Eloxx Pharmaceuticals, Inc.
Form 10-Q
November 08, 2018

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, 2018

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)

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, 2018, the registrant had 35,124,844 shares of common stock, $0.01 par value per share, outstanding.

ELOXX PHARMACEUTICALS, INC.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

Item 1. Condensed Consolidated Financial Information

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

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)

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

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,	
	2018	2017
Cash flows from operating activities:		
Net loss	$ (33,158)	$ (10,596)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	9,608	38
Depreciation	121	24
Loss on disposal	12	—
Amortization and revaluation of discount in respect to convertible loan	—	625
Accrued interest on convertible loan	—	43
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(401)	658
Other assets	(41)	—
Accounts payable	(178)	(740)
Accrued expenses	1,730	280
Net cash used in operating activities	(22,307)	(9,668)
Cash flows from investing activities:		
Purchases of property and equipment	(133)	(155)
Proceeds from sale of property and equipment	6	—
Cash paid for long-term deposits	(11)	—
Net cash used in investing activities	(138)	(155)

Cash flows from financing activities:				
Proceeds from the underwritten public offering, net of issuance costs		53,573		—
Proceeds from issuance of Series C preferred stock, net of issuance costs		—		18,669
Proceeds from convertible loan and financial derivative into Series C preferred stock		—		2,500
Proceeds from share-based compensation arrangements		103		3
Net cash provided by financing activities		53,676		21,172
Increase in cash and cash equivalents		31,231		11,349
Cash, cash equivalents and restricted cash, beginning of year		24,151		2,250
Cash, cash equivalents and restricted cash, end of period	$	55,382	$	13,599
Reconciliation of cash, cash equivalents and restricted cash to condensed consolidated balance sheets				
Cash and cash equivalents	$	55,336	$	13,538
Restricted cash included in restricted bank deposit		46		61
Total cash, cash equivalents and restricted cash	$	55,382	$	13,599

Supplemental disclosure of non-cash investing activities		
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	$ 83	$ —
Conversion of convertible loan into Series C preferred stock	$ —	$ 3,168
Issuance expenses of Series C Preferred Shares	$ —	$ 242

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO UNAUDITED CONSOLIDATED FINANCIAL STATEMENTS

(in thousands, except share and per share data)

1. Nature of the Business

Eloxx Pharmaceuticals, Inc., together with its wholly-owned subsidiary Eloxx Pharmaceuticals, Ltd. (collectively "we," "our," "us," "Eloxx" or the "Company"), is a clinical-stage biopharmaceutical company developing novel ribonucleic acid (RNA)-modulating drug candidates (designed to be eukaryotic ribosomal selective glycosides) that are formulated to treat rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt protein synthesis from messenger RNA. As a consequence, patients with premature stop codon diseases have reduced levels of, or no, critical functional proteins from the mutation bearing allele accounting for some of the most severe phenotypes in these genetic diseases. These premature stop codons have been identified in over 1,800 rare and ultra-rare diseases. Read-through therapeutic development is focused on extending mRNA (messenger RNA) half-life and increasing functional protein synthesis by enabling the cytoplasmic ribosome to read through premature stop codons to produce full-length proteins. Eloxx's lead investigational product candidate, ELX-02, is a small molecule drug candidate designed to restore production of full-length functional proteins. ELX-02 is in the early stages of clinical development focusing on cystic fibrosis and cystinosis. ELX-02 is an investigational drug that has not been approved by any global regulatory body. Eloxx's preclinical candidate pool consists of a library of novel drug candidates identified based on read-through potential. Eloxx recently announced a new program focused on rare ocular genetic disorders. Eloxx is headquartered in Waltham, MA, with research and development operations in Rehovot, Israel.

The Company's research and development strategy is to target rare or ultra-rare diseases where a high unmet medical need, nonsense mutation bearing, patient population has been identified, there are established preclinical read-through or personalized medicine models that are predictive of clinical activity, and a definable path for Orphan Drug development, regulatory approval, patient access and commercialization. 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 focus for its lead investigational drug product candidate, ELX-02, is on cystic fibrosis and cystinosis. The Company has initiated a new program focused on rare inherited retinal disease and is conducting IND enabling studies for several compounds from its library. The Company will identify an additional molecule later this year to advance into clinical development. Eloxx has entered into a multiyear partnership with the Foundation Fighting Blindness (FFB) to support its inherited retinal degenerative disease registry and educational programs. FFB will provide ELX-02 with ongoing R&D consultation and support. The Company believes this partnership has the potential to accelerate Eloxx's development programs and support patients with ocular disease and a high unmet medical need.

Eloxx Pharmaceuticals Ltd. ("Eloxx Limited") was incorporated in Israel on September 17, 2013 and was acquired by the Company in a reverse merger described below. The Company focuses its activity on the discovery, development and commercialization of compounds for the treatment of genetic diseases caused by nonsense mutations primarily through a license agreement (the "Technion Agreement") with the Technion Research and Development Foundation Ltd. ("TRDF") entered into in 2013. For more information relating to the Technion Agreement, see Note 7 to these unaudited consolidated financial statements.

Reverse Merger

On December 19, 2017, Sevion Therapeutics, Inc. ("Sevion") acquired 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 business plan. In connection with

the Transaction, Sevion acquired all of the outstanding capital stock of Eloxx Limited in exchange for the issuance of an aggregate 20,316,656 shares of Sevion's common stock, par value $0.01 per share (the "Common Stock"), after giving effect to a 1-for-20 reverse split immediately prior to the Transaction. As a result of the Transaction, Eloxx Limited became a wholly-owned subsidiary of Sevion. While Sevion was the legal acquirer in the transaction, Eloxx Limited was deemed the accounting acquirer. Immediately after giving effect to the Transaction, on December 19, 2017, Sevion changed its name to Eloxx Pharmaceuticals, Inc.

These interim unaudited 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 at the equity of the accounting acquirer. The annual audited 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.

Liquidity

As reflected in the accompanying unaudited consolidated financial statements, the Company has not generated revenue from the sale of any product and does not expect to generate significant revenue unless and until it obtains marketing approval and commercialization of one of its product candidates. As of September 30, 2018, the Company had cash and cash equivalents of $55.3 million, inclusive of net proceeds of $53.6 million received upon the completion of an underwritten public offering of 5,899,500 shares of common stock of the Company at the public offering price of $9.75 per share on April 30, 2018.

