UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-31326

ELOXX PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**84-1368850**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

950 Winter Street
Waltham, Massachusetts 02451
(Address of principal executive offices) (Zip Code)

781-577-5300
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

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: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On November 1, 2019, the registrant had 40,002,654 shares of common stock, $0.01 par value per share, outstanding.

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Special Note Regarding Forward-Looking Statements

Eloxx Pharmaceuticals, Inc., together with its subsidiaries, is collectively referred to herein as "we," "our," "us," "Eloxx" or the "Company". *Hyperlinks and web addresses are provided as a convenience and for informational purposes only. Eloxx bears no responsibility for the security or content of external websites.*

This Quarterly Report on Form 10-Q, or this Report, and the other documents we have filed with the SEC that are incorporated herein by reference, contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. In particular, you should consider the numerous risks described in the "Risk Factors" section in this Report.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. You should not rely upon forward-looking statements as predictions of future events. Unless required by law, we will not undertake and we specifically disclaim any obligation to release publicly the result of any revisions which may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of events, whether or not anticipated. In that respect, we wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made.

This Report and the other documents incorporated by reference herein may include statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

The following are some risks and uncertainties, among others, that could cause actual results to differ materially from those expressed or implied by forward looking statements in this Report:

- risks related 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;
- risks related to the scope, rate and progress of our preclinical studies and clinical trials and other research and development activities;
- risks related to the competition for patient enrollment from drug candidates in development;
- risks related to our ability to obtain the capital necessary to fund our operations;
- risks relating to the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- risks related to our ability to obtain adequate financing in the future through product licensing, public or private equity or debt financing or otherwise, as well as general business conditions, competition, and the availability of qualified personnel.

Item 1. Condensed Consolidated Financial Information

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,155	$ 48,606
Marketable securities	42,781	—
Restricted bank deposit	40	45
Prepaid expenses and other current assets	1,878	1,690
Total current assets	66,854	50,341
Property and equipment, net	220	248
Operating lease right-of-use asset	870	—
Other long-term assets	113	129
Total assets	$ 68,057	$ 50,718
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,687	$ 747
Accrued expenses	5,145	6,938
Current portion of long-term debt	3,488	—
Advances from collaboration partners	403	—
Current portion of operating lease liability	461	—
Taxes payable	43	122
Total current liabilities	11,227	7,807
Long-term debt	11,193	—
Operating lease liability	409	—
Stockholders' equity:		
Preferred stock, $0.01 par value per share, 5,000,000 shares authorized, no shares issued and outstanding at September 30, 2019 and December 31, 2018	—	—
Common stock, $0.01 par value per share, 500,000,000 shares authorized, 40,117,186 and 35,951,537 shares issued and 39,977,654 and 35,860,114 shares outstanding as of September 30, 2019 and December 31, 2018, respectively	404	360
Common stock in treasury, at cost, 139,532 and 91,423 shares at September 30, 2019 and December 31, 2018, respectively	(1,585)	(1,129)
Additional paid-in capital	171,783	129,825
Accumulated other comprehensive income	12	—
Accumulated deficit	(125,386)	(86,145)
Total stockholders' equity	45,228	42,911
Total liabilities and stockholders' equity	$ 68,057	$ 50,718

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND OTHER COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 6,801	$ 5,415	$ 20,160	$ 13,959
General and administrative	5,978	5,945	18,907	18,898
Reverse merger related expenses	—	—	—	594
Total operating expenses	12,779	11,360	39,067	33,451
Loss from operations	(12,779)	(11,360)	(39,067)	(33,451)
Other expense (income), net	96	(199)	174	(293)
Net loss	$ (12,875)	$ (11,161)	$ (39,241)	$ (33,158)
Other Comprehensive Loss:				
Net loss	$ (12,875)	$ (11,161)	$ (39,241)	$ (33,158)
Unrealized gain (loss) from available-for-sale securities	(12)	—	12	—
Comprehensive loss	$ (12,887)	$ (11,161)	$ (39,229)	$ (33,158)
Basic and diluted net loss per share	$ (0.32)	$ (0.32)	$ (1.05)	$ (1.05)
Weighted average number of common shares in computing basic and diluted net loss per share	39,944,324	35,005,979	37,394,310	31,485,067

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (39,241)	$ (33,158)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	8,631	9,608
Depreciation	68	121
Loss on disposal of property and equipment	—	12
Amortization of operating lease right-of-use asset	350	—
Amortization of debt discount	378	—
Amortization of premium and discount on investment	(228)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(150)	(401)
Other assets	—	(41)
Advances from collaboration partners	403	—
Accounts payable	940	(178)
Accrued expenses	(856)	1,730
Operating lease liabilities	(350)	—
Taxes payable	(79)	—
Net cash used in operating activities	(30,134)	(22,307)
Cash flows from investing activities:		
Purchases of marketable securities	(56,041)	—
Proceeds from maturity of marketable securities	13,500	6
Purchases of property and equipment	(40)	(133)
Cash paid for long-term deposits	(22)	(11)
Net cash used in investing activities	(42,603)	(138)
Cash flows from financing activities:		
Proceeds from underwritten public offerings, net of issuance costs	32,169	53,573
Proceeds from debt financing obligation	15,000	—
Payment of debt issuance costs	(276)	—
Payment for settlement of taxes upon vesting of restricted stock securities	(1,215)	—
Proceeds from sale of common stock under equity sales agreement	455	—
Proceeds from issuance of common stock on share-based compensation arrangements	148	103
Net cash provided by financing activities	46,281	53,676
(Decrease) increase in cash, cash equivalents and restricted cash	(26,456)	31,231
Cash, cash equivalents and restricted cash, beginning of period	48,651	24,151
Cash, cash equivalents and restricted cash, end of period	$ 22,195	$ 55,382
Reconciliation of cash, cash equivalents and restricted cash to condensed consolidated balance sheets		
Cash and cash equivalents	$ 22,155	$ 55,336
Restricted cash included in restricted bank deposit	40	46
Total cash, cash equivalents and restricted cash	$ 22,195	$ 55,382
Supplemental disclosure of cash flow activities		
Cash paid for interest	$ 703	$ —
Cash paid for income taxes	$ 79	$ —
Capital expenditures in liabilities for purchases of property, plant and equipment	$ —	$ 104
Supplemental disclosure of non-cash financing activities		
Non-cash acquisition of treasury shares	$ 46	$ 83
Non-cash issuance of shares upon exercise of warrants	$ 178	$ —
Fair value of warrants issued in connection with long-term debt	$ 421	$ —

See accompanying notes to unaudited condensed consolidated financial statements

1. Nature of the Business

Eloxx Pharmaceuticals, Inc., together with its subsidiaries (collectively "Eloxx" or the "Company"), is a clinical-stage biopharmaceutical company developing novel ribonucleic acid (RNA)-modulating drug candidates, each designed to be a eukaryotic ribosomal selective glycoside (ERSG), formulated to treat rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt the stability of the impacted messenger RNA (mRNA) and the protein synthesis from that mRNA. As a consequence, patients with premature stop codon diseases have reduced levels of, or no, protein from a gene whose product performs an essential function. This type of mutation accounts for some of the most severe phenotypes across genetic diseases. Nonsense mutations have been identified in over 1,800 rare and ultra-rare diseases. Read-through therapeutic development is focused on increasing mRNA stability and enabling functional protein synthesis. As opposed to a typical gene therapy approach of targeting a single, unique mutation in a target disease, this small molecule strategy enables targeting an entire class of mutations across the rare disease landscape. The small molecule approach has the potential to address a range of different premature stop codons in a single gene since the ERSG compounds are targeted to the ribosomes. ELX-02, the Company's lead investigational drug product candidate, is a small molecule designed to restore production of full-length functional proteins. ELX-02 is in clinical development for systemic administration for cystic fibrosis and nephropathic cystinosis. ELX-02 is an investigational drug that has not been approved by any global regulatory body. In addition, the Company recently announced a new program studying intravitreal administration of ERSG compounds for rare inherited retinal disorders with an initial focus on Usher Syndrome. During the quarter ended September 30, 2019, the Company advanced its clinical program for ELX-02 into Phase 2 studies in cystic fibrosis and nephropathic cystinosis. The Company also completed a renal impairment study with ELX-02 in subjects with mild, moderate, and severe renal impairment. The results from the renal impairment study provide support for both continuing the Company's clinical development programs and evaluating the suitability of its ERSG library for development in additional renal disorders, including autosomal dominant polycystic kidney disease and cystinuria. The Company's preclinical candidate pool consists of a library of novel ERSG drug candidates identified based on read-through potential and cytoplasmic ribosomal selectivity. The Company is headquartered in Waltham, MA, with additional offices in New Jersey, Pennsylvania and Rehovot, Israel.

The Company's research and development strategy is to target rare or ultra-rare diseases where a high unmet medical need exists, a nonsense mutation-bearing patient population is established, preclinical read-through can be established in predictive personalized medicine models, and a defined path through Orphan Drug development, regulatory approval, patient access and commercialization is identified. The Company believes patient advocacy to be an important element of patient focused drug development and seeks opportunities to collaborate with patient advocacy groups throughout the discovery and development process. The Company's current clinical program for its lead investigational drug product candidate, ELX-02, includes studies in both cystic fibrosis and nephropathic cystinosis.

During the quarter ended September 30, 2019, the Company announced that the Cystic Fibrosis Foundation (the "CF Foundation") is providing funding for a portion of the U.S. Phase 2 cystic fibrosis clinical trial and that it will form a joint program advisory group with the CF Foundation focused on the development of ELX-02 for cystic fibrosis. The Cystic Fibrosis Therapeutics Development Network ("TDN") has sanctioned the Phase 2 study protocol, which will be conducted at TDN member sites.

Liquidity

The Company has a history of net losses and negative cash flows from operating activities since inception, and as of September 30, 2019, had an accumulated deficit of $125.4 million. The Company expects to continue to incur net losses and use cash in its operations for the foreseeable future. To date, the Company has not generated revenue from the sale of any product or service and does not expect to generate significant revenue unless and until it obtains marketing approval for and commercializes its product candidates currently in development. Successful transition to profitable operations is dependent upon achieving a level of revenue adequate to support the Company's cost structure.

The Company has financed its operations primarily from the sale of equity securities and to a lesser extent, loans and grants. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital to fund its operations. The Company believes that its cash, cash equivalents and marketable securities of $64.9 million at September 30, 2019 will enable it to meet anticipated cash needs required to reach top line Phase 2 data in cystic fibrosis and in cystinosis and maintain the Company's current and planned operations into the first quarter of 2021. Management intends to fund future operations through private and public debt or equity financing transactions and may seek additional capital through arrangements with strategic partners or from other sources. If the Company is unable to obtain financing, it will evaluate options which may include reducing or deferring operating expenses, which may have a material adverse effect on the Company's operations and future prospects.

2. Summary of Significant Accounting Policies

Basis of presentation and principles of consolidation

The accompanying unaudited interim consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted, as permitted by such rules and regulations. These interim consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position, results of operations, and cash flows for the interim periods ended September 30, 2019 and 2018.

The unaudited Condensed Consolidated Statements of Operations include the Company's operating expenses related to research and development and general and administrative activities which were substantially comprised of fees for professional services and employee compensation. The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 14, 2019.

Summary of Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2018, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. During the nine months ended September 30, 2019, the Company invested in marketable securities and as a result has provided the following update.

Marketable Securities—All investment instruments with an original maturity date, when purchased, in excess of three months but less than 1 year have been classified as current marketable securities. The Company classifies securities that are available to fund current operations as current assets. These marketable securities are classified as available-for-sale and are carried at fair value. The Company records unrealized gains and losses on available-for-sale debt securities as a component of accumulated other comprehensive income, which is a separate component of stockholders' equity on its condensed consolidated balance sheet, until such gains and losses are realized. Realized gains and losses on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific identification method. The Company periodically reviews the portfolio of securities to determine whether an other-than-temporary impairment has occurred. No such losses have occurred to date. There were no realized gains or losses on the sale of securities for the three and nine months ended September 30, 2019.

Below is a summary of cash, cash equivalents and marketable securities at September 30, 2019 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash and cash equivalents	$ 22,155	$ —	$ —	$ 22,155
Marketable securities - U.S. treasuries	42,769	15	(3)	42,781
Total cash, cash equivalents and marketable securities	$ 64,924	$ 15	$ (3)	$ 64,936

Fair Value Measurements—Fair value is determined based on the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal market for the asset or liability in an orderly transaction between market participants. Authoritative guidance specifies a hierarchy of valuation techniques based upon whether the inputs to those valuation techniques reflect assumptions other market participants would use based upon market data obtained from independent sources (observable inputs) or reflect the Company's own assumptions of market participant valuation (unobservable inputs).

The fair value hierarchy consists of three levels:

Level 1 - Quoted prices ("unadjusted") in active markets that are unadjusted and accessible at the measurement date for identical, unrestricted assets or liabilities.
Level 2 - Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
Level 3 - Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Financial assets and liabilities are classified within the fair value hierarchy based on the lowest level of input that is significant to the fair value measurement. The authoritative guidance requires the use of observable market data if such data is available without undue cost and effort. When available, the Company uses unadjusted quoted market prices to measure fair value and classify such items within Level 1. If quoted market prices are not available, fair value is based upon internally developed models that use, where possible, current market-based or independently-sourced market parameters, such as interest and currency rates and comparable transactions. Items valued using internally generated models are classified according to the lowest level input or value driver that is significant to the valuation. Thus, items may be classified in Level 3 even though there may be inputs that are readily observable. If quoted market prices are not available, the valuation model used generally depends on the specific asset or liability being valued. At September 30, 2019, the Company's financial assets valued based on Level 1 inputs consisted of cash, cash equivalents and marketable securities (U.S. treasuries). During the three and nine months ended September 30, 2019, the Company did not have any transfers of financial assets between Level 2 and 3.

Some assets and liabilities are required to be recorded at fair value on a recurring basis, while other assets and liabilities are recorded at fair value on a nonrecurring basis. The carrying amounts of current financial instruments, which include accounts payable, accrued expenses, lease obligation liability and debt, approximate their fair values due to the short-term nature of these instruments.

Concentrations of Credit Risk and Off-Balance-Sheet Risk—Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents and available-for-sale marketable securities. The Company mitigates its risk with respect to cash and cash equivalents and marketable securities by maintaining its deposits and investments at high-quality financial institutions. The Company invests any excess cash in money market funds and other securities, and the management of these investments is not discretionary on the part of the financial institution. The Company has no significant off-balance-sheet risks such as foreign exchange contracts, option contracts, or other hedging arrangements.

Recent Accounting Pronouncements – Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases* ("ASU 2016-02"). ASU 2016-02 establishes ASC Topic 842 ("Topic 842") which amends ASC 840, *Leases*, by introducing a lessee model that requires balance sheet recognition for most leases and the disclosure of key information about leasing arrangements. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the income statement. Topic 842 provides several optional practical expedients in transition. The Company elected the package of practical expedients which would allow the Company to not reassess its existing conclusions on lease identification, classification and initial direct costs. Further, the Company elected the hindsight practical expedient and utilized the short-term lease exemption for all leases with an original term of 12 months or less for purposes of applying the recognition and measurement requirements of the new standard. The Company elected the practical expedient which allowed it to not separate lease and non-lease components for all its leases. The Company adopted the new standard on January 1, 2019 and applied the effective date as its date of initial application and has not updated disclosures required under the new standard for dates and periods prior to January 1, 2019. See Note 6.

Recent Accounting Pronouncements – Pending Adoption

In June 2016, the FASB issued ASU 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). This standard requires that for most financial assets, losses be based on an expected loss approach which includes estimates of losses over the life of exposure that considers historical, current and forecasted information. Expanded disclosures related to the methods used to estimate the losses as well as a specific disaggregation of balances for financial assets are also required. This standard is effective for annual periods beginning after December 15, 2019 and interim periods within those annual periods, with early adoption permitted for annual periods beginning after December 15, 2018. The Company is assessing the impact the adoption of ASU 2016-13 may have on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which modifies the disclosure requirements for fair value measurements. The new standard is effective for the Company on January 1, 2020. Early adoption is permitted. The Company is evaluating the impact the adoption of ASU 2018-13 may have on its disclosures.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets as of September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	As of	
	September 30, 2019	December 31, 2018
Prepaid research and development	$ 667	$ 864
Prepaid other	533	555
Other receivable	403	—
Prepaid insurance	269	251
Other governmental agencies receivables	6	20
	$ 1,878	$ 1,690

4. Property and Equipment

Property and equipment as of September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	As of	
	September 30, 2019	December 31, 2018
Computers and software	$ 170	$ 146
Office furniture and equipment	164	165
Leasehold improvements	158	141
	492	452
Less: Accumulated depreciation	(272)	(204)
Property and equipment, net	$ 220	$ 248

Depreciation expense was $18 thousand and $75 thousand for the three months ended September 30, 2019 and 2018 and $68 thousand and $121 thousand for the nine months ended September 30, 2019 and 2018, respectively.

5. Accrued Expenses

Accrued expenses as of September 30, 2019 and December 31, 2018 consisted of the following (in thousands):

	As of	
	September 30, 2019	December 31, 2018
Research and development expenses	$ 2,032	$ 3,086
Payroll, bonus and other employee-related expenses	1,983	2,562
Professional services	801	985
Accrued other	233	305
Accrued interest on debt	96	—
	$ 5,145	$ 6,938

6. Leases

The Company adopted the new lease accounting standard, Topic 842, effective January 1, 2019. The Company has elected the 'package of practical expedients', which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. In addition, the Company elected not to apply Topic 842 to arrangements with lease terms of 12 months or less. The Company has operating leases for its principal offices in the U.S. and Israel.

Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent the Company's obligation to make lease payments arising from its operating leases. In determining the length of the lease term to its long-term lease, the Company determined not to consider an embedded renewal option for one operating lease primarily due to i) the renewal rate is at future market rate to be determined and ii) Company does not have significant leasehold improvements that would restrict its ability to consider relocation. The Company applied its incremental borrowing rate based upon information available in determining the present value of the lease payments. The Company's incremental borrowing rate is determined using a secured borrowing rate for the same currency and term as the associated lease.

Operating lease costs under the leases for the three and nine months ended September 30, 2019 were approximately $0.1 million and $0.4 million, respectively. Lease expense for these leases is recognized on a straight-line basis over the lease term, with variable lease payments recognized in the period those payments are incurred. At lease commencement date, the Company estimated the lease liability and the right-of-use assets at present value using the Company's estimated incremental borrowing rate of 8% and determined the initial present value, at inception, of $1.5 million. On January 1, 2019, upon adoption of Topic 842, the Company recorded right-of-use assets of $1.2 million and lease liabilities of $1.2 million. These assets and obligations are reflected within 'Operating lease right-of-use asset', and 'Operating lease liability', respectively, on the unaudited Condensed Consolidated Balance Sheet. The weighted average remaining lease term at September 30, 2019 was 1.8 years.

The following table summarizes the Company's maturities of operating lease liabilities as of September 30, 2019 (in thousands):

Remainder of 2019	$ 138
2020	493
2021	310
Total lease payments	941
Less: present value discount	(71)
Total	$ 870

For comparative purposes, the Company's aggregate future minimum non-cancellable commitments under operating leases as of December 31, 2018 were as follows (in thousands):

2019	$	541
2020		490
2021		310
Total minimum lease payments	$	1,341

7. Debt

On January 30, 2019, the Company entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB") and WestRiver Innovation Lending Fund VIII, L.P. ("WestRiver", and together with SVB, the "Lenders"). Under the SVB Loan Agreement, the Lenders agreed to extend term loans to the Company in an aggregate principal amount of $25.0 million, comprised of (i) an initial loan advance of $15.0 million; and (ii) a subsequent loan advance of $10.0 million, subject to first achieving certain conditions (collectively, the "Term Loan Advances"). The initial term loan was funded on January 30, 2019. The subsequent term loan advance is available until December 31, 2019 at the Company's election after the occurrence of certain milestone events relating to data from the Company's clinical trials and receipt by the Company of certain minimum cash proceeds of at least $75 million from an additional equity offering through a private placement or a public offering.

Any outstanding principal on the Term Loan Advances will accrue interest at a floating rate equal to the greater of (i) 5.25% per annum and (i) the sum of 2.5% plus the prime rate, as published in the Wall Street Journal. Interest payments are payable monthly following the funding of a Term Loan advance. On September 30, 2019, the rate was 7.65%. The Company will be required to make principal payments on the outstanding balance of the Term Loan Advances commencing on February 1, 2020 (the "Term Loan Amortization Date") in 36 equal monthly installments, plus interest; provided that if the Company has achieved the milestones described above relating to the availability of the subsequent loan advance on or prior to December 31, 2019, then the Term Loan Amortization Date is automatically extended to February 1, 2021. Any amounts outstanding under the Term Loan Advances, if not repaid sooner, are due and payable on January 1, 2023 (the "Maturity Date").

In conjunction with the initial loan advance, the Company issued warrants (the "Warrants") to SVB and WestRiver to purchase an aggregate of 40,834 shares of the Company's common stock at a warrant exercise price of $11.02 (subject to certain adjustments), which price was calculated using the 10-day average bid price of the Company's common stock prior to the date of the SVB Loan Agreement. If the subsequent term loan is advanced, the Company will be obligated to issue Warrants to the Lender to purchase an aggregate of 27,222 shares of the Company's common stock.

The Company may prepay the outstanding principal balance of the term loans advanced by SVB in whole but not in part, subject to a prepayment fee ranging from 1% to 3% of any amount prepaid, depending upon when the prepayment occurs. The Company will also pay a final payment fee equal to 6% of the total term loans advanced, due upon the earliest of maturity or termination of the SVB Loan Agreement.

Under the terms of the SVB Loan Agreement, the Company granted first priority liens and security interests in substantially all of the Company's assets (excluding all of its intellectual property, which is subject to a negative pledge) and a pledge by the Company of the shares of one of its wholly-owned subsidiaries as collateral for the obligations thereunder. The SVB Loan Agreement also contains representations and warranties by the Company and SVB and indemnification provisions in favor of SVB and customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividends, but no financial covenants), and events of default (including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of SVB's security interest in the collateral, and events relating to bankruptcy or insolvency).

As of September 30, 2019, the carrying value of the term loan consists of $15.0 million principal outstanding less the unamortized debt issuance costs of approximately $1.2 million. The debt issuance costs have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the term loan. Interest expense relating to the term loan for the three and nine months ended September 30, 2019 was $0.4 million and $1.2 million, respectively. Interest expense is calculated using the effective interest method and is inclusive of non-cash amortization of capitalized loan costs. At September 30, 2019, the effective interest rate was 12.65%. The final maturity payment of $0.9 million is recognized over the life of the term loan through interest expense using the effective interest method.

The Company's scheduled future principal payments for the long-term debt are as follows (in thousands):

	September 30, 2019
Remainder of 2019	$ —
2020	4,583
2021	5,000
2022	5,000
2023	417
Total future principal payments	15,000
Less: unamortized discount	(1,219)
Carrying value of long-term debt	13,781
Less: current portion	(3,488)
Add: Final fee due at maturity in 2023	900
Long-term portion	$ 11,193

8. Legal and Other Contingencies

From time to time, the Company may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. The Company is currently unaware of any material pending legal proceedings to which it is a party or of which its property is the subject. However, the Company may at times in the future become involved in litigation in the ordinary course of business, which may include actions related to or based on its intellectual property and its use, customer claims, employment practices and employee complaints and other events arising out of its operations. When appropriate in management's estimation, the Company will record adequate reserves in its financial statements for pending litigation. Litigation is subject to inherent uncertainties, and an adverse result in any such matters could adversely impact its reputation, operations, and its financial operating results or overall financial condition. Additionally, any litigation to which the Company may become subject could also require significant involvement of its senior management and may divert management's attention from its business and operations.

The Company accounts for its contingent liabilities in accordance with ASC Topic 450, "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. For the periods ended September 30, 2019 and 2018, the Company was not a party to any litigation that is reasonably possible to have a material adverse effect on the Company's business, financial position, results of operations or cash flows. Legal costs incurred in connection with loss contingencies are expensed as incurred.

During the quarter ended September 30, 2019, the Company received a funding award from the CF Foundation and entered into an agreement relating to the award and provision of other services. Payment of award amounts are subject to achievement of certain milestones in connection with the Company's cystic fibrosis development program in the U.S. The funding provided to the Company is accounted for as an advance from a collaboration partner within the scope of ASC Topic 730, "Research and Development." The Company recorded a liability for advances from collaboration partners of $0.4 million as of September 30, 2019.

9. Stockholders' Equity

For accounting purposes, all common stock, preferred stock, warrants, options to purchase common stock and loss per share amounts have been adjusted to give retroactive effect to the exchange ratio and reverse stock split for all periods presented in these condensed unaudited consolidated financial statements.

On April 30, 2018, the Company completed an underwritten public offering of 5,899,500 shares of common stock at the public offering price of $9.75 per share and received net proceeds of approximately $53.6 million after deducting underwriting discounts and commissions and estimated offering expenses.

On June 24, 2019, the Company completed an underwritten public offering of 3,833,334 shares of common stock of the Company at the public offering price of $9.00 per share and received net proceeds of approximately $32.2 million after deducting underwriting discounts and commissions of $2.1 million and estimated offering expenses of $0.2 million.

Transactions related to stockholders' equity of the Company during the three and nine months ended September 30, 2019 were as follows (in thousands, except share data):

	Common stock					Treasury stock		
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated deficit	Shares	Amount	Total stockholders' equity
Balance at December 31, 2018	35,860,114	$ 360	$ 129,825	$ —	$ (86,145)	(91,423)	$ (1,129)	$ 42,911
Exercise of stock options	25,000	—	25	—	—	—	—	25
Vesting of restricted stock units	25,132	—	—	—	—	(10,467)	(121)	(121)
Issuance of shares from at-the-market sales agreement	35,362	1	454	—	—	—	—	455
Issuance of warrants	—	—	421	—	—	—	—	421
Stock-based compensation	—	—	2,658	—	—	—	—	2,658
Change in unrealized gain (loss) on investments	—	—	—	1	—	—	—	1
Net loss	—	—	—	—	(11,917)	—	—	(11,917)
Balance at March 31, 2019	35,945,608	$ 361	$ 133,383	$ 1	$ (98,062)	(101,890)	$ (1,250)	$ 34,433
Exercise of stock options	36,790	—	90	—	—	—	—	90
Issuance of shares upon exercise of warrants	44,814	—	178	—	—	(14,893)	(178)	—
Vesting of restricted stock units	54,122	3	(3)	—	—	(11,914)	(111)	(111)
Issuance of shares upon equity financing, net of the underwriting discounts and commissions and offering expenses	3,833,334	38	32,184	—	—	—	—	32,222
Stock-based compensation	—	—	3,016	—	—	—	—	3,016
Change in unrealized gain (loss) on investments	—	—	—	23	—	—	—	23
Net loss	—	—	—	—	(14,449)	—	—	(14,449)
Balance at June 30, 2019	39,914,668	$ 402	$ 168,848	$ 24	$ (112,511)	(128,697)	$ (1,539)	$ 55,224
Exercise of stock options	29,537	—	28	—	—	—	—	28
Vesting of restricted stock units	33,449	2	—	—	—	(10,835)	(46)	(44)
Equity financing issuance costs	—	—	(50)	—	—	—	—	(50)
Stock-based compensation	—	—	2,957	—	—	—	—	2,957
Change in unrealized gain (loss) on investments	—	—	—	(12)	—	—	—	(12)
Net loss	—	—	—	—	(12,875)	—	—	(12,875)
Balance at September 30, 2019	39,977,654	$ 404	$ 171,783	$ 12	$ (125,386)	(139,532)	$ (1,585)	$ 45,228

Transactions related to stockholders' equity of the Company during the three and nine months ended September 30, 2018 were as follows (in thousands, except share data):

	Common stock		Additional Paid-in Capital	Accumulated deficit	Treasury stock		Total stockholders' equity
	Shares	Amount			Shares	Amount	
Balance at December 31, 2017	27,527,738	$ 274	$ 60,047	$ (38,960)	—	$ —	$ 21,361
Stock-based compensation	—	—	735	—	—	—	735
Net loss	—	—	—	(8,591)	—	—	(8,591)
Balance at March 31, 2018	27,527,738	$ 274	$ 60,782	$ (47,551)	—	$ —	$ 13,505
Exercise of stock options	808,443	8	89	—	—	—	97
Issuance of shares upon Technion settlement	569,395	6	(6)	—	—	—	—
Issuance of shares upon execution of warrants	60,989	1	51	—	(3,385)	(52)	—
Issuance of shares upon public offering	5,899,500	60	53,513		—	—	53,573
Repurchase of common shares	(5,076)	—	—	—	(5,000)	(31)	(31)
Stock-based compensation	—	—	6,178	—	—	—	6,178
Net loss	—	—	—	(13,406)	—	—	(13,406)
Balance at June 30, 2018	34,860,989	$ 349	$ 120,607	$ (60,957)	(8,385)	$ (83)	$ 59,916
Exercise of stock options	255,394	2	4	—	—	—	6
Issuance of shares upon execution of warrants	3,385	—	—	—	—	—	—
Repurchase of common shares	5,076	—	—	—	—	—	—
Stock-based compensation	—	—	2,695	—	—	—	2,695
Net loss	—	—	—	(11,161)	—	—	(11,161)
Balance at September 30, 2018	35,124,844	$ 351	$ 123,306	$ (72,118)	(8,385)	$ (83)	$ 51,456

Warrants

In connection with the January 2019 issuance of debt, the Company granted 40,834 warrants to purchase 40,834 shares of common stock and recorded a charge in additional paid-in-capital in the amount of $0.4 million reflecting the fair value of the warrants on the date of issuance.

During the six months ended June 30, 2019, a warrant holder exercised their warrant for a total of 59,707 shares at a weighted average exercise price of $3.01 per share. This exercise has been recorded on a non-cash basis net of shares held as treasury stock. No warrants were granted, exercised or forfeited during the three months ended September 30, 2019.

Transactions related to warrants to purchase the Company's common stock during the nine months ended September 30, 2019, were as follows:

	Shares	Weighted average exercise price	Weighted average remaining contractual life
Warrants outstanding and exercisable at December 31, 2018	347,241	$ 3.77	3.92
Granted	40,834	11.02	10.00
Exercised	(59,707)	3.01	—
Forfeited	(4,474)	40.00	—
Warrants outstanding and exercisable at September 30, 2019	323,894	$ 4.32	3.99

10. Stock-Based Compensation

Stock Incentive Plans

On March 12, 2018, the Company's Board of Directors (the "Board") adopted the 2018 Equity Incentive Plan (the "2018 Plan"). The 2018 Plan became effective on April 20, 2018 upon approval by the stockholders of the Company with the outstanding options and shares available for future grant under the Sevion 2008 Incentive Compensation Plan (the "2008 Plan") and the Eloxx Limited 2013 Share Ownership and Option Plan (the "2013 Plan") being assumed by the 2018 Plan and the total number of shares available for awards to employees, non-employee directors and other key personnel increased by 5,000,000 shares. Upon the 2018 Plan becoming effective, the Company ceased granting awards under each of the 2008 Plan and the 2013 Plan.

Stock options granted have a ten-year contractual life and, upon termination, vested options are generally exercisable between one and three months following the termination date, while unvested options are forfeited immediately.

Summary of Option Activity

Transactions related to the grant of stock options to employees and directors during the nine months ended September 30, 2019 were as follows:

	Shares	Weighted average exercise price	Weighted average remaining contractual life	Aggregate intrinsic value
Options outstanding at December 31, 2018	3,261,719	$ 13.09	8.56	$ 11,650,373
Granted	1,780,200	9.43		
Exercised	(91,327)	12.98		
Forfeited	(153,552)	12.76		
Options outstanding at September 30, 2019	4,797,040	$ 11.96	8.54	$ 1,121,950
Options exercisable at September 30, 2019	1,730,606	$ 13.69	7.55	$ 1,024,195

The aggregate intrinsic value represents the total intrinsic value (the difference between the deemed fair value of the Company's common stock as of September 30, 2019 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on September 30, 2019. This amount is impacted by the changes in the fair value of the Company's common stock.

Summary of Restricted Stock Unit Activity

Transactions related to the grant of restricted stock units to employees and directors during the nine months ended September 30, 2019 were as follows:

	Shares	Weighted average grant date fair value price
Unvested at December 31, 2018	554,147	$ 9.34
Granted	100,000	11.53
Vested	(145,919)	9.90
Forfeited	—	—
Unvested at September 30, 2019	508,228	$ 9.61

In December 2017, the Company issued an inducement award outside of the prior plans to the Company's Chief Executive Officer in the form of an option to purchase 22,427 shares of the Company's common stock with an exercise price per share equal to $8.00, and an award of restricted stock units for 22,427 shares of the Company's common stock (collectively the "Performance Option Awards"). Subject to continued service through the vesting date, the Performance Option Awards will vest and become immediately exercisable upon the date that marks the first successful completion of a Phase2-B study with respect to any indication. For each of the three months ended September 30, 2019 and September 30, 2018, the Company recognized $24 thousand of expense associated with these awards and for each of the nine months ended September 30, 2019 and September 30, 2018, the Company recognized $73 thousand of expense associated with these awards.

In addition, in December 2017, the Company issued an inducement award outside of the prior plans to the Company's Chief Executive Officer in the form of an option to purchase 640,785 shares of the Company's common stock with an exercise price per share equal to $8.00, and an award of restricted stock units for 640,785 shares of the Company's common stock (collectively the "Time-Vesting Awards"). Subject to continued service through the vesting date, 1/3 of the Time-Vesting Awards will vest and become immediately exercisable on the first anniversary of the grant date, with an additional 1/12 of the Time-Vesting Awards vesting on each quarterly anniversary of the grant date, provided that vesting of the Time-Vesting Awards shall be subject to acceleration following the achievement of certain milestones.

