# 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 10, 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 rovisions:							
		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 hapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).							
	Emei	ging growth company $\Box$					
r rev		emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new inancial accounting standards provided pursuant to Section 13(a) of the Exchange Act.					

#### Item 2.02 Results of Operations and Financial Condition.

On May 10, 2018, Eloxx Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the first fiscal quarter ended March 31, 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 May 10, 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: May 10, 2018  $${\rm By:}\,$  /s/ Gregory Weaver

Gregory Weaver Chief Financial Officer



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

Company on track to initiate Phase 2 clinical trials for investigational drug ELX-02 in cystic fibrosis and cystinosis in 2018 and sufficiently funded to top line

Formation of Scientific Advisory Board with expertise in nonsense mutations and nonsense mediated decay

Company to host webcast and conference call on Thursday, May 10, 2018 at 4:30 pm ET

**Waltham, MA.** – May 10, 2018 – Eloxx Pharmaceuticals, Inc. ("Eloxx"), (ELOX, NASDAQ) 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 months ended March 31, 2018, and provided a business update.

#### **Recent Accomplishments**

- On April 30, 2018, the Company closed an underwritten public offering of 5,899,500 shares of common stock at the public offering price of \$9.75, raising net proceeds of \$53.4 million, after deducting underwriting discounts and commissions and estimated offering expenses.
- Eloxx was approved for listing on the Nasdaq Global Market and began trading under the symbol "ELOX" on Thursday, April 26, 2018.

"We are pleased to have successfully raised \$53.4 million in a public offering in April and to be trading on the Nasdaq. We are on track to seek regulatory clearance to initiate Phase 2 clinical trials for our lead investigational product candidate, ELX-02, in cystic fibrosis and cystinosis this year, and are funded through to top line data readouts," said Robert E. Ward, Chairman and CEO of Eloxx Pharmaceuticals. "We look forward to sharing additional scientific data for ELX-02 with the scientific community at the European Cystic Fibrosis Society Meeting in Belgrade, Serbia June 5-9, 2018. We are also extremely gratified to have attracted high caliber experts to our inaugural Scientific Advisory Board and expect that they will provide us with wise counsel as we advance our library of product candidates designed to be eukaryotic ribosomal selective glycosides."

## Development of Investigational Drug ELX-02 in Cystic Fibrosis and Cystinosis

We are currently developing our lead investigational drug, ELX-02, for the treatment of cystic fibrosis and cystinosis patients with diagnosed nonsense mutations. We have held pre-clinical trial application (CTA) discussions with the Federal Agency for Medicines and Health Products (FAMHP) in Brussels,

Belgium and pre-IND discussions with the U.S. Food & Drug Administration (FDA) for cystic fibrosis and cystinosis, respectively.

- We expect to submit our CTA in Belgium for cystic fibrosis in May 2018.
- We are on track for the submission of our IND in the U.S. for cystinosis soon after our CTA in Belgium.
- We completed the first two cohorts of our Phase 1 MAD study and dosing in the third cohort is ongoing. We anticipate the study will be completed in 2018. The results from the first two cohorts of the MAD study along with the results of the completed Phase 1 SAD study will be included in the planned CTA and IND submissions.
- The FDA granted orphan drug status for investigational drug ELX-02 for treatment of cystinosis.
- We expect to initiate Phase 2 studies in cystic fibrosis and cystinosis by the end of 2018, subject to regulatory review and clearance of our CTA
  and IND, respectively.

Currently, the European Medicines Agency (EMA) has designated ELX-02 as an orphan medicine for the treatment of mucopolysaccharidosis type I (MPS I), and the FDA has granted orphan drug designation to ELX-02 for the treatment of cystinosis, MPS I and for the treatment of Rett Syndrome.