The Company expects that its cash and cash equivalents will fund operations to 2020 based on its current operating plans. The Company incurred a loss for the nine months ended September 30, 2018 of $33.2 million and had a negative cash flow from operating activities of $22.3 million during the nine months ended September 30, 2018. The accumulated deficit as of September 30, 2018 was $72.1 million.

Correction of an Immaterial Error

The presentation of reverse merger related expense in the Statement of Operations for the nine-months ended September 30, 2018 includes the effects of the correction of an immaterial error of the amounts of functional operating expenses previously reported for the three months ended March 31, 2018. The Company assessed the materiality of these errors in accordance with the SEC's Staff Accounting Bulletin ("SAB") Topic 1.M, Materiality, codified in ASC Topic 250, Presentation of Financial Statements ("ASC 250"), and concluded that the previously issued unaudited condensed consolidated interim financial statements for the three months ended March 31, 2018 and 2017 were not materially misstated; however, in order to correctly reflect the adjustment as described above in the appropriate period, management has elected to correct the presentation in the Statement of Operations for the nine-months ended September 30, 2018 and will revise the affected previously issued financial statements for the three-months ended March 31, 2018 when such amounts are presented as comparative prior period balances in the Form 10-Q filing for the period ending March 31, 2019. As a result, the revised consolidated financial statements for the nine months ended September 30, 2018 reflect a $0.4 million increase to research and development expense, a $0.9 million increase in general and administrative expense, and a corresponding decrease in reverse merger related expenses of $1.3 million. This reclassification correction had no impact on net loss or net cash flows for the three months ended March 31, 2018, the three and nine months ended September 30, 2018.

The impact on specific line items in the accompanying consolidated statement of operations for the three months ended March 31, 2018 is presented below (in thousands):

	Three Months Ended March 31, 2018		
	As reported	Adjustments	As corrected
Operating expenses:			
Research and development	$4,013	$ 381	$ 4,394
General and administrative	2,480	913	3,393
Reverse merger related expenses	2,055	(1,294)	761
Total operating expenses	$8,548	$ —	$ 8,548

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 ("GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") 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, 2018 and 2017.

The Unaudited Consolidated Statements of Operations includes the Company's operating expenses related to research and development and general and administrative, along with reverse merger related expenses, which were substantially comprised of fees for professional services.

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, 2017, 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 16, 2018.

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, 2017, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. There have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2018.

Recent Accounting Pronouncements

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230): "Restricted Cash" (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The amendments in this update are effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company adopted the new guidance using the retrospective transition method as required with respect to each period presented. This new guidance does not have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases". This guidance will require that lease arrangements longer than 12 months result in an entity recognizing an asset and liability equal to the present value of the lease payments in the statement of financial position. This guidance is effective for annual periods beginning after December 15, 2018, and interim periods therein. This standard requires a modified retrospective transition approach for all leases existing at, or entered into after, the date of initial application, with an option to use certain transition relief. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its financial statements and related disclosures.

3. Prepaids and Other Current Assets

Prepaids and other current assets as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	As of September 30, 2018	As of December 31, 2017
Prepaid insurance	$ 208	$ 242
Other governmental agencies receivables	37	88
Prepaid research and development	165	—
Prepaid other	346	25

	$ 756	$ 355

4. Property and Equipment, net

Property and equipment, net consisted of the following (in thousands):

	As of September 30, 2018	As of December 31, 2017
Computers and software	$ 146	$ 124
Office furniture and equipment	166	118
Laboratory equipment	—	37
Leasehold improvements	142	53
	454	332
Less: Accumulated depreciation	109	54
Property and equipment, net	$ 345	$ 278

Depreciation expense was $75,000, and $11,000 for the three months ended September 30, 2018 and 2017, respectively. Depreciation expense was $121,000, and $24,000 for the nine months ended September 30, 2018 and 2017, respectively.

5. Accrued Expenses

Accrued expenses as of September 30, 2018 and December 31, 2017 consisted of the following (in thousands):

	As of September 30, 2018	As of December 31, 2017
Accrued payroll and related expenses	$ 1,207	$ 402
Accrued research and development expenses	1,733	704
Accrued professional services	683	787
Accrued other	104	—
	$ 3,727	$ 1,893

6. Convertible Loan

On January 26, 2017 (the “Closing Date”), the Company entered into a Convertible Loan Agreement (the “Agreement”) with five of its shareholders (the “Lenders”), pursuant to which the Company raised an aggregate amount of $2.5 million (the “Convertible Loan”). The Convertible Loan included interest at an annual rate of 5%. According to the Agreement, the outstanding portion of the Convertible Loan (without accrued interest) automatically converts upon the consummation of an equity investment by a third party of an aggregate amount of at least $5.0 million (the “Qualified

Equity Investment"), prior to the date that is two years from the Closing Date (the "Maturity Date"), into equity securities of the same class issued by the Company in such Qualified Equity Investment.

In accordance with ASC Topic 815 "Derivatives and Hedging", features related to convertible loans qualify as embedded derivative instruments at the date of issuance, since these are considered as stock settled debt. In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value. The embedded conversion feature is classified under level 3 in the hierarchy. The fair value assigned to the embedded conversion feature on the issuance dates amounted to $0.3 million. The embedded instruments are marked to market in each reporting period and changes are recorded in financial expenses. The discount is amortized using the effective interest over the loan period.

On May 31, 2017, the Convertible Loan (without accrued interest) was converted into 825,213 shares of Series C preferred stock, according to the price per share that was paid in the 2017 Share Purchase Agreement (see Note 9). During the year ended December 31, 2017, the Company recorded $0.7 million as financial and other expenses, as a result of changes in the embedded instruments. In connection with the conversion, the embedded instrument together with all accrued interest in the amount of $0.7 million and was classified to additional paid in capital.

The following table presents reconciliations for the Company's liabilities measured and recorded at fair value on a recurring basis, using significant unobservable inputs (in thousands):

	Significant Unobservable Inputs (Level 3)
Balance at January 26, 2017	$ (308)
Amortization and revaluation embedded conversion feature	(317)
Conversion of convertible loan into Series C preferred stock	625
Balance at December 31, 2017	$ —

7. Related Parties

On August 29, 2013, the Company entered into the Technion Agreement with TRDF, with respect to certain technology relating to aminoglycosides and the redesign of aminoglycosides for the treatment of human genetic diseases caused by premature stop mutations and further results of the research of the technology, in order to develop and commercialize products based on such technology. Under the Technion Agreement, TRDF is obligated to provide the Company with research services for an estimated annual payment of $0.1 million, the precise amount to be agreed by the parties prior to the beginning of each year of the research period. For the three and nine months ended September 30, 2018, the Company recorded research and development expense of $0.1 million and $0.1 million, respectively, in relation to in relation to reimbursement for the preparation, filing, prosecution and maintenance of TRDF patent rights related to Eloxx Limited. For the three and nine months ended September 30, 2017, the Company recorded general and administrative expenses amounting to $0 and $7,000, respectively, and research and development expenses amounting to $24,000 in relation to the Technion Agreement. As of September 30, 2018 and December 31, 2017, amounts recorded in accrued expenses were $6,000 and $25,000, respectively.