Stock-based compensation relates to stock options granted to employees, non-employee directors and non-employees, time-based restricted stock units granted to employees and performance-based stock options and restricted stock units granted to an employee. The total equity-based compensation expense related to all of the Company's equity-based awards were recognized as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Research and development	$ 718	$ 498	$ 1,987	$ 909
General and administrative	2,239	2,197	6,644	8,699
Total stock-based compensation expenses	$ 2,957	$ 2,695	$ 8,631	$ 9,608

11. Other Expense (Income), Net

Other expense (income), net consisted of the following (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Interest and other income	$ (272)	$ (223)	$ (766)	$ (368)
Investment income, net	(92)	—	(224)	—
Interest and other expense	460	24	1,164	75
Total other expense (income), net	$ 96	$ (199)	$ 174	$ (293)

12. Net Loss Per Share

The loss and the weighted average number of shares used in computing basic and diluted net loss per share for the periods, is as follows (amounts in thousands, except share data):

	Three months ended September 30,		Nine months ended September 30,	
	2019	2018	2019	2018
Numerator:				
Net loss	$ (12,875)	$ (11,161)	$ (39,241)	$ (33,158)
Denominator:				
Shares used in computing net loss per share of common stock, basic and diluted(1)	39,944,324	35,005,979	37,394,310	31,485,067
Net loss per share of common stock, basic and diluted	$ (0.32)	$ (0.32)	$ (1.05)	$ (1.05)

(1) The following potentially dilutive securities have been excluded from the computation of diluted weighted average shares outstanding as their effect would be anti-dilutive:

	Nine months ended September 30,	
	2019	2018
Options to purchase common stock	4,797,040	3,611,400
Restricted stock units	508,228	767,743
Warrants	323,894	347,241
Total potential common stock equivalents	5,629,162	4,726,384

13. Reverse Merger

On December 19, 2017, Sevion Therapeutics, Inc. ("Sevion") acquired Eloxx Pharmaceuticals, Limited ("Eloxx Limited") pursuant to a merger between the companies (the "Transaction" or "Reverse Merger"). Upon consummation of the Transaction (the "Closing"), Sevion adopted the business plan of Eloxx Limited and discontinued the pursuit of Sevion's pre-Closing business plan. In connection with the Transaction, Sevion agreed to acquire all of the outstanding capital stock of Eloxx Limited in exchange for the issuance of an aggregate 20,316,656 shares of the Sevion's common stock, par value $0.01 per share, after giving effect to a 1-for-20 reverse split effected immediately prior to the Transaction. Immediately after giving effect to the Transaction, on December 19, 2017, Sevion changed its name to Eloxx Pharmaceuticals, Inc.

The Reverse Merger was accounted for as a reverse recapitalization which is outside the scope of ASC Topic 805, "Business Combinations". Under reverse capitalization accounting, Eloxx Limited is considered the acquirer for accounting and financial reporting purposes and acquired the assets and assumed the liabilities of the Company. The assets acquired and liabilities assumed are reported at their historical amounts. The annual consolidated financial statements of the Company reflect the operations of the acquirer for accounting purposes together with a deemed issuance of shares, equivalent to the shares held by the former stockholders of the legal acquirer and a recapitalization of the equity of the accounting acquirer. The annual consolidated financial statements include the accounts of the Company since the effective date of the reverse capitalization and the accounts of Eloxx Limited since inception.

The following summarizes the estimated fair value of the assets and liabilities assumed at the date of the Reverse Merger (in thousands):

	December 19, 2017
Cash and cash equivalents	$ 123
Prepaid expenses and other current assets	220
Property, plant and equipment, net	39
Restricted bank deposits	6
Total assets acquired	388
Accounts payable	(215)
Accrued expenses	(343)
Total liabilities acquired	(558)
Total net liabilities acquired	$ (170)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q, or this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business, includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the important factors discussed under the caption "Risk Factors" in this Report. These and other factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Report.

Company Overview

We are a clinical-stage biopharmaceutical company developing novel ribonucleic acid (RNA)-modulating drug candidates, each designed to be a eukaryotic ribosomal selective glycoside (ERSG), formulated to treat rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt the stability of the impacted messenger RNA (mRNA) and the protein synthesis from that mRNA. As a consequence, patients with premature stop codon diseases have reduced levels of, or no, protein from a gene whose product performs an essential function. This type of mutation accounts for some of the most severe phenotypes across genetic diseases. Nonsense mutations have been identified in over 1,800 rare and ultra-rare diseases. Read-through therapeutic development is focused on increasing mRNA stability and enabling functional protein synthesis. As opposed to a typical gene therapy approach of targeting a single, unique mutation in a target disease, this small molecule strategy enables targeting an entire class of mutations across the rare disease landscape. Our small molecule approach has the potential to address a range of different premature stop codons in a single gene since our ERSG compounds are targeted to the ribosomes. ELX-02, our lead investigational drug product candidate, is a small molecule designed to restore production of full-length functional proteins. ELX-02 is in the early stages of clinical development for systemic administration for cystic fibrosis and nephropathic cystinosis. ELX-02 is an investigational drug that has not been approved by any global regulatory body. In addition, we recently announced a new program studying intravitreal administration of ERSG compounds for rare inherited retinal disorders with an initial focus on Usher Syndrome.

During the quarter ended September 30, 2019, we advanced our clinical program for ELX-02 into Phase 2 studies in cystic fibrosis and nephropathic cystinosis. We also completed a renal impairment study with ELX-02 in subjects with mild, moderate, and severe renal impairment. The results from the renal impairment study provide support for both continuing our clinical development programs and evaluating the suitability of our ERSG library for development in additional renal disorders, including autosomal dominant polycystic kidney disease, and cystinuria. Our preclinical candidate pool consists of a library of novel ERSG drug candidates identified based on read-through potential and cytoplasmic ribosomal selectivity.

Our research and development strategy targets rare or ultra-rare diseases where a high unmet medical need exists, identified nonsense mutation-bearing patient population is established, preclinical read-through can be established in predictive personalized medicine models, and a defined path through Orphan Drug development, regulatory approval, patient access and commercialization is identifiable. We believe patient advocacy to be an important element of patient focused drug development and seek opportunities to collaborate with patient advocacy groups throughout the discovery and development process. Our current clinical program for our lead investigational drug product candidate, ELX-02, includes studies in both cystic fibrosis and nephropathic cystinosis.

We intend to be the global leader in the application of the science of translational read-through and the associated pathway of nonsense mediated decay (NMD). We believe that expanding our expertise across these basic science areas of mRNA regulation, ribosomal function, and protein translation forms a solid foundation to support our discovery and development activities. Our ERSG compounds modulate the activity of the ribosome, a complex of RNAs and proteins, and therefore, a ribonucleoprotein, responsible for protein production, a process also known as translation. These novel small molecule ERSG compounds are designed to allow the ribosome to read-through a nonsense mutation in mRNA (which is transcribed from the DNA sequence), to restore the translation process to produce full-length, functional proteins and increase the amount of mRNA that would otherwise be degraded as part of a phenomenon called nonsense mediated mRNA decay. As our ERSG compounds target the general mechanism for protein production in the cell, we believe they have the potential to treat hundreds of genetic diseases where nonsense mutations have impaired gene function. Since nonsense mutations may occur at different positions within a given gene, a potential advantage of the small molecule ERSG approach is being able to use one molecule to address a range of mutations within a given disease state. Our subcutaneously injected ERSG molecules have the potential to be self-administered for systemic disease and to be active at most tissue locations across the body.

We believe that our library of related novel small molecules holds the potential to be disease-modifying therapies that may change the course of hundreds of genetic diseases and improve the lives of patients. Our early preclinical data in animal models of nonsense mutations suggests that drug product candidates from our read-through compound ERSG library may have potential beneficial effects for the following diseases: cystic fibrosis, nephropathic cystinosis, a variety of inherited retinal disorders (including Usher Syndrome), primary ciliary dyskinesia, autosomal dominant polycystic kidney disease, cystinuria, mucopolysaccharidosis type 1, Duchenne muscular dystrophy and Rett syndrome, and have shown potential for beneficial effects in multiple organs such as the brain, eye, kidney, muscles and others. Of the novel compounds in our ERSG library, approximately 30 compounds have been selected, based on read-through activity, for continued preclinical research and we anticipate additional compounds advancing toward Investigation New Drug (IND) filings.

Currently our lead program, ELX-02, is focused on development for cystic fibrosis and nephropathic cystinosis patients with diagnosed nonsense mutations. With ELX-02, we have completed a Phase 1 single ascending dose (SAD) trial at sites in Israel (ClinicalTrials.gov Identifier: NCT02807961) and Belgium (ClinicalTrials.gov Identifier: NCT03292302), a multiple ascending dose (MAD) trial in Belgium and the U.S. (ClinicalTrials.gov Identifier: NCT03309605), and a renal impairment study in the U.S. (ClinicalTrials.gov Identifier: NCT03776539) with subjects having mild, moderate and severe renal impairment. The results of the SAD study were published in the Journal of Clinical Pharmacology in Drug Development in January 2019.

In Canada, our nephropathic cystinosis CTA is approved and with the support of the Genome Canada Genomic Applications Partnership Program, we are currently enrolling 6 patients in this Phase 2 clinical trial (ClinicalTrials.gov Identifier: NCT04069260). Dr. Paul Goodyer, Professor of Pediatrics at McGill University, is serving as our principal investigator. This trial will evaluate multiple doses of ELX-02 for the primary endpoint of safety and exploratory endpoints that will include white blood cell cystine levels. Our Phase 2 cystinosis trial involves two sequential cohorts with three escalating doses per cohort. A cohort is complete when each patient has escalated through each of the three dosing levels or if the Safety Review Committee recommends halting escalation. Following the completion of each dose, the Safety Review Committee meets to review the patient safety data prior to escalation to the next dose level. The first two doses in the first cohort are complete and the safety review committee has authorized us to start the final dose in this first cohort which is currently ongoing. To date, based on preliminary results, ELX-02 has been well tolerated through the first two dose levels, and at the second 1.0 mg/kg dose level, ELX-02 demonstrated a statistically significant reduction in white blood cell cystine levels. Upon completion of the first cohort, we will review data with the Principal Investigator and conduct a separate review with a panel of cystinosis scientific and clinical experts before reporting top line data later this year. We believe that the emerging profile of ELX-02 for cystinosis is suitable for continued development and we intend to seek regulatory advice, following top line results, on initiating an extension study for patients in the first cohort and to expand the trial to include sites and patients in the United States. We believe that achievement of proof of concept for ELX-02 in cystinosis will provide a basis for expansion to studies of additional kidney diseases, as well as increasing our probability of success in other clinical uses of this dosage range.

We are actively recruiting patients for two Phase 2 cystic fibrosis trials at sites in Europe and Israel and also in the United States. During the quarter ended September 30, 2019, we announced that the Cystic Fibrosis Foundation (the “CF Foundation”) is providing funding for a portion of the U.S. Phase 2 cystic fibrosis clinical trial and that we will form a joint program advisory group with the CF Foundation focused on the development of ELX-02 for cystic fibrosis. The Cystic Fibrosis Therapeutics Development Network (“TDN”) has sanctioned the Phase 2 study protocol (ClinicalTrials.gov Identifiers: NCT04126473 and NCT04135495), which will be conducted at TDN member sites. For the U.S. trial, Dr. Ahmet Uluer, Director of the Adult Cystic Fibrosis Program at the Boston Children’s Hospital/ Brigham and Women’s Hospital CF Center, is the lead study investigator and Boston Children’s Hospital is currently recruiting patients for the trial. We are opening additional clinical sites for the U.S. trial and anticipate enrolling our first patients for this trial in the fourth quarter of 2019. In Europe, our clinical trial application (CTA) has been approved by the Federal Agency for Medicines and Health Products (FAMHP) in Brussels and our Phase 2 protocol has been given a “high priority” ranking by the European Cystic Fibrosis Society Clinical Trial Network. Professor Eitan Kerem, M.D., Head of the Division of Pediatrics, Children’s Hospital, Hadassah Medical Center in Israel, is the global lead investigator. We are currently enrolling patients at sites in Israel and plan to open additional European sites during the fourth quarter of 2019. We expect full enrollment to be achieved during the first quarter of 2020. We are changing our guidance on the time for top line data in cystic fibrosis to better align with the opening of these clinical trial sites and expected completion of patient dosing. We expect to report top line data in cystic fibrosis during the first half of 2020. During October 2019, we completed an interim CMC review meeting with the U.S. Food and Drug Administration and we have gained alignment with the agency on our manufacturing formulation and process, which we believe will be suitable for our expected drug supply needs through completion of our pivotal trials.

We presented positive data in three scientific presentations at the North American Cystic Fibrosis Conference on October 31-November 2, 2019 in Nashville, Tennessee, from our completed Phase 1 clinical trial program for ELX-02, including results from the SAD study, the MAD study, and additional preclinical data for ELX-02. These data demonstrated that ELX-02 increases functional CFTR protein in patient-derived organoids and human bronchial epithelial cells, Ussing chamber systems, FRT and transgenic mice, and that it restores CFTR mRNA to healthy control levels. ELX-02 results in a pronounced increase in both CFTR protein expression and mRNA stability and the preclinical efficacy-associated exposures from the completed MAD study translate to the selected Phase 2 clinical trial ascending dose ranges and exposures. Two abstracts for ELX-02 have been accepted for scientific presentations at the American Society of Nephrology (ASN) Kidney Week on November 5-10, 2019 in Washington, D.C.

In our inherited retinal disease program, we are conducting IND enabling studies for several ERSG compounds from our library. We continue to collaborate and engage in our multi-year partnership with the Foundation Fighting Blindness (FFB) to support its inherited retinal degenerative disease registry and educational programs. In October 2019, we presented as part of the FFB New York Vision Seminar and we believe that the ongoing research and development consultation and support provided by the FFB will accelerate our development programs that seek to support patients with ocular disorders associated with nonsense mutations, an area of high unmet medical need. At the FFB New York Vision Seminar, we presented some of our *in vivo* proof-of-concept data in a nonsense model of oculocutaneous albinism type 2. We have demonstrated a functional restoration of the OCA2 protein in this model after a single intravitreal injection. These data support that our ERSG compounds are suitable for reaching and promoting read-through in target cells within the retina.

We are also evaluating the suitability of our ERSG library for development in rare renal disorders associated with nonsense mutations, such as autosomal dominant polycystic kidney disease, and cystinuria.

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

We hold worldwide development and commercialization rights to ELX-02 and all other novel compounds in our ERSG library, for all indications, in all territories, under a license from the Technion Research and Development Foundation Ltd. (TRDF). Professor Timor Baasov, the inventor of our compounds, has served as our senior consultant since our incorporation.

During the quarter ended September 30, 2019, we appointed Dr. Thomas Haverty as our Chief Medical Officer. Dr. Haverty has over 30 years of pharmaceutical and biotechnology experience leading clinical research and operations teams with responsibility for large development portfolios in virtually all classes of molecules and indications. Prior to joining us in his current capacity, Dr. Haverty, a Board-certified Nephrologist, served as a consultant to us following a long tenured career at Johnson & Johnson, Schering Plough and Merck Research Labs. Dr. Haverty has successfully led the development and approval of over 20 leading drugs.

We believe that our cash, cash equivalents and marketable securities of $64.9 million at September 30, 2019 will enable us to meet the anticipated cash needs required to reach top line Phase 2 data in cystic fibrosis and in cystinosis and maintain our current and planned operations into the first quarter of 2021. Since our inception, we have incurred significant operating losses. As of September 30, 2019, we had an accumulated deficit of $125.4 million. To date, we have financed our operations primarily through equity capital investments, and to a lesser extent, from loans and grants from the Israeli Innovation Authority of the Ministry of Economy and Industry, or the IIA. We have devoted substantially all of our financial resources and efforts to research and development. We expect that it will be many years, if ever, before we receive regulatory approval and have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- advance ELX-02 further into clinical trials;
- continue the preclinical development of our research programs and advance candidates into clinical trials;
- identify additional product candidates and advance them into preclinical development;
- pursue regulatory authorization to conduct clinical trials of additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;

- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory, management and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support product development;
- acquire or in-license other product candidates and technologies; and
- operate as a public company.

Results of Operations

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our unaudited Condensed Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the Condensed Consolidated Financial Statements, as well as the reported expense during the reporting periods. We monitor and analyze these items for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

The critical accounting policies that we believe impact significant judgments and estimates used in the preparation of our financial statements presented in this Report are described in our Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K. There have been no material changes to our critical accounting policies through September 30, 2019, from those discussed in our Annual Report on Form 10-K filed with the SEC on March 14, 2019.

Results of Operations

The following table summarizes our results of operations for each of the periods presented (in thousands):

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2019	2018	$	%	2019	2018	$	%
Operating expenses:								
Research and development	$ 6,801	$ 5,415	$ 1,386	26%	$ 20,160	$ 13,959	$ 6,201	44%
General and administrative	5,978	5,945	33	1%	18,907	18,898	9	0%
Reverse merger related expenses	—	—	—	—	—	594	(594)	-100%
Total operating expenses	12,779	11,360	1,419	12%	39,067	33,451	5,616	17%
Loss from operations	(12,779)	(11,360)	(1,419)	12%	(39,067)	(33,451)	(5,616)	17%
Other expense (income), net	96	(199)	295	-148%	174	(293)	467	-159%
Net loss	$ (12,875)	$ (11,161)	$(1,714)	15%	$ (39,241)	$ (33,158)	$(6,083)	18%

Research and development expense

Research and development expenses were $6.8 million for the three months ended September 30, 2019 compared to $5.4 million for the same period in 2018, an increase of $1.4 million. Research and development expenses increased $0.4 million primarily related to fees incurred for subcontractors, consultants and advisors in connection with ongoing clinical trials and research and development activities and $1.0 million due to an increase in headcount and related salaries, stock-based compensation, and other personnel related costs. Research and development expenses for the three months ended September 30, 2019 and 2018 included non-cash stock-based compensation expense totaling $0.7 million and $0.5 million, respectively.

Research and development expenses were $20.2 million for the nine months ended September 30, 2019 compared to $14.0 million for the same period in 2018, an increase of $6.2 million. Research and development expenses increased $3.3 million primarily related to fees incurred for subcontractors, consultants and advisors in connection with ongoing clinical trials and research and development activities and $2.9 million due to an increase in headcount and related salaries, stock-based compensation, and other personnel related costs. Research and development expenses for the nine months ended September 30, 2019 and 2018 included non-cash stock-based compensation expense totaling $2.0 million and $0.9 million, respectively.

