumulated deficit	(72,118)	(38,960)
Total stockholders' equity	51,456	21,361
Total	$ 56,535	$ 24,784

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Operating expenses:				
Research and development	$ 5,415	$ 3,280	$ 13,959	$ 8,230
General and administrative	5,945	720	18,898	1,581
Reverse merger related expenses	—	—	594	—
Total operating expenses	11,360	4,000	33,451	9,811
Loss from operations	(11,360)	(4,000)	(33,451)	(9,811)
Other (income) expense, net	(199)	40	(293)	785
Net loss	$ (11,161)	$ (4,040)	$ (33,158)	$ (10,596)
Weighted average number of common shares in computing basic and diluted net loss per share	35,005,979	4,208,088	31,485,067	4,206,226
Basic and diluted net loss per share	$ (0.32)	$ (1.15)	$ (1.05)	$ (2.92)