In addition, TRDF granted the Company a license to use, market, sell or sub-license the rights of the product developed under the TRDF research results (the "Licensed Product"), as fully defined in the Technion Agreement, for the following considerations: (a) milestone payments, to be transferred upon meeting certain milestones as defined in the Technion Agreement, up to total consideration of $6.1 million; (b) certain royalties on a low- to mid- single-digit percentage of net sales (subject to change in the case of (x) sublicensing to a big pharmaceutical or biotechnology company, or (y) payment of royalties to third parties, or (z) commercialization by a third party of an authorized generic to a licensed product), for a period until the later of (i) the expiration of a valid claim on the Licensed Product in each country the Licensed Product is sold to, or (ii) a certain amount of years from the date of the first commercial sale of the Licensed Product in such country, and (c) a low- to mid- double-digit percentage of any non-royalty sub-license income received by the Company from a sub-licensed entity. In addition, the Company will be required to pay a fee to TRDF upon an exit event as described in the Technion Agreement.

Moreover, upon the closing of an Exit Event which is not Initial Public Offering ("IPO"), as defined in the Technion Agreement, TRDF shall be entitled to an amount equal to 3% of all non-refundable, non-contingent consideration, whether in cash or in kind, actually received by the Company and / or its shareholders. Upon the closing of an exit event which is IPO, as defined in the Technion Agreement, TRDF shall be entitled to a number of Ordinary Shares of

the Company representing 3% of the Company's outstanding shares on a fully diluted basis immediately prior to the closing of such IPO.

On August 9, 2017 the Company received a legal claims letter from TRDF regarding TRDF’s alleged entitlement to an exit fee in accordance with the Technion Agreement. The Company recorded a $3.4 million research and development expense with an offsetting adjustment to additional paid-in capital for the year ended December 31, 2017 related to the planned issuance of shares to TRDF at fair market value on the purported date of the exit event. On June 13, 2018 the Company issued 569,395 shares to TRDF in satisfaction of this claim.

8. Legal and Other Contingencies

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, 2018 and 2017, the Company was not a party to any litigation that is likely 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.

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.

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

	Common stock		Additional paid-in	Accumulated	Treasury stock		Total stockholders'
	Shares	Amount	Capital	deficit	Shares	Amount	equity
Balance at December 31, 2017	27,527,738	$ 274	$ 60,047	$ (38,960)	—	$ —	$ 21,361
Issuance of common stock related to share-based compensation	1,063,837	10	93	—	—	—	103
Issuance of common stock Technion settlement	569,395	6	(6)	—	—	—	—
Issuance of shares upon execution of warrants	64,374	1	51	—	(3,385)	(52)	—
Issuance of shares upon public offering	5,899,500	60	53,018	—	—	—	53,078
Equity component of deferred financing costs of shares upon public offering	—	—	495	—	—	—	495
Repurchase of Common Stock	—	—	—	—	(5,000)	(31)	(31)
Share-based compensation expense related to share-based award	—	—	9,608	—	—	—	9,608
Net loss	—	—	—	(33,158)	—	—	(33,158)
Balance at September 30, 2018	35,124,844	$ 351	$ 123,306	$ (72,118)	(8,385)	$ (83)	$ 51,456

Preferred and Common Stock

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

On May 22, 2017, Eloxx Limited entered into a Share Purchase Agreement (the “2017 SPA”) (and subsequently joinder agreements) with certain existing and new investors, whereby, an aggregate gross amount of $21.5 million, which included the conversion of certain loans (as detailed in Note 6), was received by Eloxx Limited in exchange for the issuance of 7,136,289 shares of Series C preferred stock with a par value of $0.01 with the initial closing, of which 39,293 shares were issued as a result of the anti-dilution effect of the Reverse Merger. The related issuance costs of $0.6 million were recorded in the three and nine months ended September 30, 2017. All outstanding shares of Series C preferred stock were converted to common stock upon closing of the Reverse Merger.

In connection with the 2017 SPA, the Company granted 142,524 warrants to purchase 142,524 shares of Series C preferred stock as fees to certain service providers.

Upon the closing of the Reverse Merger, the Company issued 6,333,333 shares of common stock related to the closing of the 2017 SPA for an aggregate gross amount of $17.5 million. Additionally, Sevion raised $1.5 million prior to the Reverse Merger. The related issuance costs recorded in the three and nine months ended September 30, 2018 for these transactions was zero and $0.5 million, respectively.

Warrants

Transactions related to warrants to purchase the Company's common stock during the period ended September 30, 2018, were as follows:

	Shares	Weighted average exercise price	Weighted average remaining contractual life
Warrants outstanding at December 31, 2017	480,049	$ 3.97	4.24
Exercised	(64,374)	0.80	
Forfeited	(68,434)	8.00	
Warrants outstanding at September 30, 2018	347,241	$ 3.77	4.18
Warrants exercisable at September 30,2018	347,241	$ 3.77	4.18

10. Stock-Based Compensation

Prior to April 20, 2018, the Company had two equity compensation plans; the Sevion 2008 Incentive Compensation Plan (the "2008 Plan") and the Eloxx Limited 2013 Share Ownership and Option Plan (the "2013 Plan"). On April 20, 2018, the Company's 2018 Equity Incentive Plan (the "2018 Plan") became effective. All of the plans are described below.

The 2018 Equity Incentive Plan

On March 12, 2018, our Board of Directors (the "Board") adopted the 2018 Plan which was subsequently approved by our stockholders on March 26, 2018. On April 20, 2018, the 2018 Plan became effective and the Company ceased granting awards under each of the 2008 Plan and the 2013 Plan (the "Prior Plans").