General and administrative expenses

General and administrative expenses were $6.0 million for the three months ended September 30, 2019, compared to $5.9 million for the same in 2018, an increase of $0.1 million. The increase in general and administrative expenses was primarily due to an increase in stock-based compensation and other infrastructure-related costs of $0.4 million offset by a decrease in other personnel related costs of $0.3 million, including legal, accounting and other professional fees following the reverse merger. General and administrative expenses for the three months ended September 30, 2019 and 2018 included non-cash stock-based compensation expense totaling $2.2 million in each period.

General and administrative expenses were $18.9 million for the nine months ended September 30, 2019 and for the same period in 2018, with an insignificant increase in the current period. This current year period had higher personnel costs and other infrastructure costs, including legal, accounting and other professional fees following the reverse merger, offset by lower non-cash stock-based compensation. General and administrative expenses for the nine months ended September 30, 2019 and 2018 included non-cash stock-based compensation expense totaling $6.6 million and $8.7 million, respectively.

Reverse merger related expenses

During the nine months ended September 30, 2018, we recorded $0.6 million in professional service fees related to the reverse merger we completed on December 19, 2017. There were no reverse merger related expenses recorded during the three and nine months ended September 30, 2019.

Other expense (income), net

We recorded $0.1 million in other expense, net for the three months ended September 30, 2019, compared to $0.2 million in other income, net for the same period in 2018. The change in other expense, net was primarily due to debt issuance costs and interest expense of $0.3 million associated with our bank debt issued in the first quarter of 2019 offset by interest income of $0.1 million. Our interest income increased primarily due to higher cash balances as a result of $32.2 million received from our public offering of common stock in June 2019.

We recorded $0.2 million in other expense, net for the nine months ended September 30, 2019, compared to $0.3 million in other income, net for the same period in 2018. The change in other expense, net was primarily due to an increase in debt issuance costs and interest expense of $0.9 million associated with our bank debt issued in the first quarter of 2019 offset by interest income $0.3 million, for the same reason described above, and foreign exchange changes of $0.1 million.

Liquidity and Capital Resources

Liquidity is the ability of a company to generate funds to support its current and future operations, satisfy its obligations, and otherwise operate on an ongoing basis. Significant factors in the management of liquidity are funds generated by operations, levels of accounts receivable and accounts payable and capital expenditures. Since our inception and through September 30, 2019, we have funded our operations primarily through equity and capital investments.

We have a history of net losses and negative cash flows from operating activities since inception, and as of September 30, 2019, had an accumulated deficit of $125.4 million. We expect to continue to incur net losses and use cash in our operations in the foreseeable future. To date, we have not generated revenue from the sale of any product or service and do not expect to generate significant revenue unless and until obtaining marketing approval and commercialization of our product candidates currently in development. A successful transition to profitable operations is dependent upon achieving a level of revenue adequate to support our cost structure.

We have financed our operations primarily from the sale of our equity securities and to a lesser extent, loans and grants. We may never achieve profitability, and unless and until we do, we will continue to need to raise additional cash to fund our operations. We believe that our cash, cash equivalents and marketable securities of $64.9 million at September 30, 2019 will enable us to meet the anticipated cash needs required to reach top line Phase 2 data in cystic fibrosis and in cystinosis and maintain our current and planned operations into the first quarter of 2021. Our cash, cash equivalents and marketable securities are highly liquid investments with original maturities of 90 days or less at the date of purchase and consist of cash in operating accounts and secured investments, primarily in U.S. treasuries.

Management intends to fund future operations through private or public debt or equity financing transactions and may seek additional capital through arrangements with strategic partners or from other sources. If we are unable to obtain financing, we will evaluate options which may include reducing or deferring operating expenses, which may have a material adverse effect on our operations and future prospects.

Principal Financing Activities

On April 30, 2018, we completed an underwritten public offering of 5,899,500 shares of common stock at the public offering price of $9.75 per share (the "2018 Offering"). We received net proceeds of approximately $53.6 million after deducting underwriting discounts and commissions and estimated offering expenses.

In November 2018, we entered into an Equity Distribution Agreement (the "Agreement") with Citigroup Global Markets Inc. and Cantor Fitzgerald & Co. (collectively, the "Sales Agents"), pursuant to which we may sell and issue shares of our common stock up to an aggregate of $50.0 million through the Sales Agents. The shares were offered pursuant to the April 2018 shelf registration statement, which is more fully described below. In January 2019, we sold 35,362 shares of common stock and received net proceeds of $0.7 million. At September 30, 2019, there was approximately $47.0 million available for future sales pursuant to the Agreement.

On January 30, 2019, we entered into a Loan and Security Agreement (the "SVB Loan Agreement") with Silicon Valley Bank ("SVB"), in its capacity as administrative agent, collateral agent and lender, and WestRiver Innovation Lending Fund VIII, L.P. ("WestRiver", together with SVB, the "Lenders"). Pursuant to the terms and conditions of the SVB Loan Agreement, the Lenders agreed to extend term loans to us in an aggregate principal amount of up to $25.0 million, comprised of (i) an initial loan advance of $15.0 million and (ii) a subsequent loan advance of $10.0 million, subject to first achieving certain conditions (collectively, the "Term Loan Advances"). The initial term loan was funded on January 30, 2019. The subsequent loan advance is available at our election prior to December 31, 2019 after the occurrence of certain milestone events relating to data from our clinical trials and receipt by us of certain minimum cash proceeds of at least $75.0 million from an additional equity offering through a private placement or a public offering.

On June 24, 2019, we completed an underwritten public offering of 3,833,334 shares of common stock at the public offering price of $9.00 per share (the "2019 Offering"). We received net proceeds of approximately $32.2 million after deducting underwriting discounts and commissions and estimated offering expenses.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Nine months ended September 30,	
	2019	2018
Net cash used in operating activities	$ (30,134)	$ (22,307)
Net cash used in investing activities	(42,603)	(138)
Net cash provided by financing activities	46,281	53,676

Our operating activities used cash of $30.1 million and $22.3 million during the nine months ended September 30, 2019 and 2018, respectively. For the nine months ended September 30, 2019, net cash used in operating activities resulted primarily from our net loss of $39.2 million partially offset by total non-cash charges of $9.2 million and total changes in working capital of $0.1 million. Non-cash charges primarily related to $8.6 million of stock-based compensation, $0.3 million of amortization of our lease asset, $0.4 million of our amortization of debt discount and $0.1 million of depreciation expense offset by $0.2 million of amortization on our investments. Changes in working capital were primarily related to higher prepaid and other current assets of $0.2 million and advances from collaboration partners of $0.4 million related to the achievement of a milestone in connection with the CF Foundation funding commitment for our cystic fibrosis development program in the U.S. For the nine months ended September 30, 2018, net cash used in operating activities resulted primarily from our net loss of $33.2 million partially offset by non-cash charges of $9.6 million related to stock-based compensation, $0.1 million of depreciation expense and $1.2 million related to changes in working capital primarily for accounts payable and accrued expenses.

Our investing activities used cash of $42.6 million and $0.1 million during the nine months ended September 30, 2019 and 2018, respectively. For the nine months ended September 30, 2019, cash used in investing activities was primarily for the purchase of marketable securities of $56.0 million offset by proceeds of $13.5 million received upon the maturity of marketable securities. For the nine months ended September 30, 2018, cash used in investing activities was primarily driven by the net purchase of property and equipment and long-term deposits.

Our financing activities provided cash of $46.3 million and $53.7 million during the nine months ended September 30, 2019 and 2018, respectively. For the nine months ended September 30, 2019, net cash provided by financing activities resulted primarily from net proceeds of $32.2 million from the 2019 Offering, issuance of debt of $15.0 million in January 2019 and proceeds of $0.4 million from the sale of common stock offset by the payment of taxes of $1.2 million associated with the vesting of restricted stock units and $0.3 million of debt issuance costs. For the nine months ended September 30, 2018, net cash provided by financing activities resulted primarily from net proceeds from the 2018 Offering of $53.6 million and $0.1 million of proceeds from stock-based compensation arrangements.

Form S-3 and Equity Sales Agreement

On April 10, 2018, we filed a shelf registration statement (the "April 2018 Shelf") on Form S-3 with the U.S. Securities and Exchange Commission (the "SEC"). The April 2018 Shelf (File No. 333-224207) was declared effective on April 20, 2018 and covers the offering, issuance and sale of up to $125.0 million of our common stock, preferred stock, debt securities or warrants and other securities, either individually or in combination.

On November 16, 2018, we filed a shelf registration statement (the "November 2018 Shelf") on Form S-3 with the SEC. The November 2018 Shelf (File No. 333-228430) was declared effective on November 21, 2018 and covers the offering, issuance and sale of up to $200.0 million of our common stock, preferred stock, debt securities or warrants and other securities, either individually or in combination.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, and we do not have, any off-balance sheet arrangements, as such term is defined under Item 303 of Regulation S-K, that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenue or expense, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Not applicable to a "smaller reporting company", as defined in Item 10(f)(1) of SEC Regulation S-K.

Item 4. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities and Exchange Act of 1934 is (1) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2019, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities and Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2019, our disclosure controls and procedures were effective in ensuring that material information relating to the Company, including its consolidated subsidiaries, required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized, and reported within the time period specified in the SEC's rules and forms, including ensuring that such material information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2019, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. We are currently unaware of any material pending legal proceedings to which we are party or of which our property is the subject. However, we may at times in the future become involved in litigation in the ordinary course of business, which may include actions related to or based on our intellectual property and its use, customer claims, employment practices and employee complaints and other events arising out of our operations. When appropriate in management's estimation, we will record adequate reserves in our financial statements for pending litigation. Litigation is subject to inherent uncertainties, and an adverse result in any such matters could adversely impact our reputation, operations, and our financial operating results or overall financial condition. Additionally, any litigation to which we may become subject could also require significant involvement of our senior management and may divert management's attention from our business and operations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all other information in this Report, before you decide to purchase our common stock. If any of the possible adverse events described below actually occurs, we may be unable to conduct our business as currently planned and our financial condition and operating results could be harmed. In addition, the trading price of our common stock could decline due to the occurrence of any of the events described below, and you may lose all or part of your investment. Additional risks that we currently do not know about, or that we currently believe immaterial, may also impair our business.

Risks Related to Drug Discovery, Development, Regulatory Approval and Commercialization

We depend heavily on the success of our lead product candidate, ELX-02. If ELX-02 fails during development or suffers any material delays, it may adversely impact the commercial viability of ELX-02 and our business.

We currently have no products approved for sale. To date, we have invested substantial efforts and financial resources in the research and development of ELX-02, which is currently our only product candidate in clinical development. We have increased investment in our pre-clinical candidate portfolio but have yet to advance other molecules into clinical development.

Our ability to achieve and sustain profitability depends on obtaining regulatory approvals, and successfully commercializing ELX-02 and any future product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our therapeutic product candidates, we or a collaborator must conduct extensive preclinical studies and clinical trials to demonstrate the safety and efficacy in humans of our product candidates. The clinical trials, manufacturing and marketing of ELX-02, and any future product candidates, will be subject to extensive and rigorous review and regulation by numerous governmental authorities in the U.S., the EU and other jurisdictions where we intend to test and, if approved, market our current and future product candidates. Before obtaining regulatory approvals for the commercial sale of any product candidate, we must demonstrate through preclinical studies and clinical trials that the product candidate is safe and effective for use in each target indication, and potentially in specific patient populations, including the pediatric population. This process can take many years and may include post-marketing studies and surveillance, which would require the expenditure of substantial resources. Of the large number of drugs in development for approval in the U.S. and the EU, only a small percentage successfully complete the FDA or EMA regulatory approval processes and are commercialized. Accordingly, even if we are able to obtain the requisite financing to continue to fund our research, development and clinical programs, we cannot assure you that ELX-02 or any of our future product candidates will be successfully developed or commercialized.

Preclinical studies and clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to outcome. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparative therapeutic or required prior or combination therapy, clinical outcomes or financial constraints. For instance, delays or difficulties in patient enrollment or difficulties in retaining trial participants can result in increased costs, longer development times or termination of a clinical trial. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease the product candidate is intended to treat and who meet other eligibility criteria. Rates of patient enrollment are affected by many factors, including the size of the patient population, the eligibility criteria for the clinical trial, the age and condition of the patients, the stage and severity of disease, the nature of the protocol, the proximity of patients to clinical sites and the availability of effective treatments for the relevant disease.

The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or safety profiles, notwithstanding promising results in earlier trials. Accordingly, we, or any development partners, may ultimately be unable to provide regulatory agencies with satisfactory data on clinical safety and efficacy sufficient to obtain approval for any indication.

Further, we may experience delays in clinical trials of our product candidates. We do not know whether ongoing clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board, or IRB, approval at each clinical trial site;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on third parties, such as CROs and clinical trial sites, to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we may have limited influence over their actual performance.

We could encounter delays if prescribing physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, our collaborators, the IRB of the institutions in which such trials are being conducted, the Data Safety Monitoring Board, or DSMB, for such trial, or by the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols,
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold,
- unforeseen safety issues or adverse side effects,
- failure to demonstrate a benefit from using a drug,
- changes in governmental regulations or administrative actions, or
- lack of adequate funding to continue the clinical trial.

In addition, significant adverse events with respect to individuals who are not enrolled in any of our clinical trials but who receive our drug candidate under our compassionate use policy (typically under a single-patient IND (investigational new drug application) administered by the individual’s treating physician) may result in a partial or full clinical hold on our on-going clinical trials. A clinical hold may result in the inability to enroll new patients in our studies until the hold is removed and make it more difficult to enroll patients thereafter. Additionally, a clinical hold may also result in, among other things, protocol redesign, changes in eligibility criteria and increased costs, any of which could adversely affect our projected development timelines and jeopardize successful completion of our clinical programs.

If we experience delays in the completion of any clinical trial of our product candidates, the commercial prospects of our product candidates may be impaired and our ability to generate product revenues from such product candidates may be delayed. In addition, any delays in completing our clinical trials may increase our costs, slow down our product development and approval process and may jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may have an adverse impact on our business, financial condition and prospects. Further, the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

We and our collaborating partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we or our collaborating partners are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

All marketing activities associated with product candidates that are approved for sale in the U.S., if any, will be, directly or indirectly through our customers, subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products in the U.S., including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and the Health Insurance Portability and Accountability Act ("HIPAA"). These laws may adversely impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of co-payments and deductibles, ownership interests and providing anything at less than its fair market value. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the PPACA, which, among other things, amends the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes. Pursuant to the amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Penalties for violations of the federal Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other state or federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The "qui tam" provisions of the False Claims Act allow a private individual to bring civil actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties up to approximately $22,000 for each separate false claim.

The HIPAA created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. Moreover, to the extent that any of our product candidates, if approved for marketing, will be sold in a foreign country, we and our current or future collaborators, may be subject to similar foreign laws and regulations. If we or any of our current or future collaborators are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring or our operations, any of which could have a material adverse effect on our business, results of operations and financial condition.

Positive results from preclinical or in vitro and in vivo testing of ELX-02 are not necessarily predictive of the results of future clinical trials of ELX-02. If we cannot achieve positive results in our clinical trials for ELX-02, we may be unable to successfully develop, obtain regulatory approval for and commercialize ELX-02.

Positive results from our preclinical testing of ELX-02 in vitro and in vivo may not necessarily be predictive of the results from our ongoing and planned clinical trials in humans. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical and in vitro and in vivo studies, and we, or the third parties whose product candidates we expect to be co-administered with ELX-02, may face similar setbacks. Preclinical and clinical data are often susceptible to varying interpretations and analyses, and the FDA or EMA or other regulatory agencies may require changes to our protocols or other aspects of our clinical trials or require additional studies. Additionally, many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. If we fail to secure positive results from our clinical trials of ELX-02 or regulatory agencies require us to undertake significant additional studies as a result of our data, the development timeline, regulatory approval and commercialization prospects for our lead product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected, which may result in termination of development activities, the inability to raise additional needed capital and/or a precipitous decline in our stock price, as well as impair our ability to enter into collaboration arrangements or damage existing strategic partnerships.

Our product candidates, including ELX-02, may cause adverse events or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Undesirable side effects caused by our product candidates, such as ELX-02, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. It is possible that, during the course of the clinical development of ELX-02 or other product candidates, results of our clinical trials (or significant adverse events experienced by individuals receiving drug under our compassionate use policy) could reveal an unacceptable severity and prevalence of side effects. For example, in preclinical testing of ELX-02, we observed renal toxicities in the animals we tested following administration of this compound at doses in excess of the doses we expect to administer in our clinical trials. As a result of this or any other side effects, our clinical trials could be suspended or terminated or not even allowed to commence, and the FDA or comparable foreign regulatory authorities could order us to cease further development, or deny approval, of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

Additionally, if one or more of our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product or impose restrictions on its distribution in the form of a new or modified risk evaluation and mitigation strategy;
- regulatory authorities may require additional labeling, such as additional warnings or contraindications, which may negatively impact sales;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Our clinical trials may be costly and lengthy, time-consuming and difficult to design and implement, may result in unforeseen costs and could be delayed or terminated, which may have a material adverse effect on our business, results of operations and financial condition.