#### 41st European Cystic Fibrosis Conference (ECFS)

Eloxx will present two abstracts at ECFS in Belgrade, Serbia, June 6-9, 2018, including one Later-Breaker, for our lead investigational candidate, ELX-02. The details of these presentations are as follows:

• Oral Presentation Title: "Translational read-through of CFTR nonsense mutations and inducement of cystic fibrosis transmembrane conductance regulator (CFTR) function by ELX-02"

Presenter: Neal Sharpe, Ph.D., Vice President, Translational Sciences, R & D, Eloxx Pharmaceuticals

Time: Thursday, June 7, 2018 from 3:30 pm - 3:45 pm CET, or 9:30 am - 9:45 am ET

Oral Late Breaker Presentation Title: "Evaluation of ELX-02 in Cystic Fibrosis Organoids with Non-Sense Mutations"

Presenter: Dr. Pedro Huertas, Chief Medical Officer, Eloxx Pharmaceuticals

Time: Friday, June 8, 2018 from 5:00 pm - 5:30 pm CET, or 11:00 am - 11:30 pm ET

#### **Scientific Advisory Board**

Eloxx announced today the formation of its inaugural Scientific Advisory Board (SAB) and the appointment of the following world leading experts:

 Timor Baasov, Ph.D., Irving and Jeanette Benveniste Chair in Life Sciences and Professor of Chemistry at the Schulich Faculty of Chemistry, Technion-Israel Institute of Technology, Haifa, Israel. Dr. Baasov is a recipient of the 2016 Israel Chemical Society Prize for Technological Innovation for developing new chemicals as therapeutic agents for the treatment of genetic

- diseases caused by nonsense mutations. Eloxx's technology is originated from the Technion, and results from research led by Prof. Baasov.
- David Bedwell, Ph.D., Professor and Chairman, James C. and Elizabeth T. Lee Endowed Chair of Biochemistry, Department of Biochemistry &
  Molecular Genetics, University of Alabama at Birmingham School of Medicine. Dr. Bedwell also currently serves as Associate Director of the Cystic
  Fibrosis Research Center and Co-Director of the UAB Structural Biology Program. He was elected Fellow of the American Academy of
  Microbiology in 2011. Dr. Bedwell's lab studies the mechanistic details of translation termination and Nonsense-Mediated mRNA Decay (NMD).
- Rachel Green, Ph.D., Bloomberg Distinguished Professor, Molecular Biology and Genetics, Howard Hughes Medical Institute, Johns Hopkins University. Dr. Green's work has focused on diverse aspects of translation and its regulation in bacteria, yeast, and higher eukaryotic systems using primarily biochemistry and high throughput sequencing approaches. Recent work on mRNA surveillance mechanisms in yeast has synergized with interests in ribosome homeostasis and translational control in various tissue types. She is an elected fellow of the National Academy of Sciences (2012), and the National Academy of Medicine (2017).
- Sudhir Kumar, Ph.D., Laurel H. Carnel Professor, and the founding Director of the Institute of Genomics and Evolutionary Medicine, Department of Biology, College of Science and Technology, Temple University. Dr. Kumar was elected Fellow of the American Association for the Advancement of Science for exemplary contributions in evolutionary bioinformatics, particularly in developing high-impact comparative analysis software for biologists and in illuminating the evolutionary dynamics of mutations and species through comparative genomics.
- Lynne Elizabeth Maquat, Ph.D., J. Lowell Orbison Endowed Chair and Professor of Biochemistry & Biophysics in the School of Medicine and Dentistry, Director of the Center for RNA Biology, and Chair of Graduate Women in Science at the University of Rochester, Rochester, NY, USA. After obtaining her Ph.D. in Biochemistry from the University of Wisconsin-Madison and undertaking post-doctoral work at the McArdle Laboratory for Cancer Research, she joined Roswell Park Cancer Institute before moving to the University of Rochester. Professor Maquat discovered nonsense-mediated mRNA decay (NMD) in 1981 and, subsequently while elucidating the mechanism of NMD, the exon-junction complex (EJC) and how the EJC marks mRNAs for a quality-control "pioneer" round of protein synthesis. She also discovered Staufen-mediated mRNA decay, which mechanistically competes with NMD and, by so doing, new roles for short interspersed elements and long non-coding RNAs. Additional current interests include microRNA decay and functional links between transcription factors and RNA-binding proteins. She is an elected Fellow of the American Association for the Advancement of Science (2006), and an elected Member of the American Academy of Arts & Sciences (2006), the National Academy of Sciences (2011), and the National Academy of Medicine (2017). Dr. Maquat was a Batsheva de Rothschild Fellow of the Israel Academy of Sciences & Humanities (2012-3) and has received the William C. Rose Award from the American Society for Biochemistry & Molecular Biology (2014), a Canada Gairdner International Award (2015), the international RNA Society Lifetime Achievement Award in Service (2010) and in Science (2017), the Vanderbilt Prize in Biomedical Science (2017).