The purpose of the 2018 Plan is to provide a means whereby the Company can align the long-term financial interests of its employees, consultants, and directors with the financial interests of its stockholders. In addition, the Board believes that the ability to grant options and other equity-based awards will help the Company to attract, retain, and motivate employees, consultants, and directors and encourages them to devote their best efforts to the Company's business and financial success. The 2018 Plan authorizes the grant and issuance of awards that may take the form of stock options, stock appreciation rights, restricted stock, stock units, and performance-based incentive awards.

The 2018 Plan became effective on April 20, 2018, with the outstanding awards and shares available for future grants under the Prior Plans 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. As of September 30,

2018, there were 3,805,297 shares available for future grant under the 2018 Plan.

The 2008 Incentive Compensation Plan

In December 2008, the Company adopted the 2008 Plan, which provided for the grant of stock options, stock grants and stock purchase rights to certain designated employees and certain other persons performing services for the Company, as designated by the Company's Board of Directors. Upon effectiveness of the 2018 Plan, the shares available for awards under the 2008 Plan were added to the shares available for issuance under the 2018 Plan.

The 2013 Share Ownership and Option Plan

In December 2013, Eloxx Limited's Board of Directors adopted the 2013 Plan in accordance with section 102 and 3(i) of the Israeli Income Tax Ordinance. Under the 2013 Plan, options to purchase ordinary shares of Eloxx Limited or ordinary shares of Eloxx Limited may be granted to employees, officers, directors, service providers and consultants of Eloxx Limited. Upon effectiveness of the 2018 Plan, the shares available for award under the 2013 Plan were added to the shares available for issuance under the 2018 Plan.

Summary of Option Activity

Transactions related to the grant of options to employees and directors during the period ended September 30, 2018 were as follows:

	Shares	Weighted average exercise price	Weighted average remaining contractual life	Aggregate intrinsic value
Options outstanding at December 31, 2017	3,215,661	$ 4.91	7.65	$15,174,026
Granted[1]	1,637,381	18.26		
Exercised[1]	(922,524)	0.10		
Forfeited	(319,118)	7.82		
Options outstanding at September 30, 2018	3,611,400	$ 11.67	8.72	$28,510,857
Options exercisable at September 30,2018	984,975	$ 9.54	6.11	$11,573,006

[1] Includes 141,389 option grant to a director at $23.27 per share which fully vested on the grant date.

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, 2018, 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, 2018. This amount is impacted by the changes in the fair value of the Company's shares.

The weighted average grant date fair value of the options granted during the period ended September 30, 2018, was $10.97.

Summary of Restricted Stock Unit Activity

Transactions related to the grant of restricted stock units to employees and directors during the period ended September 30, 2018 were as follows:

	Shares	Weighted

		average grant date fair value price
Unvested at December 31, 2017	663,212	$ 8.00
Granted	207,852	15.03
Vested	—	—
Forfeited	(103,321)	14.95
Unvested at September 30, 2018	767,743	$ 8.97

The Company granted 22,427 performance-based options and 22,427 performance-based restricted stock units to an employee during the nine months ended September 30, 2018. The performance-based restricted stock units immediately vest upon the occurrence of the successful completion of a Phase-2B study. For the three and nine months ending September 30, 2018, the Company recognized $0.1 million of expense associated with these awards granted.

Stock-based compensation relates to options granted to employees, non-employee directors and non-employees, time-based restricted stock units granted to employees and performance-based 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:

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Research and development	$ 498	$ 12	$ 909	$ 24
General and administrative	2,197	5	8,699	14
Total stock-based compensation expenses	$ 2,695	$ 17	$ 9,608	$ 38

On January 15, 2018, the Company issued an award outside of the Prior Plans to an employee of the Company in the form of an option to purchase 69,000 shares of the Company's common stock with an exercise price per share equal to $6.65. Subject to continued service through the vesting date, one-sixteenth of the awards will vest on each quarterly anniversary of the grant date. As of September 30, 2018, 732,212 options to purchase the Company's stock and 663,212 restricted share units that were issued outside of the Prior Plans were outstanding.

On June 15, 2018, the Company issued a fully vested stock award to a director of 141,389 shares.

11. Income Taxes

The United States enacted the Tax Cuts and Jobs Act ("Tax Act") on December 22, 2017, most provisions of which took effect in years beginning after December 31, 2017. The Tax Act made substantial changes to U.S. taxation of corporations, including lowering the U.S. federal corporate income tax rate from 34% to 21%. The effect on deferred tax assets and liabilities of a change in law or tax rates is recognized in income in the period that includes the enactment date. The Tax Act also includes a provision designed to currently tax global intangible low-taxed income ("GILTI"). The Company elected to record the U.S. income tax effect of future GILTI inclusions in the period in which they arise, if ever, and the Company has estimated that there will not be a GILTI inclusion for the year ended December 31, 2018.

In accordance with ASC 740-270, Income Taxes – Interim Reporting, the Company is required at the end of each interim period to determine the best estimate of its annual effective tax rate and apply that rate to year-to-date ordinary income or loss. The resulting tax expense (or benefit) is adjusted for the tax effect of specific events, if any, required to be discretely recognized in the interim period as they occur. For the nine months ended September 30, 2018 and 2017, the Company recorded zero and immaterial tax expense (or benefit), respectively, attributable to the operations of a U.S. subsidiary which files income tax returns on a stand-alone basis. The Company has not recorded net deferred tax assets as of September 30, 2018, or December 31, 2017, because it maintained a full valuation allowance against

all material deferred tax assets, and management has determined that it is more likely than not, that the Company will be unable to realize those future benefits. The Company's effective tax rate differs from the statutory rates of 21% and 34% as of September 30, 2018 and 2017, respectively, due to losses for which no future benefit is expected. As of September 30, 2018, and December 31, 2017, the Company had no uncertain tax positions recorded in its consolidated balance sheets.

After the enactment of the Tax Act, the SEC issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In its financial statements for the period ended December 31, 2017, the Company calculated an estimate of the impact of the Tax Act related to the remeasurement of our net U.S. deferred tax asset due to the change in U.S. federal corporate income tax rate. The provisional amount recorded was deferred tax expense of $10.2 million, but which was fully and equally offset by a deferred tax benefit related to a corresponding reduction in our valuation allowance. The Company has not adjusted the provisional amount in these financial statements for the period ended September 30, 2018, but it expects to complete this analysis within the one-year measurement period provided by SAB 118.