For human trials, patients must be recruited, and each product candidate must be tested at various doses and formulations for each clinical indication. In addition, to ensure safety and effectiveness, the effect of drugs often must be studied over a long period of time, especially for the chronic genetic diseases that we will be studying. Many of our programs focus on diseases with small patient populations making patient recruitment and enrollment difficult. Insufficient patient enrollment in our clinical trials could delay or cause us to abandon a product development program. We may decide to abandon development of a product candidate or a study at any time due to unfavorable results, or we may have to spend considerable resources repeating clinical trials or conducting additional trials, either of which would increase costs and delay any revenue from those product candidates, if any.

Failure or delay in the commencement or completion of our clinical trials may be caused by several factors, including:

- slower than expected rates of patient recruitment, particularly with respect to trials of rare diseases such as nonsense mutation cystic fibrosis;
- determination of dosing levels and corresponding effect analysis;
- unforeseen safety issues;
- lack of effectiveness during clinical trials;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators and IRBs to follow our clinical protocols; and
- lack of sufficient funding to finance the clinical trials.

We may find it difficult to recruit and enroll patients in our clinical trials, which could cause significant delays in the completion of such trials or may cause us to abandon one or more clinical trials.

Some of the diseases that our product candidates are intended to treat are rare and ultra-rare and we expect only a subset of the patients with these diseases will be eligible for our clinical trials. Because ELX-02 targets small populations and patient numbers have not been determined definitively, we must be able to identify patients in order to complete our development programs, secure regulatory approval and commercialize ELX-02 successfully.

In addition, the protocol for our clinical trials generally mandates that a patient cannot be involved in more than one clinical trial for the same indication. Therefore, subjects that participate in ongoing clinical trials for products that are competitive with our product candidates are not available to participate in our clinical trials. We cannot guarantee that any of our programs will identify a sufficient number of patients to complete clinical development, pursue regulatory approval and market our product candidates if approved. The combined number of patients in the U.S., Japan and Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with ELX-02, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business. An inability to recruit and enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether, which could impact our ability to develop our product candidates and may have a material adverse effect on our business, results of operations and financial condition.

Because our clinical trials depend upon third-party researchers, scientists and consultants, the results of our clinical trials and such research activities are subject to delays and other risks that are, to a certain extent, beyond our control, which could impair our clinical development programs and our competitive position.

We depend on independent investigators, consultants, researchers, medical experts, collaborators, chemists, toxicologist and a small number of medical institutions and third-party contract research organizations to assist with our research efforts and conduct our preclinical and clinical trials and related activities. These collaborators, scientists, consultants and other third parties have provided, and we expect that they will continue to provide, valuable advice and services regarding our clinical development programs and product candidates. These collaborators, scientists, consultants and other third parties are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. We cannot control the amount or timing of resources that they devote to our preclinical and or clinical development programs and they may not assign as great a priority to our preclinical or clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. If outside collaborators fail to devote sufficient time and resources to our preclinical and clinical development programs, or if their performance is substandard, the authorization of investigational new drug applications ("INDs") and pre-clinical trial applications ("CTAs") and the approval of anticipated new drug applications ("NDAs") and other marketing applications, and our introduction of new drugs, if any, may be delayed or impeded, which could impair our clinical development programs and would have a material adverse effect on our business and results of operations. These collaborators may also have relationships with other commercial entities, some of whom may compete with us and we may be unable to prevent them from establishing competing businesses or developing competing products.

We are subject to extensive governmental regulation including the requirements of FDA and comparable foreign regulatory authorities for development and approval of our product candidates before they can be marketed.

We, our product candidates, our suppliers, our contract manufacturers, our contract testing laboratories and our clinical trial sites and clinical trial researchers are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. Failure to comply with applicable requirements of the FDA or comparable foreign regulatory authorities could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- holds on the initiation or continuation of clinical trials;
- delays in the FDA's or other foreign regulatory authorities' approving, or the refusal of any regulatory authority to approve, any product candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval requirements, other numerous and pervasive regulatory requirements apply, both before and after approval of our product candidates, to us, our product candidates, and our suppliers, contract manufacturers, and contract laboratories, and our clinical trial sites and clinical trial researchers including requirements related to testing, manufacturing, quality control, labeling, advertising, promotion, distribution, exporting product materials, reporting to the FDA of certain adverse experiences associated with use of the product candidate, and obtaining additional approvals for certain modifications to the product candidate or its labeling or claims following approval, if any.

We also are subject to inspection by the FDA and comparable foreign regulatory authorities, to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, contract testing laboratories, and our clinical trial sites and clinical researchers and there can be no assurance that the FDA or any other comparable foreign regulatory authority will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We may be required to make modifications to our manufacturing operations in response to these inspections, which may require significant resources and may have a material adverse effect upon our business, results of operations and financial condition.

The approval process for any product candidate may also be delayed by changes in government regulation, future legislation or administrative action or changes in policy of the FDA and comparable foreign regulatory authorities that occur prior to or during their respective regulatory reviews of such product candidate. Delays in obtaining regulatory approvals with respect to any product candidate may:

- delay commercialization of, and our ability to derive product revenue from, such product candidate;
- delay any regulatory-related milestone payments payable under outstanding collaboration agreements;
- require us to perform costly procedures with respect to such product candidate; or
- otherwise diminish any competitive advantages that we may have with respect to such product candidate.

We may not obtain the necessary FDA, EMA or other worldwide regulatory approvals to commercialize our product candidates in a timely manner, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

We need FDA approval to commercialize our product candidates in the U.S., EMA approval to commercialize our product candidates in the EU and approvals from other foreign regulatory authorities to commercialize our product candidates elsewhere in the world. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. In the EU, we must submit a Marketing Authorization Application, or MAA, to the EMA. Satisfaction of the FDA's, the EMA's and other foreign regulatory authorities' regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. Even if we comply with all the requests of regulatory authorities, they may ultimately reject any marketing applications that we file for our product candidates, or we might not obtain regulatory clearance in a timely manner if at all. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings or other comparable results for such clinical trials. Further, even if favorable testing data is generated during the clinical trials of a product candidate, the applicable regulatory authority may not accept or approve the marketing application filed by a pharmaceutical or biotechnology company for the product candidate. Failure to obtain approval of the FDA, EMA or comparable foreign regulatory authorities of any of our product candidates in a timely manner, if at all, will severely undermine our business, financial condition and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenue.

Our research and clinical efforts may not result in drugs that the FDA, EMA or other foreign regulatory authorities consider safe for humans and effective for indicated uses, which would have a material adverse effect on our business, results of operations and financial condition. After clinical trials are completed for any product candidate, if at all, the FDA, EMA and other foreign regulatory authorities have substantial discretion in the drug approval process of the product candidate in their respective jurisdictions and may require us to conduct additional clinical testing or perform post- marketing studies, which would cause us to incur additional costs. Incurring such costs may have a material adverse effect on our business, results of operations and financial condition.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell any of our product candidates that obtain regulatory approval, we may be unable to generate any revenue.

We have no experience selling and marketing our product candidates or any other products. To successfully commercialize any products that may result from our clinical development programs and obtain regulatory approval, we will need to develop these capabilities, either on our own or with the assistance of others. We may seek to enter into collaborations with other entities to utilize their marketing and distribution capabilities, but we may be unable to do so on favorable terms, if at all. If any future collaborative partners do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies or successfully commercialize any of our product candidates.

Even though we have received orphan drug designation from the FDA for ELX-02 for the treatment of cystinosis, we may not be able to obtain orphan drug marketing exclusivity for ELX-02 or any of our other potential product candidates for other indications.

Regulatory authorities in some jurisdictions, including the U.S. and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S. Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either the condition affects no more than five in 10,000 persons in the EU when the application is made or the product, without the benefits derived from orphan status, would unlikely generate sufficient return in the EU to justify the necessary investment. Moreover, in order to obtain orphan designation in the EU, it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition authorized for marketing in the EU, or if such a method exists, that the product will be of significant benefit to those affected by the condition.

The FDA has granted orphan drug designation for ELX-02 for the treatment of cystinosis as well as for the treatment of MPS I and the treatment of Rett syndrome. We may seek orphan drug designation for our other product candidates, and with respect to other indications. Generally, if a drug with an orphan drug designation subsequently receives the first FDA marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the U.S. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the candidate from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the applicable regulatory authority can subsequently approve another drug for the same condition if it concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Similarly, if our competitors are able to obtain orphan product exclusivity for their products in the same indications for which we are developing our product candidates, we may not be able to have our products approved by the applicable regulatory authority for a significant period of time.

Developments by competitors may render our products or technologies obsolete or non-competitive which would have a material adverse effect on our business, results of operations and financial condition.

We compete with fully integrated biopharmaceutical companies and smaller biopharmaceutical companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Our product candidates will have to compete with existing therapies and potential therapies under development by our competitors. In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our product candidates. Other companies have product candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to develop product candidates. Some of these potential competing drugs are further advanced in development than our product candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

Most of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, staff and facilities, and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining marketing approvals from the FDA and other regulatory authorities;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

These organizations also compete with us to attract qualified personnel, acquisitions and joint ventures candidates and for other collaborations.

Efforts to compete and the pursuit of activities of our competitors may impose unanticipated costs on our business, which would have a material adverse effect on our business, results of operations and financial condition.

If we are unable to develop and commercialize our product candidates, our business will be adversely affected.

A key element of our strategy is to develop and commercialize a portfolio of new products. We seek to do so through our internal research programs and strategic collaborations for the development of new products. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- a product candidate is not capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate that is developed and approved may not be accepted by patients, the medical community or third-party payors;
- competitors may develop alternatives that render our product candidates obsolete;

- the research methodology used may not be successful in identifying potential product candidates; or
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be safe or effective or otherwise does not meet applicable regulatory approval requirements.

Any failure to develop or commercialize any of our product candidates may have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Our Financial Position and Need for Additional Capital

We have incurred significant operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.

We have a history of net losses and negative cash flows from operating activities since inception, and as of September 30, 2019, had an accumulated deficit of $125.4 million. Historically, we have financed our operations primarily through equity capital investments, and to a lesser extent from loans and grants from the Israeli Innovation Authority of the Ministry of Economy and Industry, or the IIA. We have devoted substantially all of our financial resources and efforts to research and development. We expect that it will be many years, if ever, before we receive regulatory approval and have a product candidate ready for commercialization. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if and as we:

- advance ELX-02 further into clinical trials;
- continue the preclinical development of our research programs and advance candidates into clinical trials;
- identify additional product candidates and advance them into preclinical development;
- pursue regulatory authorization to conduct clinical trials of additional product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory, management and scientific personnel;
- add operational, financial and management information systems and personnel, including personnel to support product development;
- acquire or in-license other product candidates and technologies; and
- operate as a public company.

We have never generated any revenue from product sales and may never be profitable. To become and remain profitable, we and our collaborators must develop and eventually commercialize one or more product candidates with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, obtaining marketing approval for these product candidates, manufacturing, marketing and selling those product candidates for which we may obtain marketing approval, securing coverage and reimbursement for those product candidates for which we may obtain marketing approval, and satisfying any post-marketing requirements. We may never succeed in these activities and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our Company could also cause you to lose all or part of your investment.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, continue and initiate clinical trials of, and seek marketing approval for ELX-02, and as we become obligated to make milestone payments pursuant to our outstanding license agreements. In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution of the approved product. Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of drug discovery, clinical development, laboratory testing and clinical trials for ELX-02 and other product candidates;
- the costs, timing and outcome of any regulatory review of ELX-02 and other product candidates;
- the cost of any other product candidate programs we pursue;
- the costs and timing of commercialization activities, including manufacturing, marketing, sales and distribution, and securing coverage and reimbursement for any product candidates that receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Identifying potential product candidates and conducting preclinical studies and clinical trials are time consuming, expensive and uncertain processes that take years to complete, and we may never generate the necessary data or results required to obtain marketing approval or achieve product sales for any of our current or future product candidates. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenue, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if at all.

Accordingly, despite the public offerings in April 2018 and June 2019, we will need substantial additional funding in connection with our continuing operations and to achieve our goals. However, our existing cash and cash equivalents may prove to be insufficient for these activities. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or future commercialization efforts. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional financing due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our operating plans.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity and debt financings, as well as entering into new collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, and may be secured by all or a portion of our assets. If we raise funds by entering into new collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through collaborations, strategic alliances or licensing arrangements when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Our Business and Operations

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management's attention and affect our ability to attract and retain qualified board members.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish. As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, and Nasdaq stock market rules. The requirements of these rules and regulations have increased and will continue to significantly increase our legal and financial compliance costs, including costs associated with the hiring of additional personnel, making some activities more difficult, time-consuming or costly, and may also place undue strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place, as well as maintaining these controls and procedures, is a costly and time-consuming effort that needs to be re-evaluated frequently. Section 404 of the Sarbanes-Oxley Act, or Section 404, requires that we annually evaluate our internal control over financial reporting to enable management to report on the effectiveness of those controls. In connection with the Section 404 requirements, we test our internal controls and could, as part of that documentation and testing, identify material weaknesses, significant deficiencies or other areas for further attention or improvement.

Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, require the hiring of additional finance, accounting and other personnel, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, adequate internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to satisfy the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could cause the market value of our common stock to decline.

Various rules and regulations applicable to public companies make it more difficult and more expensive for us to maintain directors' and officers' liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors' and officers' liability insurance, our ability to recruit and retain qualified officers and directors, especially those directors who may be deemed independent for purposes of the Nasdaq stock market rules, will be significantly curtailed.

We are seeking to expand our business through strategic initiatives. Our efforts to identify opportunities or complete transactions that satisfy our strategic criteria may not be successful, and we may not realize the anticipated benefits of any completed acquisition, collaboration or other strategic transaction.

Our business strategy includes expanding our product candidates and capabilities. We regularly evaluate potential merger, acquisition, partnering and in-license opportunities that we expect will expand our pipeline or product offerings, and enhance our research or development programs.

We may engage in strategic transactions that could cause us to incur additional liabilities, commitments or significant expense. Any such transactions will be dependent on our ability to appropriately evaluate the potential risks and uncertainties, integrate any new technology, product and/or business, and generate revenues (including through upfront payments, milestones and/or royalties) sufficient to meet our underlying objectives.

Any strategic transaction undertaken may result in unforeseen development costs, timeline delays, regulatory approval challenges and uncertainties relating to the commercial market opportunity, any of which could cause us to fail to realize the anticipated value of the transaction and may have a material adverse effect on our business and financial condition.

To manage effectively our current and future potential growth, we must also continue to enhance and develop our global employee base, and our operational and financial processes. Supporting our growth strategy will require significant capital expenditures and management resources, including investments in research, development, sales and marketing, manufacturing and other areas of our operations. The development or expansion of our business, any acquired business or any acquired or in-licensed products may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our capital stock, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest in our Company.

Our business could be affected by litigation, government investigations and enforcement actions.

We operate in many jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the U.S. or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, Qui Tam, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment, and other claims and legal proceedings which may arise from conducting our business. Any of these actions or proceedings may result in significant costs, fines, penalties or imposition of burdensome restrictions on the Company, any of which could have a material adverse effect on our business, results of operations and financial condition.

Comprehensive tax reform bills could adversely affect our business and financial condition.

On December 22, 2017, and effective January 1, 2018, the U.S. government enacted H.R. 1, "An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018" (informally titled the "Tax Cuts and Jobs Act"), which includes significant changes to the taxation of business entities. The Tax Cuts and Jobs Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), implementation of a "base erosion anti-abuse tax" which requires U.S. corporations to make an alternative determination of taxable income without regard to tax deductions for certain payments to affiliates, taxation of certain non-U.S. corporations' earnings considered to be "global intangible low taxed income" (also referred to as "GILTI"), repeal of the alternative minimum tax, or AMT, for corporations and changes to a taxpayer's ability to either utilize or refund the AMT credits previously generated, changes in the attribution rules relating to shareholders of certain "controlled foreign corporations", limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the Tax Cuts and Jobs Act remains subject to interpretation and further guidance from U.S. taxing authorities and as a result the overall impact of this tax reform is uncertain and may change due to interpretation changes, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various U.S. states will conform their tax laws to the Tax Cuts and Jobs Act. The impact of the Tax Cuts and Jobs Act on holders of our common stock is also uncertain and could be adverse. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our effective tax rates in the future in countries where we have operations and have an adverse effect on our overall tax rate in the future, along with increasing the complexity, burden and cost of tax compliance. We urge our stockholders to consult with their legal and tax advisors with respect to the Tax Cuts and Jobs Act and the potential tax consequences of investing in or holding our common stock.

Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.

As of September 30, 2019, we had U.S. federal and state net operating loss, or "NOL", carry forwards of $89.8 million and $40.0 million, respectively, and federal research tax credit carryforwards of $0.7 million. Certain U.S. NOL carryforwards will begin to expire, if not utilized, beginning in 2019 through 2037, and the research tax credits will expire beginning in 2027 through 2037. Included in these U.S. federal NOL carryforwards are $13.1 million of NOLs generated after the effective date of the Tax Cuts and Jobs Act which are not subject to expiration. Under the Tax Cuts and Jobs Act, federal NOLs generated in 2018 and future years may be carried forward indefinitely but may not be carried back and are only eligible to offset up to a maximum of 80% of taxable income generated in a given year. It is uncertain if and to what extent various U.S. states will conform their net operating loss rules to the Tax Cuts and Jobs Act.