Eloxx today also announced that it has entered into a technology evaluation agreement with Ionis Pharmaceuticals, Inc. to explore potential therapeutic applications of antisense technology and eukaryotic ribosomal selective glycosides for use in rare or ultrarare genetic disorders.

#### First Quarter 2018 Financial Results

As of March 31, 2018, we had cash and cash equivalents of \$18.3 million, On April 30, 2018, we closed on an underwritten public offering raising an estimated \$53.4 million, net of fees. 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 investigation product, ELX-02, in cystic fibrosis and cystinosis.

We incurred a loss for the three months ended March 31, 2018, of \$8.6 million or 0.31 per share, which includes one-time charges of \$2.1 million in working capital, and \$0.7 million non-cash expenses related to stock-based compensation. The Company incurred a net loss for the three months ended March 31, 2017, of \$2.7 million, or \$0.73 per share. For the three months ended March 31, 2018, the net cash used in operating activities was \$5.8 million. For the three months ended March 31, 2017, the net cash used in operating activities was \$2.7 million driven primarily by our net loss.

Our research and development expenses were \$4.0 million for the three months ended March 31, 2018, compared to \$2.4 million for the three month period ended March 31, 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 \$2.5 million for the three months ended March 31, 2018 compared to approximately \$0.3 million for the three months ended March 31, 2017, an increase of approximately \$2.2 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, as well as other personnel and facility related costs.

#### **Conference Call Information:**

Date: Thursday, May 10, 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/n7s8dtq6. 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 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**

Certain statements included in this press release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve a number of risks and uncertainties. These statements may be identified by introductory words such as "may," "expects," "plan," "believe," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. These include statements of management's intentions, beliefs, plans and future expectations and, therefore, you are cautioned not to place undue reliance on them. Such forward-looking statements involve risks and uncertainties and actual results could differ materially from any forward-looking statements expressed or implied herein. The risks and uncertainties that could result in actual results to differ materially from these forward-looking statements expressed or implied herein include, but are not limited to: 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 the 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 success of the Company's license agreements; 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; the ability of the Company to manage the transition to being listed on The Nasdaq Global Market; the ability of the Company to work with its Scientific Advisory Board; as well as other factors expressed from time to time in the Company's periodic filings with the Securities and Exchange Commission (the "SEC"). As a result, this press release should be read in conjunction with the Company's 10-K, 10-Qs and other filings with the SEC. The forward-looking statements contained herein are made only as of the date of this press release, and the Company undertakes no obligation to publicly update or revise such forward-looking statements to reflect subsequent events or circumstances.

Contact:

Barbara Ryan 203-274-2825 barbarar@eloxxpharma.com

## ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

# UNAUDITED CONSOLIDATED BALANCE SHEETS (in thousands, except share and per share data)

	March 31, 2018		Dec	December 31, 2017	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	18,290	\$	24,049	
Restricted bank deposit		106		102	
Prepaid expenses and other current assets		445		355	
Total current assets		18,841		24,506	
Property and equipment, net		314		278	
Total	\$	19,155	\$	24,784	
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	\$	2,173	\$	1,530	
Accrued expenses		3,478		1,893	
Total current liabilities		5,651		3,423	
Stockholders' equity:		<u></u>			
Series A, B-1, B-2 and C Preferred Stock; Preferred stock, \$0.01 par value 5,000,000 shares authorized, no shares					
issued and outstanding at March 31, 2018 and December 31, 2017		_		_	
Common stock, \$0.01 par value 500,000,000 shares authorized, 27,527,738 shares issued and outstanding at					
March 31, 2018 and December 31, 2017, respectively		274		274	
Additional paid in capital		60,782		60,047	
Accumulated deficit		(47,552)		(38,960)	
Total stockholders' equity		13,504		21,361	
Total		19,155	\$	24,784	

# ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

# UNAUDITED CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands, except share and per share data)

		Three Months Ended March 31,			
		2018		2017	
Operating expenses:					
Research and development	\$	4,013	\$	2,355	
General and administrative		2,480		277	
Reverse merger related expenses		2,055			
Total operating expenses		8,548		2,632	
Loss from operations		(8,548)		(2,632)	
Financial and other expenses		43		46	
Net loss	\$	(8,591)	\$	(2,678)	
Basic and diluted net loss per share	\$	(0.31)	\$	(0.73)	
Weighted average number of common shares in computing basic and diluted net loss per share	27	,527,738	4,	205,278	