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 numbers):

	Three months ended September 30,		Nine months ended September 30,	
	2018	2017	2018	2017
Numerator:				
Net loss	$11,161	$4,040	$33,158	$10,596
Dividends accumulated for the period[1]	—	802	—	1,669
Net loss available to stockholders of Common Stock	$11,161	$4,842	$33,158	$12,265
Denominator:				
Shares used in computing net loss per share of Common Stock, basic and diluted[2]	35,005,979	4,208,088	31,485,067	4,206,226
Net loss per share of Common Stock, basic and diluted	$0.32	$1.15	$1.05	$2.92

(1) The net loss used for the computation of basic and diluted net loss per share with respect to 2017 include 8% per share per annum compounded annually which was related to distributions for preferred stockholders of Eloxx Limited. On December 19, 2017, in conjunction with the Reverse Merger all preferred shares were converted to common shares.

(2) 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,	
	2018	2017
Options to purchase common stock	3,611,400	1,915,887
Restricted stock units	767,743	—
Warrants	347,241	3,779,704
Preferred stock	—	14,735,667
Total potential common stock equivalents	4,726,384	20,431,258

13. Segment and Geographic Information

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) about which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is the Chief Executive Officer. The chief operating decision maker reviews consolidated operating results to make decisions about allocating resources and assessing performance for the entire company. The Company views its operations and manages its business as one operating segment; however, it operates in two geographic regions: United States (Waltham, MA) and Israel (Rehovot).

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. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q. These and other factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this Quarterly Report on Form 10-Q.

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 business plan. In connection with the Transaction, Sevion acquired all of the outstanding capital stock of Eloxx Limited in exchange for the issuance of an aggregate 20,316,656 shares of Sevion's common stock, par value $0.01 per share (the "Common Stock"), after giving effect to a 1-for-20 reverse split effected immediately prior to the Transaction. As a result of the Transaction, Eloxx Limited became a wholly-owned subsidiary of Sevion. While Sevion was the legal acquirer in the transaction, Eloxx Limited was deemed the accounting acquirer. Immediately after giving effect to the Transaction, on December 19, 2017, Sevion changed its name to Eloxx Pharmaceuticals, Inc. (collectively "we", "our", "us", "Eloxx" or the "Company").

The unaudited consolidated financial statements of the Company, included elsewhere in this Quarterly Report on Form 10-Q, 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 at 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.

Company Overview

We are a clinical-stage biopharmaceutical company developing novel ribonucleic acid (RNA)-modulating drug candidates (designed to be eukaryotic ribosomal selective glycosides) that are formulated to treat rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt protein synthesis from messenger RNA. As a consequence, patients with premature stop codon diseases have reduced levels of, or no, critical functional proteins from the mutation bearing allele accounting for some of the most severe phenotypes in these genetic diseases. These premature stop codons have been identified in over 1,800 rare and ultra-rare diseases. Read-through therapeutic development is focused on extending mRNA (messenger RNA) half-life and increasing functional protein synthesis by enabling the cytoplasmic ribosome to read-through premature stop codons to produce full-length proteins. Eloxx's lead investigational drug product candidate, ELX-02, is a small molecule designed to restore production of full-length functional proteins. ELX-02 is in the early stages of clinical development focusing on cystic fibrosis and cystinosis. ELX-02 is an investigational drug that has not been approved by any global regulatory body. Eloxx's preclinical candidate pool consists of a library of novel drug candidates designed to be eukaryotic ribosomal selective glycosides identified based on read-through potential. Eloxx recently announced a new program focused on rare ocular genetic disorders. Eloxx is headquartered in Waltham, MA, with R&D operations in Rehovot, Israel.

Our research and development strategy is to target rare or ultra-rare diseases where a high unmet medical need, nonsense mutation bearing, patient population has been identified, there are established preclinical read-through or personalized medicine models that are predictive of clinical activity, and a definable path for Orphan Drug development, regulatory approval, patient access and commercialization. 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 focus for our lead investigational drug product candidate, ELX-02, is on cystic fibrosis and cystinosis. We have initiated a new program focused on rare inherited retinal disease and are conducting IND enabling studies for several compounds from our library. We will identify an additional molecule later this year to advance into clinical development. Eloxx has entered into a multiyear partnership with the Foundation Fighting Blindness (FFB) to

support our inherited retinal degenerative disease registry and educational programs. FFB will provide ELX-02 with ongoing R&D consultation and support. We believe this partnership has the potential to accelerate Eloxx's development programs and support patients with ocular disease and a high unmet medical need.

We intend to be the global leader in the application of the science of translational read-through and the associated pathway of nonsense mediated messenger ribonucleic acid ("mRNA") decay. 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 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 cellular process 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. Our subcutaneously injected small molecules have the potential to be self-administered 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 in vitro and in vivo models of nonsense mutations suggests that drug product candidates from our read-through compound library may have potential beneficial effects for the following diseases: cystic fibrosis, cystinosis, mucopolysaccharidosis type 1, Duchenne muscular dystrophy, Rett syndrome and a variety of rare ocular genetic diseases. We have demonstrated the potential for beneficial effects in multiple organs such as the brain, kidney, muscles, eye and others.

Currently our lead program, ELX-02, is focused on development for cystic fibrosis and cystinosis patients with diagnosed nonsense mutations. Our pre-clinical trial application ("CTA") has been approved by the Federal Agency for Medicines and Health Products (the "FAMHP") in Brussels and our IND submitted to the U.S. Food and Drug Administration (the "FDA") is now open. We expect to initiate Phase 2 studies in cystic fibrosis and cystinosis following completion of our ongoing Phase 1 multiple ascending dose ("MAD") study and report top line results in 2019.

As part of our clinical program for ELX-02, we have completed a Phase 1 single ascending dose ("SAD") study in a total of 60 healthy volunteers at sites in Israel (ClinicalTrials.gov Identifier: NCT02807961) and Belgium (ClinicalTrials.gov Identifier: NCT03292302). The results of the SAD study have been submitted for publication. Currently ongoing is the Phase 1 multiple ascending dose ("MAD") study in Belgium (ClinicalTrials.gov Identifier: NCT03309605). We have completed the first four cohorts of the MAD study and have initiated the fifth cohort.

We have initiated a new program focused on rare ocular genetic disorders and is conducting pre-IND enabling studies for several compounds from our library and will identify an additional molecule later this year to take into clinical development.