In general, under Section 382 of the United States Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-ownership change NOLs to offset future taxable income. We may have experienced ownership changes in the past, including in connection with the reverse merger on December 19, 2017 at which time our pre-change U.S. federal NOL carryforward was $77.2 million and research tax credit was $0.7 million. We may experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. Although we have not completed our analysis, it is reasonably possible that our federal NOLs available to offset future taxable income could materially decrease. This reduction will be offset by an adjustment to the existing valuation allowance for an equal and offsetting amount. Additionally, our state NOLs available to offset future state income could similarly decrease which would also be offset by an equal and offsetting adjustment to the existing valuation allowance. Given the offsetting adjustments to the existing valuation allowance, any ownership change is not expected to have an adverse material effect on our Consolidated Financial Statements. Finally, as of September 30, 2019, we had Israeli NOL carryforwards of $34.6 million, which carry forward indefinitely.

Our ability to utilize our NOLs is dependent on attaining profitability sufficient to offset such available NOLs prior to their expiration. In addition, we may not be able to utilize a portion of the NOLs reflected on our balance sheet, even if we attain profitability.

We could be subject to additional tax liabilities.

We are subject to federal, state and local taxes in the U.S. and Israel. Significant judgment is required in evaluating our tax positions and our worldwide provision for taxes. During the ordinary course of business, there are many activities and transactions for which the ultimate tax determination is uncertain. In addition, our tax obligations and effective tax rates could be adversely affected by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations, including those relating to income tax nexus, by our earnings being lower than anticipated in jurisdictions where we have lower statutory rates and higher than anticipated in jurisdictions where we have higher statutory rates, by changes in foreign currency exchange rates, or by changes in the valuation of our deferred tax assets and liabilities. We may be audited in various jurisdictions, and such jurisdictions may assess additional taxes against us. Although we believe our tax estimates are reasonable, the final determination of any tax audits or litigation could be materially different from our historical tax provisions and accruals, which could have a material adverse effect on our operating results or cash flows in the period or periods for which a determination is made.

Changes in healthcare laws and implementing regulations, as well as changes in healthcare policy, may affect coverage and reimbursement of our product candidates in ways that we cannot currently predict and these changes could adversely affect our business and financial condition.

In the U.S., a number of legislative and regulatory initiatives have focused on containing the cost of healthcare. The Patient Protection and Affordable Care Act, or PPACA, was enacted in March 2010. This law substantially changes the way healthcare is financed by both governmental and private insurers in the U.S., and significantly impacts the pharmaceutical industry. PPACA contains a number of provisions that are expected to impact our business and operations, in some cases in ways we cannot currently predict. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under health insurance exchanges, expansion of the 340B program, expansion of state Medicaid programs, fraud and abuse enforcement and rules governing the approval of biosimilar products. These changes will impact existing government healthcare programs and will result in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program. In early 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA. These regulations became effective on April 1, 2016. Moreover, in the future, Congress could enact legislation that further increases Medicaid drug rebates or other costs and charges associated with participating in the Medicaid Drug Rebate Program. Legislative changes to the PPACA also remain possible and appear likely under the current administration. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program has and will continue to increase our costs and the complexity of compliance, has been and will be time-consuming, and could have a material adverse effect on our results of operations.

Governments in countries where we operate have adopted or have shown significant interest in pursuing legislative initiatives to reduce costs of healthcare. We expect that the implementation of current laws and policies, the amendment of those laws and policies in the future, as well as the adoption of new laws and policies, could have a material adverse effect on our industry generally and on our ability to generate or increase future product sales, if any, or successfully commercialize our product candidates, or could limit or eliminate our future spending on development projects. In many cases, these government initiatives, even if enacted into law, are subject to future rulemaking by regulatory agencies. Although we have evaluated these government initiatives and the impact on our business, we cannot know with certainty whether any such law, rule or regulation will adversely affect coverage and reimbursement of our product candidates, or to what extent, until such laws, rules and regulations are promulgated, implemented and enforced, which could sometimes take many years. The announcement or adoption of regulatory or legislative proposals could delay or prevent our entry into new markets, affect our reimbursement or sales in the markets where we are already selling our approved products, if any, and materially harm our business, financial condition and results of operations.

We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage.

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information. Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. For example, in May 2016, the EU formally adopted the General Data Protection Regulation, or GDPR, which applies to all EU member states as of May 25, 2018 and replaces the former EU Data Protection Directive. The regulation introduces new data protection requirements in the EU and imposes substantial fines for breaches of the data protection rules. The GDPR must be implemented into national laws by the EU member states imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different EU member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the EU, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the GDPR and related national laws of EU member states could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. The GDPR will increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with EU data protection rules.

Security breaches, cyber-attacks, or other disruptions could expose us to liability and affect our business and reputation.

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees, and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We have implemented information security measures to protect patients’ personal information against the risk of inappropriate and unauthorized external use and disclosure. However, despite these measures, and due to the ever-changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. If our systems failed or were breached or disrupted, patient and other data and information may become compromised, we could lose sales for approved products, if any, and suffer reputational damage and loss of confidence by patients, investors and business partners. Such incidents would result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under federal and state laws that protect the privacy and security of personal information. Any one of these events, or similar events occurring through one of our vendors that maintain such information on our behalf, could cause our business to be materially harmed and our results of operations to be adversely impacted.

We expect to rely on third parties to conduct some or all aspects of our product manufacturing, protocol development, research and preclinical and clinical testing, and these third parties may not perform satisfactorily.

We do not expect to independently conduct all aspects of our product manufacturing, protocol development, research and preclinical and clinical testing. We currently rely, and expect to continue to rely, on third parties with respect to these items.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all applicable laws and regulations and study protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the preclinical studies and clinical trials required to support future NDA submissions and approval of our product candidates.

Reliance on third-party manufacturers, testing sites, and investigators entails risks to which we would not be subject if we developed, researched, tested, and manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing, testing, and research agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third-party manufacturers, testing laboratories, and research sites and investigators for all aspects of manufacturing, testing, and research activities;
- termination or nonrenewal of manufacturing, testing, or research agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers or suppliers, testing facilities, or research sites caused by conditions unrelated to our business or operations, including unrelated regulatory action against or the bankruptcy of the manufacturer or supplier, testing facility, or research site.

Any of these events could lead to clinical trial delays, failure to obtain regulatory approval or impact our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production or testing. Any one of these events could cause our business to be materially harmed and our results of operations would be adversely impacted.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

The success of our business is dependent in large part on our continued ability to attract and retain our senior management, and other highly qualified personnel in our scientific, clinical, manufacturing and commercial organizations. Intense competition exists in the biopharmaceutical industry for these types of personnel. Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies. We may not be able to continue to attract and retain the highly qualified personnel necessary for developing, manufacturing and commercializing our product candidates. If we are unsuccessful in our recruitment and retention efforts, or if our recruitment efforts take longer than anticipated, our business may be harmed.

We are highly dependent on principal members of our senior management, including Robert Ward, our Chief Executive Officer. While we have entered into employment agreements or offer letters with each of our executive officers, any of them could leave our employment at any time, as all of our employees are “at will” employees. Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, will also be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies or clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit or loss of the services of any executive, key employee, consultant or advisor may impede the progress of our research, development and commercialization objectives. If we fail to attract and retain highly qualified personnel, we may not be able to successfully develop, manufacture or commercialize our product candidates.

Risks Related to Intellectual Property

If we fail to adequately protect or enforce our intellectual property rights or secure rights to third party patents, the value of our intellectual property rights would diminish, and our business, competitive position and results of operations would suffer.

As of December 31, 2018, we owned or licensed 19 issued patents and 34 pending patent applications in the U.S. and abroad, not including U.S. provisional applications. However, with regard to the pending provisional applications, the filing of a patent application does not mean that we will be issued a patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a currently pending patent application may delay the approval of such patent application which could have a material adverse effect on our business, results of operations and financial condition. In addition, there are a number of factors that could cause our current or future issued patents to become invalid or unenforceable or that could cause our pending patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or lack of originality of the technology. Our competitive position and future revenue will depend in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors and those who infringe upon our patents, including whether third parties will find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our owned or licensed patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings, which may be costly, and whether we win or lose.

If patent rights covering our products or technologies are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the U.S. Patent and Trademark Office or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors and those who infringe upon our patents.

Furthermore, the life of our patents is limited. With regard to our lead compound ELX-02, patents that have issued or that may issue in the future from our primary composition of matter patent family are currently set to expire in 2031. We have pending patent families directed to specific methods of using and manufacturing ELX-02, and any patents that may issue from these families would be expected to expire in 2035 and 2038, respectively. However, these applications may not issue, and even if they do issue the resultant patents may not provide adequate coverage to meaningfully block competitors from launching their products. We will likely pursue additional patent protection relating to ELX-02 in the future, including for example additional methods of use or manufacture, specific formulations, or combinations of ELX-02 with other therapeutic agents. However, as with our pending patent families, any applications we file in the future may not issue or may not result in adequate coverage to adequately protect our assets.

Depending upon the timing, duration, and conditions of any FDA marketing approval for ELX-02, one or more of our patents may be eligible for patent term extension of up to five years under the Hatch-Waxman Act. However, we may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply for an extension within applicable deadlines, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. Only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval and only those claims covering the approved drug, an approved method of using the approved drug, or a method of manufacturing the approved drug may be extended. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for ELX-02 will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, and our business could be harmed.

If we cannot obtain new patents, maintain our existing patents and protect the confidentiality and proprietary nature of our trade secrets and other intellectual property, our business and competitive position may be harmed.

Our success will depend in part on our ability to obtain and maintain patent and regulatory protections for our product candidates, to preserve our trade secrets and other proprietary rights, to operate without infringing the proprietary rights of third parties, and to prevent third parties from circumventing our rights. Due to the time and expense of bringing new product candidates through development and regulatory approval to the marketplace, there is particular importance in obtaining patent and trade secret protection for significant new technologies, products and processes.

We have and may in the future obtain patents or the right to practice patents through ownership or license. Our patent applications may not result in the issue of patents in the U.S. or other countries. Our patents may not afford adequate protection for our products. Third parties may challenge our patents. If any of our patents are narrowed, invalidated or become unenforceable, competitors may develop and market products similar to ours that do not conflict with or infringe our patents rights, which could have a material adverse effect on our financial condition. We may also finance and collaborate in research conducted by government organizations, hospitals, universities or other educational or research institutions. Such research partners may be unwilling to grant us exclusive rights to technology or products developed through such collaborations. There is also a risk that disputes may arise as to the rights to technology or products developed in collaboration with other parties. Our product candidates are expensive and time-consuming to test and develop. Even if we obtain and maintain patents, our business may be significantly harmed if the patents are not broad enough to protect our products from copycat products.

Significant legal questions exist concerning the extent and scope of patent protection for biopharmaceutical products and processes in the U.S. and elsewhere. Accordingly, there is no certainty that patent applications owned or licensed by us will issue as patents, or that our issued patents will afford meaningful protection against competitors. Once issued, patents are subject to challenge through both administrative and judicial proceedings in the U.S. and other countries. Such proceedings include re-examinations, inter partes reviews, post-grant reviews and interference proceedings before the U.S. Patent and Trademark Office, as well as opposition proceedings before the European Patent Office and other non-U.S. patent offices. Litigation may be required to enforce, defend or obtain our patent and other intellectual property rights. Any administrative proceeding or litigation could require a significant commitment of our resources and, depending on outcome, could adversely affect the scope, validity or enforceability of certain of our patent or other proprietary rights.

In addition, our business requires using sensitive technology, techniques and proprietary compounds that we protect as trade secrets. However, we may also rely heavily on collaboration with, or discuss the potential for collaboration with, suppliers, outside scientists and other biopharmaceutical companies. Collaboration and discussion of potential collaboration present a strong risk of exposing our trade secrets. If our trade secrets were exposed, it would help our competitors and adversely affect our business prospects.

If we are found to be infringing on patents owned by others, we may be forced to pay damages to the patent owner and/or obtain a license to continue the manufacture, sale or development of our product candidates. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our product candidates, which would adversely affect our business.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages and required to defend against litigation which could result in substantial costs and may have a material adverse effect on our business, results of operations and financial condition.

We have not received to date any claims of infringement by any third parties. However, as our product candidates progress into clinical trials and commercialization, if at all, our public profile and that of our product candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we may incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement, which could significantly impede development and impair or block our ability to secure regulatory approval of any redesigned product or process;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our product candidates;

- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

Any costs incurred in connection with such events or the inability to develop or sell our products may have a material adverse effect on our business, results of operations and financial condition.

We rely on confidentiality agreements that could be breached and may be difficult to enforce which could have a material adverse effect on our business and competitive position.

Our policy is to enter agreements relating to the non-disclosure of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to the intellectual property. If a dispute arises, a court may determine that the rights belong to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors and other third parties. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements may have a material adverse effect on our business and competitive position.

If we cannot meet requirements under our license agreement, we could lose the rights to our product candidates, which could have a material adverse effect on our business.

We depend on the license agreement with TRDF to maintain the intellectual property rights to certain of our product candidates. Our license agreement requires us to make payments and satisfy performance obligations in order to maintain our rights under this agreement. This agreement lasts either throughout the life of the patents that are the subject of the agreement, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreement in a timely manner, we could lose the rights to our proprietary technology, which could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Our Regional Operations

Potential political and economic instability in regions where we conduct business may adversely affect our results of operations.

In addition to our operations in the United States, we currently conduct certain research and clinical development activities through our regional operations located in Israel, and may, in the future, expand operations to other regional locations in Europe and elsewhere as circumstances require. Accordingly, political and economic conditions in general and in Israel and the surrounding region in particular, may directly affect our operations at such locations. Regional instability may lead to a deterioration in the political and trade relationships that exist between countries in the region, making it more difficult to conduct operations.

In addition, our insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East or for any resulting disruption in our operations. Although the Israeli government has in the past covered the reinstatement value of direct damages that were caused by terrorist attacks or acts of war, we cannot provide assurance that this government coverage will be maintained or, if maintained, will be sufficient to compensate us fully for damages incurred.

Furthermore, in the past, Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with Israel and with Israeli companies. These restrictive laws and policies, even though we are a U.S.-based company, may have an adverse impact on our operating results, financial conditions or the expansion of our business.

We received Israeli government grants for our research and development activities and programs. The terms of such grants may require us, in the future, to pay royalties and, under certain circumstances, penalties in addition to payment of royalties.

Our research and development efforts were initially financed, in part, through royalty-bearing grants from the Israel Innovation Authority, or IIA. We received an aggregate of approximately $2.6 million from the IIA for the development of our technologies. With respect to such grants we are required to pay certain royalties (including accrued LIBOR interest) up to approximately $2.7 million. We are required to comply with the requirements of the Israeli Encouragement of Research, Development and Technological Innovation in the Industry Law, 5744-1984, as amended, and related regulations, or the R&D Law, with respect to these past grants. If we fail to comply with the R&D Law, we may be required to refund certain grants previously received and/or to pay interest and penalties and we may become subject to criminal charges.

With respect to such grants, we are obligated to pay royalties at a rate of 3% to 6% from the revenue generated from the sale of any products or services developed using IIA grants up to a maximum amount equal to repayment of the grant proceeds received plus accrued interest. We have not commenced the payment obligation of these royalties since we have not yet generated income, and we have a contingent obligation with respect to such future royalty payments including LIBOR interest, in the amount of approximately $2.7 million**.**

The R&D Law and the terms of the prior grants restrict the transfer of certain know-how, and the transfer of manufacturing or manufacturing rights of products developed with grant funds, outside of Israel, without the prior approval of the IIA. Therefore, if aspects of our technologies are deemed to have been developed with IIA funding according to the R&D Law, the discretionary approval of the IIA may be required for any assignment and/or transfer to third parties inside or outside of Israel of know-how or transfer outside of Israel of manufacturing or manufacturing rights and may result in payment of increased royalties and/or payment of additional amounts to the IIA. Furthermore, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development outside of Israel. Such approvals may not be granted by the IIA and any conditions imposed may not be acceptable to the Company.

The R&D Law and the regulations promulgated thereunder provide that the transfer of IIA-supported technology or know-how outside of Israel may involve the payment of additional amounts depending upon the value of the transferred technology or know-how, the amount of IIA support, the time of completion of the IIA-supported research project and other factors up to a maximum of six times the amount of grants received. These restrictions and requirements for payment may impair our ability to sell our technology assets outside of Israel or to outsource or transfer development or manufacturing activities with respect to any product or technology outside of Israel. Furthermore, the consideration available to our stockholders in a transaction involving the transfer outside of Israel of technology or know-how developed with IIA funding may be reduced by any amounts that we are required to pay to the IIA. Our obligations and limitations pursuant to the R&D Law are not limited in time and may not be terminated by us at will. As of the date hereof, we have not been required to pay any royalties with respect to the IIA grants.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment or engagement are assigned to us or owned exclusively by us without the employee retaining any rights. A significant portion of our intellectual property has been developed by our employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the "Patent Law"), inventions conceived by an employee during the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "Committee"), a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her inventions. Previous decisions by the Committee have created uncertainty in this area regarding whether the right to receive remuneration for service inventions can be voluntarily waived by an employee and whether such waiver is enforceable. In addition, the Committee determined that even if such right to receive compensation and royalties for service inventions may be waived, the waiver should be specific. Subsequent court cases have not provided significant clarity on these matters.

Risks Related to Our Common Stock

Our stock price may be volatile and purchasers of our common stock could incur substantial losses.