We believe there is a significant unmet medical need in the treatment of cystic fibrosis patients carrying nonsense mutations on one or both alleles of the Cystic Fibrosis Transmembrane Conductance Regulator ("CFTR") gene. Cystic fibrosis is the most prevalent genetic disease in the western world and there are no currently approved therapies that target the impairment associated with Class 1 CFTR mutations. Similarly, in cystinosis, we believe there is also a high unmet medical need as there are no currently approved therapeutics that target the nonsense mutation mediated impairment of cystinosin. Cystinosin is the cystine-selective transport channel in the lysosomal membrane that is attributed as the cause for the accumulation of cystine in this disease state. Given the high proportion of pediatric patients in each of these rare orphan diseases, we intend to apply for relevant Orphan Drug incentives in the US and Europe, including the Rare Pediatric Disease Priority Review Voucher in the U.S.

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

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

On April 30, 2018 the Company completed an underwritten public offering of 5,899,500 shares of common stock of the Company at the public offering price of $9.75 per share. The Company received net proceeds of approximately

$53.6 million after deducting underwriting discounts and commissions and estimated offering expenses. As of September 30, 2018, we had cash and cash equivalents of $55.3 million. We expect that our current cash and cash equivalents will be sufficient to fund our current operations to 2020.

Since our inception, we have incurred significant operating losses. Our net losses were $33.2 million and $10.6 million for each of the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $72.1 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 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 revenues and expenses during the reporting periods. These items are monitored and analyzed by us 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 Quarterly Report on Form 10-Q 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, 2018, from those discussed in our Annual Report on Form 10-K filed with the SEC on March 16, 2018.

Results of Operations

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	$5,415	$3,280	$13,959	$8,230
General and administrative	5,945	720	18,898	1,581
Reverse merger related expenses	—	—	594	—
Total operating expenses	11,360	4,000	33,451	9,811
Loss from operations	(11,360)	(4,000)	(33,451)	(9,811)
Other (income) expense, net	(199)	40	(293)	785
Net loss	$(11,161)	$(4,040)	$(33,158)	$(10,596)

Research and development expenses.

Research and development expenses were $5.4 million for the three months ended September 30, 2018 compared to $3.3 million for the period ended September 30, 2017, an increase of $2.1 million. The increase in research and development expenses was primarily related to fees incurred to subcontractors, consultants and advisors in connection with research and development of ELX-02 of $1.6 million. Additionally, salaries and other personnel and occupancy related costs increased by $0.5 million.

Research and development expenses were $14.0 million for the nine months ended September 30, 2018, compared to $8.2 million for the period ended September 30, 2017, an increase of $5.8 million. The increase in research and development expenses was primarily related to fees incurred to subcontractors, consultants and advisors in connection with research and development of ELX-02 of $4.5 million. Additionally, salaries and other personnel and occupancy related costs increased by $1.3 million.

General and administrative expenses.

General and administrative expenses were $5.9 million for the three months ended September 30, 2018, compared to $0.7 million for the period ended September 30, 2017, an increase of $5.2 million. The increase in general and administrative expenses was primarily due to an increase in headcount and related salaries, stock-based compensation, and other personnel related costs of $3.6 million, and professional service fees and other fees of $1.6 million.

General and administrative expenses were $18.9 million for the nine months ended September 30, 2018, compared to $1.6 million for the period ended September 30, 2017, an increase of $17.3 million. The increase in general and administrative expenses was primarily due to stock-based compensation to a director of $5.0 million, an increase in headcount and related salaries, stock-based compensation, and other personnel related costs of $6.3 million, and professional service fees and other fees of $6.0 million.

Reverse merger related expenses.

We recorded professional service fees of $0.6 million for the nine months ended September 30, 2018 related to the reverse merger we completed on December 19, 2017. No professional service fees were recorded during the three months ended September 30, 2018.

Other (income) expense, net.

We recorded $0.2 million in other income, net of expense for the three months ended September 30, 2018, compared to $40,000 in other expense, net of income for the period ended September 30, 2017. The increase of $0.2 million was due to an increase in interest income.

We recorded $0.3 million in other income, net of expense for the nine months ended September 30, 2018, compared to $0.8 million in other expense, net of income for the period ended September 30, 2017. The increase of $1.1 million was primarily due to an increase in interest income of $0.3 million and a $0.8 million decrease in interest expense on debt issuance costs.

Liquidity and Capital Resources

General

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, 2018, we have funded our operations primarily through equity and convertible debt financings in private placements, as described below.

As of September 30, 2018, we had cash and cash equivalents of $55.3 million. On April 30, 2018, the Company completed an underwritten public offering (“2018 Offering”) of 5,899,500 shares of common stock of the Company at the public offering price of $9.75 per share. The Company received net proceeds of approximately $53.6 million after deducting underwriting discounts and commissions and estimated offering expenses. We expect that our cash and cash equivalents will enable us to fund our current operations to 2020.

Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations. Although we have been successful in raising capital in the past, there is no assurance that we will be successful in obtaining such additional financing on terms acceptable to us, if at all. If we are unable to obtain funding, we could be forced to delay, reduce or eliminate our research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect our business prospects, or we may be unable to continue operations.

Principal Financing Activities

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

On May 22, 2017, Eloxx Limited entered into a Share Purchase Agreement (the “2017 SPA”) (and subsequently joinder agreements) with certain existing and new investors, whereby, an aggregate gross amount of $21.5 million, which included the conversion of the loan as detailed in Note 6 to the unaudited condensed consolidated financial statements contained in this report, was received by Eloxx Limited in exchange for the issuance of 7,136,289 shares of Series C preferred stock with par value of $0.01 with the initial closing, of which 39,293 shares were issued as a result of the anti-dilution effect of the Reverse Merger. The related issuance costs were $0.6 million.

In connection with the 2017 SPA, the Company granted 142,524 warrants to purchase 142,524 shares of Series C preferred stock as fees to certain service providers.

Upon the closing of the Reverse Merger in December 2017, the Company issued 6,333,333 shares of common stock related to the closing of the 2017 SPA with a par value of $0.01 for an aggregate gross amount of $17.5 million. Additionally, Sevion raised $1.5 million prior to the Reverse Merger. The related issuance costs for these transactions was $0.5 million. For more information, see Note 9 to the unaudited condensed consolidated financial statements contained in this report.

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,	
	2018	2017
Net cash used in operating activities	$(22,307)	$(9,668)
Net cash used in investing activities	(138)	(155)
Net cash provided by financing activities	53,676	21,172

Operating Activities

During the nine months ended September 30, 2018, net cash used in operating activities was $22.3 million, which 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 payables and accrued expenses.

During the nine months ended September 30, 2017, the net cash used in operating activities was $9.7 million, primarily driven by our net loss of $10.6 million, partially offset by the amortization and revaluation of an embedded conversion feature of $0.6 million and $0.2 million related to changes in working capital primarily for other current assets and accrued expenses offset by decreases in accounts payables.

Investing Activities

During the nine months ended September 30, 2018, the net cash used in investing activities was $0.1 million, primarily driven by the net purchase of property and equipment and long-term deposits.

During the nine months ended September 30, 2017, the net cash used in investing activities was $0.2 million, primarily driven by the purchase of property and equipment.

Financing Activities

During the nine months ended September 30, 2018, the net cash provided by financing activities was $53.7 million, primarily due to the net proceeds from the 2018 offering of $53.6 million.

During the nine months ended September 30, 2017, the net cash provided by financing activities was $21.2 million, resulting from the proceeds from the issuance of Series C preferred stock of $18.7 million and proceeds from the issuance of convertible loan and financial derivatives relating to the Series C preferred stock of $2.5 million.

Technion Research and Development Foundation Limited (“TRDF”) Agreement

On August 29, 2013, the Company entered into the Technion Agreement with TRDF, with respect to certain technology relating to aminoglycosides and the redesign of aminoglycosides for the treatment of human genetic diseases caused by premature stop mutations and further results of the research of the technology, in order to develop and commercialize products based on such technology. Under the Technion Agreement, TRDF is obligated to provide the Company with research services for an estimated annual payment of $0.1 million, the precise amount to be agreed by the parties prior to the beginning of each year of the research period. For the three and nine months ended September 30, 2018, the Company recorded research and development expense of $0.1 million and $0.1 million, respectively, in relation to in relation to reimbursement for the preparation, filing, prosecution and maintenance of TRDF patent rights related to Eloxx Limited. For the three and nine months ended September 30, 2017, the Company recorded general and administrative expenses amounting to $0 and $7,000, respectively, and research and development expenses amounting to $24,000 in relation to the Technion Agreement. As of September 30, 2018 and December 31, 2017, amounts recorded in accrued expenses were $6,000 and $25,000, respectively.

In addition, TRDF granted us a license to use, market, sell or sub-license the rights of the product developed under the TRDF research results (the “Licensed Product”), as fully defined in the Technion Agreement, for the following considerations: (a) milestone payments, to be transferred upon meeting certain milestones as defined in the Technion Agreement, up to total consideration of $6.1 million; (b) certain royalties on a low- to mid- single-digit percentage of net sales (subject to change in the case of (x) sublicensing to a big pharmaceutical or biotechnology company, or (y) payment of royalties to third parties, or (z) commercialization by a third party of an authorized generic to a licensed product), for a period until the later of (i) the expiration of a valid claim on the Licensed Product in each

country the Licensed Product is sold to, or (ii) a certain amount of years from the date of the first commercial sale of the Licensed Product in such country, and (c) a low- to mid- double-digit percentage of any non-royalty sub-license income received by us from a sub-licensed entity. In addition, we will be required to pay a fee to TRDF upon an exit event as described in the Technion Agreement.

Moreover, upon the closing of an Exit Event which is not Initial Public Offering ("IPO"), as defined in the Technion Agreement, TRDF shall be entitled to an amount equal to 3% of all non-refundable, non-contingent consideration, whether in cash or in kind, actually received by the Company and / or its shareholders. Upon the closing of an exit event which is IPO, as defined in the Technion Agreement, TRDF shall be entitled to a number of Ordinary Shares of the Company representing 3% of the Company's outstanding shares on a fully diluted basis immediately prior to the closing of such IPO.

On August 9, 2017, we received a legal claims letter from TRDF regarding TRDF's alleged entitlement to an exit fee in accordance with the Technion Agreement as a result of the announced Reverse Merger. We recorded a $3.4 million research and development expense with an offsetting adjustment to additional paid-in capital for the year ended December 31, 2017, related to the planned issuance of shares to TRDF at fair market value on the purported date of the exit event. On June 13, 2018, we issued 569,395 shares to TRDF in satisfaction of this claim.

Contractual Obligations

There have been no material changes to our contractual obligations during the nine months ended September 30, 2018. Please refer to our contractual obligations reported in our Annual Report on Form 10-K for the year ended December 31, 2017.

Off-Balance Sheet Arrangements

We did not have during the periods presented, 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, revenues or expenses, 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, 2018, 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, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2018, 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 Quarterly Report on Form 10-Q, 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 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.

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.

Since our inception, we have incurred significant operating losses. Our net loss was $33.2 million and $10.6 million for the nine months ended September 30, 2018 and 2017, respectively. As of September 30, 2018, we had an accumulated deficit of $72.1 million. On April 30, 2018, we completed an underwritten public offering of 5,899,500 shares of our common stock at a price to the public of $9.75 per share, including 769,500 shares sold pursuant to the

exercise in full of the underwriters' option to purchase additional shares, or the Public Offering. The gross proceeds from the Public Offering were approximately $53.6 million, before deducting the underwriting discounts and commissions and offering expenses. 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. Although we recently completed the Public Offering, 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;
- the costs, timing and outcome of any regulatory review of ELX-02;
- 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, even with the Public Offering, 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 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 substantially all of our efforts and financial resources in the research and development of ELX-02, which is currently our only product candidate in 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 United States, the European Union 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 United States and the European Union, 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.

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 United States, 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 United States, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act and 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 Health Insurance Portability and Accountability Act of 1996 (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 payers. 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 future collaborators, may be subject to similar foreign laws and regulations. If we or any of our 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 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, results of our clinical trials 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 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 institutional review boards 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 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 and market our product candidates if approved. The combined number of patients in the United States, 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 service 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 drugs (“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, 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 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 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.

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 revenues 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 U.S., 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 United States, EMA approval to commercialize our product candidates in the European Union 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 an 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 European Union, 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 the marketing applications that we file for our product candidates, or we might not obtain regulatory clearance in a timely manner. 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 revenues.

Our research and clinical efforts may not result in drugs that the FDA, EMA or 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 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.

Risks Related to Commercialization

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 United States and the European Union, 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 United States. 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 European Union when the application is made or the product, without the benefits derived from orphan status, would unlikely generate sufficient return in the European Union to justify the necessary investment. Moreover, in order to obtain orphan designation in the European Union, it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition authorized for marketing in the European Union, 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. 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 United States. 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 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 or other strategic transaction.

Our business strategy includes expanding our products 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 platforms.

To manage effectively our current and future potential growth, we must 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 financial condition and results of operations.