Our common stock began trading on The Nasdaq Global Market on April 26, 2018 under the symbol "ELOX." The trading price of our common stock has been volatile and may continue to be volatile and subject to wide fluctuations in the future. Many factors could have an impact on our stock price, including fluctuations in our or our competitors' operating results, clinical trial results or adverse events associated with our product candidates, product development by us or our competitors, changes in laws, including healthcare, regulatory, tax or intellectual property laws, intellectual property developments, acquisitions or other strategic transactions, changes in financial or operational estimates or projections and the perceptions of our investors that we are not performing or meeting expectations. The trading price of the common stock of many biopharmaceutical companies, including ours, has experienced extreme price and volume fluctuations, which have at times been unrelated to the operating performance of the companies whose stocks were affected. In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of shares of our common stock.

Our directors, executive officers, principal stockholders and affiliated entities own a significant percentage of our capital stock, and they may make decisions that an investor may not consider to be in the best interests of our stockholders.

Our directors, executive officers, principal stockholders and affiliated entities beneficially own, in the aggregate, a significant percentage of our common stock, giving effect to options and other derivative securities that are held by such persons. As a result, if some or all of them acted together, they would have the ability to exert substantial influence over the election of our board of directors and the outcome of issues requiring approval by our stockholders. This concentration of ownership may have the effect of delaying or preventing a change in control of our Company that may be favored by other stockholders. This could prevent the consummation of transactions favorable to other stockholders, such as a transaction in which stockholders might otherwise receive a premium for their shares over current market prices.

Future sales and issuances of our securities or rights to purchase securities, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the prices of our securities to fall.

Additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time. If we sell common stock, convertible securities or other equity securities in one or more transactions, existing investors may be materially diluted by subsequent sales, and new investors could gain rights superior to our existing stockholders.

Pursuant to the 2018 Plan, our management is authorized to grant share options and other equity-based awards to our employees, directors and consultants. The 2018 Plan became effective on April 20, 2018. As of September 30, 2019, individuals held share options to purchase an aggregate of 4,687,557 shares of our common stock. If our board of directors elects to increase the number of shares available for future grant by the maximum amount each year, our stockholders may experience additional dilution, which could have a negative effect on our share price.

Risks Related to the Reverse Merger

The risks arising with respect to the historic Sevion business and operations may be different from what we anticipate, which could lead to significant, unexpected costs and liabilities and could materially and adversely affect our business going forward.

We may not have fully anticipated the extent of the risks associated with the reverse merger between Sevion and Eloxx Limited. After the reverse merger, Sevion's historic business was discontinued, but prior to the transaction Sevion had a long operating history. As a consequence, we may be subject to claims, demands for payment, regulatory issues, costs and liabilities that were not and are not currently expected or anticipated. Notwithstanding our exercise of due diligence pre-transaction and risk mitigation strategies post-transaction, the risks involved with taking over a business with a long operating history and the costs and liabilities associated with these risks may be greater than we anticipate. Further, we do not have rights of indemnification against the pre-transaction stockholders of Sevion. We may not be able to contain or control the costs or liabilities associated with Sevion's historic business, which could materially and adversely affect our business, liquidity, capital resources or results of operation, and may divert management's time and attention from conducting the business of the Company.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

The following is a list of exhibits filed as part of this Report. Where so indicated, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
10.1*	Change in Control Severance Benefit Plan				
31.1*	Certification of the Company's Chief Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
31.2*	Certification of the Company's Chief Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities and Exchange Act of 1934, as amended, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1***	Certification of the Company's Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
32.2***	Certification of the Company's Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.				

* Filed herewith.

*** This certification is being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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, thereunto duly authorized.

ELOXX PHARMACEUTICALS, INC.

Date: November 6, 2019

by: /s/ Gregory Weaver

Gregory Weaver

Chief Financial Officer

(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.1

ELOXX PHARMACEUTICALS, INC.

CHANGE IN CONTROL SEVERANCE BENEFIT PLAN

APPROVED BY THE BOARD OF DIRECTORS: SEPTEMBER 17, 2019

SECTION 1. INTRODUCTION.

The Eloxx Pharmaceuticals, Inc. Change in Control Severance Benefit Plan (the "***Plan***") is hereby established effective September 17, 2019 (the *"**Effective Date***"). The purpose of the Plan is to provide for the payment of severance benefits to eligible employees of the Company in the event that such employees become subject to involuntary or constructive employment terminations in connection with a Change in Control. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

(a) ***"Affiliate"*** means any corporation (other than the Company) in an "unbroken chain of corporations" beginning with the Company, if each of the corporations other than the last corporation in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(b) "***Base Salary***" means base pay (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation, in each case, unless required to be included as "base pay" under applicable law) as in effect immediately prior to a Covered Termination and prior to any reduction that would give rise to an employee's right to resign for Good Reason.

(c) "***Board***" means the Board of Directors of the Company; provided, however, that if the Board has delegated authority to administer the Plan to a committee of the Board, then "***Board***" shall also mean such committee.

(d) "***Cause***" means, with respect to a Participant, the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, embezzlement, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud, embezzlement or act of dishonesty against the Company or an Affiliate; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or an Affiliate or of any statutory duty owed to the Company or an Affiliate; (iv) such Participant's unauthorized use or disclosure of the Company's or an Affiliate's confidential information or trade secrets; (v) the refusal or omission by the Participant to perform any duties required of him or her if such duties are consistent with duties customary for the position held with the Company or an Affiliate or persistent unsatisfactory performance or neglect of his or her job duties; or (vi) such Participant's gross misconduct. The determination whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion. Any determination by the Plan Administrator that the employment of a Participant was terminated with or without Cause hereunder will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.in any written agreement between such employee and the Company defining such term.

(e) "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(1) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control will not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company's securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control will be deemed to occur;

(2) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(3) the stockholders of the Company approve or the Board approves a plan of complete dissolution of liquidation of the Company, or a complete dissolution or liquidation of the Company will otherwise occur, except for a liquidation into a parent corporation;

(4) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(5) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the "***Incumbent Board***") cease for any reason to constitute at least a majority of the members of the Board; provided, however, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member will, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, the term Change in Control will not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company. To the extent required for compliance with Section 409A, in no event will a Change in Control be deemed to have occurred if such transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). The Board may, in its sole discretion and without a Participant's consent, amend the definition of "Change in Control" to conform to the definition of "Change in Control" under Section 409A.

(f) "***Change in Control Period***" means the period commencing upon a Change in Control and ending twelve (12) months following the Closing of a Change in Control.

(g) "***Closing***" means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

(h) "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended.

(j) "***Company***" means Eloxx Pharmaceuticals, Inc. or, following a Change in Control, the surviving entity resulting from such event; provided, that the term "Company" as used in this Plan shall be deemed to include, as applicable, the Designated Subsidiaries.

(k) "***Covered Termination***" means an Involuntary Termination that occurs within the Change in Control Period.

(l) "***Designated Subsidiaries***" means each Subsidiary of the Company on the Effective Date and future Subsidiaries of the Company, in each case, that are not specifically excluded from participation by the Plan Administrator from time to time in its sole discretion. In the event that the Company has Subsidiaries located in jurisdictions outside of the United States, any such Subsidiary shall not be a Designated Subsidiary unless the Plan Administrator specifically designates such Subsidiary as a Designated Subsidiary.

(m) "***Director***" means a member of the Board.

(n) "***Eligible Employee***" means an employee of the Company who meets the requirements to be eligible to receive Plan benefits as set forth in Section 2.

(o) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(p) "***Equity Plan***" means, as applicable, the Company's 2018 Equity Incentive Plan, the Company's Share Ownership and Option Plan (2013) or any successor or other equity incentive plan(s) adopted by the Company which govern a Participant's stock or stock-based awards.

(q) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(r) "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company's then outstanding securities.

(s) "***Good Reason***" for an employee's resignation means the occurrence of any of the following events, conditions or actions taken by the Company without Cause and without such employee's consent; provided that any resignation by the employee due to any of the following conditions shall only be deemed for Good Reason if: (i) the employee gives the Company written notice of the intent to terminate for Good Reason within thirty (30) days following the first occurrence of the condition(s) that the employee believes constitutes Good Reason, which notice shall describe such condition(s); (ii) the Company fails to remedy, if remediable, such condition(s) within thirty (30) days following receipt of the written notice (the "***Cure Period***") of such condition(s) from the employee; and (iii) the employee actually resigns the employee's employment within the first thirty (30) days after expiration of the Cure Period: (1) any material reduction by the Company of the employee's base salary, as the same may be increased from time to time; or (2) a requirement that the employee relocate to a principal place of employment more than seventy-five (75) miles from their current place of employment.

(t) "***Involuntary Termination***" means a termination of employment that is due to: (1) a termination by the Company without Cause or (2) an employee's resignation for Good Reason.

(u) "***Own***," "***Owned***," "***Owner***," "***Ownership***" means a person or Entity will be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(v) "***Participant***" means an Eligible Employee who, on the date of the Covered Termination fulfils the eligibility and participation requirements, as provided herein.

(w) "***Plan Administrator***" means the Board, or a duly authorized committee thereof.

(x) "***Section 409A***" means Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect.

(y) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

(z) "***Target Bonus***" means with respect to a Participant, if there is a cash bonus plan applicable to such Participant for the year in which such Covered Termination occurs ("***Cash Bonus Plan***"), the cash bonus payable to such Participant under such Cash Bonus Plan as if all the applicable performance goals for such year were attained at a level of 100%. If no Cash Bonus Plan is in effect for the year in which such Covered Termination occurs, the Target Bonus Amount will be the target bonus, if any, in such Participant's then-effective employment agreement or offer letter with the Company, as if all of the applicable performance goals for such year were attained at a level of 100%.

SECTION 2. ELIGIBILITY FOR BENEFITS.

(a) **Eligible Employee**. An employee of the Company is eligible to participate in the Plan if (i) as of immediately prior to a Covered Termination, such employee is a full-time employee of the Company other than any officer of the Company who is subject to the reporting rules under Section 16 of the Exchange Act; (ii) the Plan Administrator has designated such employee as eligible to participate in the Plan; (iii) such employee's employment with the Company terminates due to a Covered Termination; (iv) such employee meets the other Plan eligibility requirements set forth in this Section 2; (v) unless otherwise determined by the Plan Administrator in its discretion, such employee is not entitled to severance payments or benefits under any severance benefit plan, policy or practice previously maintained by the Company, including any severance benefits set forth in any individually negotiated employment contract or agreement between the Company and an employee; and (vii) such employee is not covered by a collective bargaining agreement, unless the collective bargaining agreement expressly requires that such employee is eligible to participate in the Plan. Notwithstanding anything in the Plan to the contrary, (A) individuals who provide services to the Company whom the Company does not classify under its customary worker classification procedures as employees, including, but not limited to, independent contractors, contractor's employees and leased employees (irrespective of whether such individuals are common law employees) shall not be eligible to participate in the Plan, and (B) individuals who are absent from work on unpaid leaves of absence shall not be

eligible to participate in the Plan except to the extent eligibility is required by applicable law. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons. After the Effective Date, the Plan Administrator may, in its sole and absolute discretion, designate additional employees of the Company as Eligible Employees, and may exclude an employee from participating in the Plan or exclude an Eligible Employee who is a Participant from continuing to participate in the Plan. If a Participant is promoted to an employee group or salary band title with a higher tier of benefits pursuant to Section 3 of the Plan, in each case as determined by the Plan Administrator in its sole discretion, then, except as otherwise determined by the Plan Administrator in its sole discretion, the benefits to be received by such Participant will automatically adjust.

(b) Release Requirement; Additional Agreements. In order to be eligible to receive benefits under the Plan, a Participant also must timely execute and return to the Company a general waiver and release of all claims in a form acceptable to the Company (the "***Release***"), within the applicable time period set forth therein, but in no event more than fifty (50) days following the date of the applicable Covered Termination, and such Release must become effective in accordance with its terms. As a condition of being eligible to receive benefits under the Plan, a Participant shall be required to be in full compliance with a non-compete/confidentiality and trade secrets/inventions undertaking agreement or similar agreement as may be required or requested by the Company from time to time.

(c) Plan Benefits Provided in Lieu of Individual Agreement Severance Benefits. Unless otherwise determined by the Plan Administrator in its discretion, a Participant shall not be eligible to receive severance benefits under this Plan if the Participant is otherwise eligible to receive severance benefits under the terms of an individually negotiated employment contract or agreement with the Company or any other severance arrangement with the Company.

(d) Exceptions to Benefit Entitlement. An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

(1) The employee voluntarily terminates employment with the Company without Good Reason or terminates employment due to the employee's death or disability. Voluntary terminations include, but are not limited to, resignation, retirement or failure to return from a leave of absence on the scheduled date.

(2) The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate.

(3) The employee is offered an identical or substantially equivalent or comparable position with the Company or an Affiliate. For purposes of the foregoing, a "substantially equivalent or comparable position" is one that provides the employee substantially the same level of responsibility and compensation and would not give rise to the employee's right to resign for Good Reason.

(4) The employee is offered immediate reemployment by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control and the terms of such reemployment would not give rise to the employee's right to resign for Good Reason. For purposes of the foregoing, "immediate reemployment" means that the employee's employment with the successor to the Company or an Affiliate or the purchaser of its assets, as the case may be, results in uninterrupted employment such that the employee does not incur a lapse in pay or benefits as a result of the change in ownership of the Company or the sale of its assets.

(5) The employee is rehired by the Company or an Affiliate and recommences employment prior to the date benefits under the Plan are scheduled to commence.

(6) Upon a termination of employment other than a Covered Termination.

SECTION 3. AMOUNT OF BENEFIT.

(a) **Severance Benefit**. Upon a Covered Termination, benefits under the Plan shall be provided to each Participant as follows:

(1) *Cash Severance Benefit*. The Participant will be entitled to:

(i) continue to receive the Participant's then-current Base Salary for the following number of months set forth in the following table (such period of months, the "***Severance Period***"):

Employee Group / Salary Band Title	Severance Period
Vice President	12 months
Senior Director/Director	9 months
Associate Director/Manager	6 months
All Other Participants	3 months

Such payments shall be payable in substantially equal installments in accordance with the Company's payroll practices, as in effect from time to time, with the first payment commencing on the first payroll date following the effective date of the Participant's Release, and the first payment to include any payments that are due to be paid between the date of the Participant's Covered Termination and the date of the first payment; and

(ii) the Participant will additionally be entitled to a portion of the Participant's Target Bonus, if any, for the year in which the Participant's Covered Termination occurs, in an amount equal to the Participant's annual Target Bonus for such year, if any, multiplied by the quotient of the Severance Period divided by twelve (12), which shall be payable in a lump sum payment within ten (10) business days following the effective date of the Participant's Release.

(2) *Accelerated Vesting of Stock Awards.*

(i) Effective as of the effective date of the Participant's Release, to the extent not previously vested: (A) the vesting and exercisability of all outstanding stock options under an Equity Plan to purchase the Company's common stock that are held by the Participant on such date shall be accelerated in full, (B) any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to any other stock award granted to the Participant by the Company under an Equity Plan shall lapse in full, and (C) the vesting of any other stock awards granted to the Participant by the Company under an Equity Plan, and any issuance of shares triggered by the vesting of such stock awards, shall be accelerated in full. Notwithstanding the foregoing, this Section 3(a)(2)(i) shall not apply to stock awards issued under or held in any plan sponsored by the Company or an Affiliate that is intended to be qualified under Section 401(a) of the Internal Revenue Code. For purposes of determining the number of shares that will vest pursuant to the foregoing provision with respect to any performance based vesting award that has multiple vesting levels depending upon the level of performance, vesting acceleration shall occur with respect to the number of shares subject to the award as if the applicable performance criteria had been attained at a 100% level.

(3) Notwithstanding anything to the contrary set forth herein, the Participant's stock awards shall remain subject to earlier termination in connection with a "Corporate Transaction" or "Significant Event", as applicable, as provided in the applicable Equity Plan or substantially equivalent provisions applicable to the Participant's stock award.

(4) *Payment of Continued Group Health Plan Benefits.*

(i) If applicable, if the Participant timely elects continued group health plan continuation coverage under COBRA the Company shall pay the full amount of the Participant's COBRA premiums, or shall provide coverage under any self-funded plan, on behalf of the Participant for the Participant's continued coverage under the Company's group health plans, including coverage for the Participant's eligible dependents, for the Severance Period (the "***COBRA Payment Period***"). Upon the conclusion of such period of insurance premium payments made by the Company, or the provision of coverage under a self-funded group health plan, the Participant will be responsible for the entire payment of premiums (or payment for the cost of coverage) required under COBRA for the duration of the Participant's eligible COBRA coverage period. For purposes of this Section, (A) references to COBRA shall be deemed to refer also to analogous provisions of state law and (B) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by the Participant under an Internal Revenue Code Section 125 health care reimbursement plan, which amounts, if any, are the Participant's sole responsibility.

(ii) Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Participant's behalf, the Company will instead pay to the Participant on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "***Special Severance Payment***"), such Special Severance Payment to be made without regard to the Participant's election of COBRA coverage or payment of COBRA premiums and without regard to the Participant's continued eligibility for COBRA coverage during the COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the COBRA Payment Period.