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 US 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 US 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, 2018, we had U.S. federal and state NOL carryforwards of $77.2 million and $27.4 million, respectively, and federal research tax credit carryforwards of $0.7 million. Our U.S. net operating loss 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.

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 of Sevion Therapeutics, Inc. on December 19, 2017 at which time our pre-change U.S. federal NOL carryforward was $77.1 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, 2018, we had Israeli NOL carryforwards of $24.9 million, which carryforward 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.

Under the Tax Cuts and Jobs Act, 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.

We could be subject to additional tax liabilities.

We are subject to federal, state and local taxes in the United States 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 the U.S. 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 maintain or increase our product sales 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 are 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 European Union formally adopted the General Data Protection Regulation, or GDPR, which apply 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 European Union and substantial fines for breaches of the data protection rules. The GDPR must be implemented into national laws by the EU member states and will impose 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 European Union, and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with the rules arising from the EU Data Protection Directive 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 product sales, 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 required 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 the bankruptcy of the manufacturer or supplier, testing facility, or research site.

Any of these events could lead to clinical trial delays or 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 products and 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 September 30, 2018, we owned or licensed 17 issued patents and 36 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 revenues 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. The patents we hold, and the patents that may be issued in the future based on currently pending patent applications, relating to our lead product candidate are expected to expire between 2031 and 2038.

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 will be harmed.

Our success will depend in part on our ability to obtain and maintain patent and regulatory protections for our products and investigational compounds, 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 products and 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 products. If we cannot obtain a license, we may be prevented from the manufacture, sale or development of our products, 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;

39

- 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 belongs 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 products, 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 Operations in Israel

Potential political, economic and military instability in Israel, where our research facilities are located, may adversely affect our results of operations.

Our research offices and lab are located in Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, and certain militant groups and terrorist organizations. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. Since October 2000, there have been increasing occurrences of terrorist violence in the region. Ongoing and revived hostilities or other Israeli political

or economic factors, could negatively affect business conditions in Israel in general and our business in particular.

In addition, since 2010 political uprisings and conflicts in various countries in the Middle East are affecting the political stability of those countries and the region in general. It is not clear how this instability will develop and how it will affect the political and security situation in the Middle East. This instability has raised concerns regarding security in the region and the potential for armed conflict. Additionally, various groups are involved in hostilities in the region. Although these groups' activities have not directly affected the political and economic conditions in Israel, a stated purpose is to take control of the Middle East, including Israel. The tension between Israel and these other groups may escalate in the future and turn violent, which could affect the Israeli economy in general and us in particular. Such instability may lead to deterioration in the political and trade relationships that exist between Israel and certain other countries. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, and additional countries may impose restrictions on doing business with Israel and Israeli companies if hostilities in Israel or political instability in the region continues or increases. Similarly, Israeli companies are limited in conducting business with entities from several countries. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

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 and the government may cease providing such coverage or the coverage might not suffice to cover potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions generally and our business in particular.

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.

Our research operations may be disrupted by the obligations of our personnel to perform military service which could have a material adverse effect on our business.

Our employees and consultants in Israel may be obligated to perform one month, and in some cases longer periods, of military reserve duty until they reach the age of 40 (or older, for citizens who hold certain positions in the Israeli armed forces reserves) and, in the event of a military conflict or emergency circumstances, may be called to immediate and unlimited active duty. In the event of severe unrest or other conflict, individuals could be required to serve in the military for extended periods of time. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be similar large-scale military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our Israeli personnel military service. Such disruption could adversely affect our business and research operations. Additionally, the absence of a significant number of the employees of our Israeli suppliers and contractors related to military service or the absence for extended periods of one or more of their key employees for military service may disrupt their operations.

Because a certain portion of our expenses are incurred in New Israeli Shekels, or NIS, our results of operations may be seriously harmed by currency fluctuations and inflation.

We report our financial statements in U.S. dollars, our functional currency. Although most of our expenses are incurred in U.S. dollars, we pay a portion of our expenses in New Israeli Shekels, or NIS, and as a result, we are exposed to risk to the extent that the inflation rate in Israel exceeds the rate of devaluation of the NIS in relation to the U.S. dollar or if the timing of these devaluations lags behind inflation in Israel. In that event, the U.S. dollar cost of our operations in Israel will increase and our U.S. dollar-measured results of operations will be adversely affected. To the extent that the value of the NIS increases against the dollar, our expenses on a dollar cost basis increase. Our operations also could be adversely affected if we are unable to guard against currency fluctuations in the future. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects.

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 to satisfy specific conditions if and to the extent we receive future

royalties or in order to complete the sale of such grant-based technologies and programs. We may be required to pay penalties in addition to payment of the royalties.

Our research and development efforts have been financed, in part, through royalty-bearing grants from the Israel Innovation Authority, or IIA. To date, we have received the aggregate amount of approximately $2.6 million from the IIA for the development of our technologies. With respect to such grants we are committed to pay certain royalties (including accrued LIBOR interest) up to $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.

We have not commenced the payment obligation of the royalties and have a contingent obligation with respect to royalty-bearing participation received or accrued, to include LIBOR interest, in the amount of approximately $2.7 million.

In addition, with respect to such grants we are obligated to pay royalties at a rate of 3% to 6% from the revenues generated from the sale of product (as well as revenue from associated services) developed using the IIA grants.

The R&D Law and the regulations promulgated thereunder provide that when a company develops know-how, technology or products using IIA grants, the terms of these grants and the R&D Law restrict the transfer of such know-how, and the transfer of manufacturing or manufacturing rights of such products, technologies or know-how 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 related to those aspects of such technologies, and may result in payment of increased royalties (both increased royalty rates and increased royalties ceilings) and/or payment of additional amounts to the IIA. Such approvals may be subject to conditions and\or may not be received. Furthermore, according to the R&D Law, the IIA may impose certain conditions on any arrangement under which it permits us to transfer technology or development out of Israel (including for the purpose of manufacturing).

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, depending on the jurisdiction, 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.

We recently received approval for up-listing to The Nasdaq Global Market, and our common stock began trading on The Nasdaq Global Market on April 26, 2018 under the symbol "ELOX." In addition, as mentioned above, on April 30, 2018, we completed the Public Offering, which resulted in gross proceeds to us of approximately $57.5 million. 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 2013 Plan, the 2008 Plan, and 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, 2018, individuals held options to purchase an aggregate of 3,611,400 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.

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 Quarterly Report on Form 10-Q. 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.

		Incorporated by Reference			
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date
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 8, 2018

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