(b) **Additional Benefits**. Notwithstanding the foregoing, the Company may, in its sole discretion, provide benefits to employees or consultants who are not Eligible Employees ("***Non-Eligible Employees***") chosen by the Plan Administrator, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other Non- Eligible Employee, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" or "Participant" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

(c) **Certain Reductions**. The Company, in its sole discretion, shall have the authority to reduce a Participant's severance benefits, in whole or in part, by any other severance benefits, pay and benefits provided during a period following written notice of a plant closing or mass layoff, pay and benefits in lieu of such notice, or other similar benefits payable to a Participant by the Company or an Affiliate that become payable in connection with a Participant's Covered Termination pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other similar state law, (ii) any individually negotiated employment contract or agreement or any other written employment or severance agreement with the Company, or (iii) any Company policy or practice providing for a Participant to remain on the payroll for a limited period of time after being given notice of the termination of a Participant's employment, and the Plan Administrator shall so construe and implement the terms of the Plan. Any such reductions that the Company determines to make pursuant to this Section 3(c) shall be made such that any benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice *(i.e.,* any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice, and any continued insurance benefits under the Plan shall be reduced solely by any continued insurance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Participant and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other Participant, even if similarly situated. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

(d) Parachute Payments.

(1) Any provision of the Plan to the contrary notwithstanding, if any payment or benefit a Participant would receive from the Company pursuant to the Plan or otherwise ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment will be equal to the Reduced Amount (defined below). The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Participant's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Participant. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

(2) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, the Participant agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, the Participant will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

(3) Unless the Participant and the Company agree on an alternative accounting firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the a change in ownership or control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the change in ownership or control, the Company shall appoint a nationally recognized accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting firm required to be made hereunder.

SECTION 4. RETURN OF COMPANY PROPERTY.

A Participant will not be entitled to any severance benefit under the Plan unless and until the Participant returns all Company Property. For this purpose, "***Company Property***" means all Company documents (and all copies thereof) and other Company property which the Participant had in his or her possession at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part).

Section 5. Time of Payment and Form of Benefit; Withholding.

The Company reserves the right to specify whether severance payments under the Plan will be paid in a single sum, in installments, or in any other form and to determine the timing of such payments. All such payments under the Plan will be subject to applicable withholding for federal, state and local taxes. All severance benefits provided under the Plan are intended to satisfy the requirements for an exemption from application of Section 409A of the Code to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly; provided, however, that to the extent such an exemption is not available, the severance benefits provided under the Plan are intended to comply with the requirements of Section 409A to the extent necessary to avoid adverse personal tax consequences and any ambiguities herein shall be interpreted accordingly.

Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under the Plan that constitute "deferred compensation" within the meaning of Section 409A shall not commence in connection with a Participant's termination of employment unless and until the Participant has also incurred a "separation from service," as such term is defined in Treasury Regulations Section 1.409A-1(h) ("***Separation from Service***"), unless the Company reasonably determines that such amounts may be provided to the Participant without causing the Participant to incur the adverse personal tax consequences under Section 409A.

It is intended that (i) each installment of any benefits payable under the Plan to a Participant be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), (ii) all payments of any such benefits under the Plan satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9)(iii), and (iii) any such benefits consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemption from the application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(9)(v). However, if the Company determines that any such benefits payable under the Plan constitute "deferred compensation" under Section 409A and the Participant is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i), then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (A) the timing of such benefit payments shall be delayed until the earlier of (1) the date that is six (6) months and one (1) day after the Participant's Separation from Service and (2) the date of the Participant's death (such applicable date, the "***Delayed Initial Payment Date***"), and (B) the Company shall (1) pay the Participant a lump sum amount equal to the sum of the benefit payments that the Participant would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefits had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

In no event shall payment of any benefits under the Plan be made prior to a Participant's termination date or prior to the effective date of the Release. If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Participant's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Participant's Separation from Service occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective any earlier than the latest permitted effective date (the "***Release Deadline***"). If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, then except to the extent that payments may be delayed until the Delayed Initial Payment Date pursuant to the preceding paragraph, on the first regular payroll date following the effective date of a Participant's Release, the Company shall (1) pay the Participant a lump sum amount equal to the sum of the benefit payments that the Participant would otherwise have received through such payroll date but for the delay in payment related to the effectiveness of the Release and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

All severance payments under the Plan shall be subject to applicable withholding for federal, state and local taxes, as determined by the Plan Administrator in its sole discretion. If a Participant is indebted to the Company at his or her termination date, the Company reserves the right to offset any severance payments under the Plan by the amount of such indebtedness.

SECTION 6. REEMPLOYMENT.

In the event of a Participant's reemployment by the Company during the period of time in respect of which severance benefits pursuant to the Plan have been paid, the Company, in its sole and absolute discretion, may require such Participant to repay to the Company all or a portion of such severance benefits as a condition of reemployment.

SECTION 7. RIGHT TO INTERPRET AND ADMINISTER PLAN; AMENDMENT AND TERMINATION.

(a) Interpretation and Administration. The Board, or a duly authorized committee thereof, shall be the Plan Administrator. The Plan Administrator (or its designee) has full discretion and exclusive right, power and authority in its sole discretion to administer, apply, and interpret the Plan and any other Plan documents and to decide any and all matters (including legal and factual issues) arising under, or in connection with, the operation or administration of the Plan, including without limitation the right to (i) make findings of fact; (ii) take all actions and make all decisions with respect to and to otherwise determine eligibility for participation, benefits, and other rights under the Plan and the amount payable under the Plan; (iii) determine whether any notice requirement or other administrative procedure under the Plan has been adequately observed; (iv) determine the proper recipient(s) of any Plan benefits; (v) formulate, interpret and apply rules, regulations and policies necessary to administer the Plan in accordance with its terms; (vi) remedy, resolve and/or clarify any possible ambiguities, inconsistencies, or omissions arising under the Plan or other Plan documents by general rule or particular decision; (vii) decide questions (including legal or factual questions) relating to the calculation and payment of benefits under the Plan; (viii) process and approve or deny benefit claims and rule on any exclusions therefrom; (ix)

decide for purposes of paying benefits hereunder, whether, based on the terms of the Plan, a termination of employment is a Covered Termination; (x) determine the standard of proof required in any case; and (xi) otherwise to interpret the Plan in accordance with its terms. The Plan Administrator's (or its designee's) interpretations, determinations, and decisions with respect to any matter arising under the Plan and any other relevant documents and on any and all questions arising out of the interpretation or administration of the Plan shall be final, conclusive and binding on all parties, including all Eligible Employees, all Participants, all beneficiaries and any other individuals claiming benefits under the Plan.

(b) **Delegation of Authority**. Prior to the Closing, the Plan Administrator, in its sole discretion, may delegate to other persons responsibilities for performing certain of the duties of the Plan Administrator under the terms of the Plan.

(c) **Retention of Professional Assistance**. The Plan Administrator may employ such legal counsel, accountants and other persons as may be required in carrying out its work in connection with the Plan.

(d) **Indemnification**. Neither the Plan Administrator nor any of its designees will be liable for any action or determination made in good faith with respect to the Plan. The Company will, to the extent permitted by law, by the purchase of insurance or otherwise, indemnify and hold harmless the Plan Administrator and each director, officer and employee of the Company and its Affiliates for liabilities or expenses they and each of them incur in carrying out their respective duties under this Plan, other than for any liabilities or expenses arising out of such individual's willful misconduct or fraud.

(e) **Amendment**. Although the Plan is designed to provide severance and other benefits to selected employees as provided herein, the Board may amend or terminate the Plan in whole or in part at any time upon at least sixty (60) days' prior written notice to Participants; provided, however, that any amendment of the Plan shall not adversely affect the benefits to which a Participant is entitled on the Participant's Covered Termination, if such Covered Termination occurred prior to the date of the amendment of the Plan, without the Participant's written consent; and provided, further, that no amendment that has the effect of reducing or diminishing the right of any Participant shall be effective during the Change in Control Period, without the written consent of a majority of the Participants.

(f) **Termination**. The Board may amend or terminate the Plan at any time in its sole discretion; provided, however, that any termination of the Plan shall not adversely affect the benefits to which a Participant is entitled on the Participant's Covered Termination, if such Covered Termination occurred prior to the date of the termination of the Plan, without the Participant's written consent; and provided, further, that no termination that has the effect of reducing or diminishing the right of any Participant shall be effective during the Change in Control Period, without the written consent of a majority of the Participants.

(g) **Successors and Assigns**. The Plan shall be binding on all successors and permitted assigns of a Participant including, without limitation, the estate of such Participant and the executor, administrator or trustee of such estate. Except in the event of death, a Participant does not have the power to transfer, assign, anticipate, mortgage or otherwise encumber any rights or any amounts payable under the Plan; nor will any such rights or amounts payable under the Plan be subject to seizure, attachment, execution, garnishment or other legal or equitable process, or for the payment of any debts, judgments, alimony, or separate maintenance, or be transferable by operation of law in the event of bankruptcy, insolvency, or otherwise. In the event a Participant attempts to assign, transfer or dispose of such right, or if an attempt is made to subject such right to such process, such assignment, transfer or disposition will be null and void. If a Participant dies while any amount would still be payable to the Participant hereunder had the Participant continued to live, all such amounts, unless otherwise provided in the Plan, shall be paid in accordance with the terms of the Plan to the Participant's beneficiary. If the Participant has not named a beneficiary, then such amounts shall be paid to the Participant's devisee, legatee, or other designee, or if there is no such designee, to the Participant's estate. Each Participant may designate one or more persons or entities as the primary and/or contingent beneficiaries of any amounts owing to the Participant under the Plan. Such designation must be in the form of a signed writing acceptable to the Plan Administrator. A Participant may make or change such designations at any time.

(h) **Severability**. In case any provision of the Plan shall be deemed or held to be unlawful or invalid for any reason, such fact shall not adversely affect the other provisions of the Plan unless such determination shall render impossible or impracticable the functioning of the Plan, and in such case, an appropriate provision or provisions shall be adopted so that the Plan may continue to function properly.

(i) **Foreign Participants**. Notwithstanding any provision of the Plan to the contrary, in order to comply with the laws in other countries in which the Company and its Subsidiaries operate or have employees, or in order to comply with the requirements of any foreign stock exchange, the Plan Administrator, in its discretion, shall have the power and authority to: (i) determine which Subsidiaries shall be covered by the Plan; (ii) determine which Eligible Employees outside the United States are eligible to be Participants in the Plan; (iii) establish subplans and modify terms and procedures, to the extent such actions may be necessary or advisable (any such subplans and/or modifications shall be attached to the Plan as appendices); and (iv) take any action that it deems advisable to obtain approval or comply with any necessary local governmental regulatory exemptions or approvals or listing requirements of any such foreign stock exchange. Notwithstanding the foregoing, the Plan Administrator may not take any actions hereunder that would violate the Code or any other applicable law.

SECTION 8. RIGHTS OF PARTICIPANTS.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved. Any amount(s) payable hereunder will not be taken into account in computing the amount of salary or compensation for purposes of any severance plan, 401(k), pension, or other employee benefit plan(s) in which the Company or its Affiliates is a participating employer.

SECTION 9. LEGAL CONSTRUCTION.

This Plan is intended to be governed by and shall be construed in accordance with the Employee Retirement Income Security Act of 1974 ("***ERISA***") and, to the extent not preempted by ERISA, the laws of the State of California.

SECTION 10. CLAIMS, INQUIRIES AND APPEALS.

(a) Applications for Benefits and Inquiries. Any application for benefits, inquiries about the Plan or inquiries about present or future rights under the Plan must be submitted to the Plan Administrator in writing by an applicant (or his or her authorized representative). The Plan Administrator is:

Eloxx Pharmaceuticals, Inc.
Board of Directors
950 Winter Street
Waltham, Massachusetts 02451
(781) 577-5300

(b) Denial of Claims. In the event that any application for benefits is denied in whole or in part, the Plan Administrator must provide the applicant with written or electronic notice of the denial of the application, and of the applicant's right to review the denial. Any electronic notice will comply with the regulations of the U.S. Department of Labor. The notice of denial will be set forth in a manner designed to be understood by the applicant and will include the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a description of any additional information or material that the Plan Administrator needs to complete the review and an explanation of why such information or material is necessary; and

(4) an explanation of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA following a denial on review of the claim, as described in Section 10(d) below.

This notice of denial will be given to the applicant within ninety (90) days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional ninety (90) days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial ninety (90) day period.

This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the application.

(c) **Request for a Review**. Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within sixty (60) days after the application is denied. A request for a review shall be in writing and shall be addressed to:

Eloxx Pharmaceuticals, Inc.
Board of Directors
950 Winter Street
Waltham, Massachusetts 02451
(781) 577-5300

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The applicant (or his or her representative) shall have the opportunity to submit (or the Plan Administrator may require the applicant to submit) written comments, documents, records, and other information relating to his or her claim. The applicant (or his or her representative) shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim. The review shall take into account all comments, documents, records and other information submitted by the applicant (or his or her representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(d) **Decision on Review**. The Plan Administrator will act on each request for review within sixty (60) days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional sixty (60) days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial sixty (60) day period. This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the review. The Plan Administrator will give prompt, written or electronic notice of its decision to the applicant. Any electronic notice will comply with the regulations of the U.S. Department of Labor. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will set forth, in a manner calculated to be understood by the applicant, the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a statement that the applicant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim; and

(4) a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA.

(e) **Rules and Procedures**. The Plan Administrator will establish rules and procedures, consistent with the Plan and with ERISA, as necessary and appropriate in carrying out its responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial of benefits to do so at the applicant's own expense.

(f) **Exhaustion of Remedies**. No legal action for benefits under the Plan may be brought until the applicant (i) has submitted a written application for benefits in accordance with the procedures described by Section 10(a) above, (ii) has been notified by the Plan Administrator that the application is denied, (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 10(c) above, and (iv) has been notified that the Plan Administrator has denied the appeal. Notwithstanding the foregoing, if the Plan Administrator does not respond to an Participant's claim or appeal within the relevant time limits specified in this Section 10, the Participant may bring legal action for benefits under the Plan pursuant to Section 502(a) of ERISA. In addition, no lawsuit may be commenced more than two (2) years after the date on which the Plan Administrator renders a decision denying the applicant's benefit upon review under Section 10(a) (or the date the cause of action first arose, if earlier).

Section 11. Basis of Payments to and From Plan.

The Plan shall be unfunded, and all cash payments under the Plan shall be paid only from the general assets of the Company.

Section 12. Other Plan Information.

(a) **Employer and Plan Identification Numbers**. The Employer Identification Number assigned to the Company (which is the "Plan Sponsor" as that term is used in ERISA) by the Internal Revenue Service is 84-1368850. The Plan Number assigned to the Plan by the Plan Sponsor pursuant to the instructions of the Internal Revenue Service is 501-002.

(b) **Ending Date for Plan's Fiscal Year**. The date of the end of the fiscal year for the purpose of maintaining the Plan's records is December 31.

(c) **Agent for the Service of Legal Process**. The agent for the service of legal process with respect to the Plan is:

Eloxx Pharmaceuticals, Inc.
General Counsel
950 Winter Street
Waltham, Massachusetts 02451

In addition, service of legal process may be made upon the Plan Administrator.

(d) **Plan Sponsor**. The "Plan Sponsor" is:

Eloxx Pharmaceuticals, Inc.
950 Winter Street
Waltham, Massachusetts 02451
(781) 577-5300

(e) **Plan Administrator**. The Plan Administrator is the Board (or a duly appointed committee thereof). The Plan Administrator's contact information is:

Eloxx Pharmaceuticals, Inc.
Board of Directors – CIC Plan Administrator
950 Winter Street
Waltham, Massachusetts 02451
(781) 577-5300

The Plan Administrator is the named fiduciary charged with the responsibility for administering the Plan.

SECTION 13. STATEMENT OF ERISA RIGHTS.

Participants in this Plan (which is a welfare benefit plan sponsored by Eloxx Pharmaceuticals, Inc.) are entitled to certain rights and protections under ERISA. If you are an Eligible Employee, you are considered a Participant in the Plan and, under ERISA, you are entitled to:

(a) **Receive Information About Your Plan and Benefits.**

(1) Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series), if applicable, filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration;

(2) Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500 Series), if applicable, and an updated (as necessary) Summary Plan Description. The Administrator may make a reasonable charge for the copies; and

(3) Receive a summary of the Plan's annual financial report, if applicable. The Plan Administrator is required by law to furnish each Participant with a copy of this summary annual report.

(b) **Prudent Actions by Plan Fiduciaries**. In addition to creating rights for Plan Participants, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Participants and beneficiaries. No one, including your employer, your union or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a Plan benefit or exercising your rights under ERISA.

(c) **Enforce Your Rights**. If your claim for a Plan benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan, if applicable, and do not receive them within thirty (30) days, you may file suit in a Federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator.

If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or Federal court; provided that, no lawsuit may be commenced more than two (2) years after the date on which the Plan Administrator renders a decision denying your benefit upon review under Section 10(a) (or the date the cause of action first arose, if earlier).

If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

(d) **Assistance with Your Question**s. If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

Exhibit 31.1

CERTIFICATION

I, Robert E. Ward, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eloxx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2019

/s/ Robert E. Ward
Robert E. Ward
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Gregory Weaver, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eloxx Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2019

/s/ Gregory Weaver
Gregory Weaver
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION[1]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Robert E. Ward, Chief Executive Officer of Eloxx Pharmaceuticals, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019, to which this Certification is attached as Exhibit 32.1 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 6th day of November, 2019.

/s/ Robert E. Ward
Robert E. Ward
Chief Executive Officer
(Principal Executive Officer)

(1) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eloxx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION[1]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Gregory Weaver, Chief Financial Officer of Eloxx Pharmaceuticals, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2019, to which this Certification is attached as Exhibit 32.2 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 6th day of November, 2019.

/s/ Gregory Weaver
Gregory Weaver
Chief Financial Officer
(Principal Financial and Accounting Officer)

(1) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eloxx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.