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 June 30, 2021

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)**

480 Arsenal Way
Watertown, Massachusetts 02472
(Address of principal executive offices) (Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	ELOX	The Nasdaq Global Market

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

On August 9, 2021, the registrant had 86,202,772 shares of common stock, $0.01 par value per share, outstanding.

ELOXX PHARMACEUTICALS, INC.
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Special Note Regarding Forward-Looking Statements

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

This Quarterly Report on Form 10-Q, or this Report, and information incorporated herein, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of present and historical facts contained in this Report, including without limitation, statements regarding expected timing of trials and results from our clinical program, strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. Without limiting the foregoing, in some cases, you can identify forward-looking statements by terms such as “aim,” “may,” “will,” “would,” “should,” “expect,” “exploring,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential,” “seeks,” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. No forward-looking statement is a guarantee of future results, performance, or achievements, and one should avoid placing undue reliance on such statements.

Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to us. Such beliefs and assumptions may or may not prove to be correct. Additionally, such forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified in Part I. Item 1A. “Risk Factors” and Part II. Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These risks and uncertainties include, but are not limited to:

- risks related to our dependence on our lead product candidate, ELX-02 and our ability to progress any of our product candidates in preclinical or clinical trials;
- the length and expense of preclinical and clinical trial development and the uncertain outcomes from such trials;
- risk related to doing business with collaborators, healthcare professionals, principal investigators, consultants, vendors, customers, and third-party payors;
- risks that our product candidates may cause adverse events or other properties that delay or prevent regulatory approval or market acceptance;
- risks related to the scope, rate and progress of our preclinical studies and clinical trials and other research and development activities;
- risks related to patient recruitment and enrollment in our clinical trials;
- the impact of the global COVID-19 pandemic or other public health epidemics and other factors beyond our control on our clinical trials, operations, vendors, suppliers and employees;
- risks related to regulatory approvals and other requirements applicable to our product candidates;
- risks related to our ability to obtain the capital necessary to fund our operations;
- risks relating to the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- risks related to our ability to obtain adequate funding to finance our operations;
- our and our stockholders ability to realize benefits from our strategic initiatives, including our acquisition of Zikani Therapeutics, Inc. in April 2021; and
- general business conditions, regulatory environment, competition and market for our products.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risks and uncertainties.

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

MARKET AND INDUSTRY DATA

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

RISK FACTOR SUMMARY

The following is a summary of the principal risks of an investment in our common stock. This summary does not list all the risks that we face. Additional discussion of the risks summarized below follow directly under the heading "Risk Factors" and should be carefully considered, together with other information in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the "SEC") on March 12, 2021 and our other filings with the SEC before making an investment decision regarding our common stock.

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

- The success of our lead product candidate, ELX-02, is critical to our business. If ELX-02 fails during development, it may adversely impact the commercial viability of ELX-02 and have a material adverse effect on our business.
- Positive results from preclinical testing of ELX-02 are not necessarily predictive of the results of clinical trials of ELX-02. If we cannot achieve positive results in our clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize ELX-02.
- 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.
- Our clinical trials are costly, 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.
- 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.
- 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 beyond our control, which could impair our clinical development programs.
- We are subject to extensive governmental regulation including the requirements of the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory authorities for development and approval of our product candidates before they can be marketed.
- We may not obtain the necessary FDA, European Medicines Agency (or "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.
- 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.
- Even though we have received orphan drug designation from the FDA for ELX-02 for the treatment of cystic fibrosis, cystinosis, MPS I, and Rett syndrome, 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.
- 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.

Risks Related to Our Financial Position and Need for Additional Capital

- We have incurred significant operating losses since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never achieve or maintain profitability.
- We 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.
- Raising additional capital will cause dilution to our stockholders, and may restrict our operations or require us to relinquish rights to our technologies or product candidates.

Risks Related to Our Business and Operations

- We may seek to expand our business through strategic initiatives. Our efforts to identify opportunities or complete transactions that satisfy our strategic criteria may not be successful, and we may not realize the anticipated benefits of any completed acquisition, collaboration or other strategic transaction.
- 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.
- Our business could be adversely affected by the effects of widespread public health epidemics and other factors beyond our control.
- Security breaches, cyber-attacks, or other disruptions could expose us to liability and affect our business and reputation.
- We 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 or may experience delays and disruptions that may negatively impact our operations.
- Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

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

Risks Related to Our Regional Operations

- Potential political and economic instability in regions where we conduct business may adversely affect our results of operations.
- We received Israeli government grants for our research and development activities and programs. The terms of such grants may require us, in the future, to pay royalties and under certain circumstances, penalties in addition to payment of royalties.

General Risk Factors

- Our stock price may be volatile and may or may not reflect our operations or value, and therefore purchasers of our common stock could incur substantial losses.
- 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.
- Our ability to use our net operating losses to offset future taxable income may be subject to certain limitations.
- 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.
- 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 decline.

PART I. FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Information

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,734	$ 24,668
Restricted cash	246	56
Prepaid expenses and other current assets	1,579	1,169
Total current assets	58,559	25,893
Property and equipment, net	185	133
Operating lease right-of-use asset	1,866	421
Other long-term assets	—	30
Total assets	$ 60,610	$ 26,477
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,024	$ 481
Accrued expenses	3,302	2,886
Current portion of long-term debt	5,686	5,239
Advances from collaboration partners	3,411	805
Current portion of operating lease liability	753	389
Taxes payable	34	38
Total current liabilities	15,210	9,838
Long-term debt	3,637	6,376
Operating lease liability	1,120	33
Total liabilities	19,967	16,247
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.01 par value per share, 5,000,000 shares authorized, no shares issued or outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.01 par value per share, 500,000,000 shares authorized, 86,463,355 and 40,350,922 shares issued and 86,201,767 and 40,157,187 shares outstanding as of June 30, 2021 and December 31, 2020, respectively	863	404
Common stock in treasury, at cost, 261,588 and 193,735 shares as of June 30, 2021 and December 31, 2020, respectively	(2,065)	(1,828)
Additional paid-in capital	258,193	183,250
Accumulated deficit	(216,348)	(171,596)
Total stockholders' equity	40,643	10,230
Total liabilities and stockholders' equity	$ 60,610	$ 26,477

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 5,704	$ 3,738	$ 9,777	$ 8,505
General and administrative	7,355	3,848	11,696	8,854
In process research and development	22,670	—	22,670	—
Restructuring charges	—	—	—	3,994
Total operating expenses	35,729	7,586	44,143	21,353
Loss from operations	(35,729)	(7,586)	(44,143)	(21,353)
Other expense, net	329	301	609	480
Net loss	$ (36,058)	$ (7,887)	$ (44,752)	$ (21,833)
Net loss per share, basic and diluted	$ (0.54)	$ (0.20)	$ (0.84)	$ (0.54)
Weighted average number of shares of common stock used in computing net loss per share, basic and diluted	66,389,865	40,129,304	53,357,401	40,101,789
Comprehensive loss:				
Net loss	$ (36,058)	$ (7,887)	$ (44,752)	$ (21,833)
Other comprehensive income:				
Change in unrealized gain on available-for-sale securities	—	(52)		(5)
Comprehensive loss	$ (36,058)	$ (7,939)	$ (44,752)	$ (21,838)

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Cash flows from operating activities:		
Net loss	$ (44,752)	$ (21,833)
Adjustments to reconcile net loss to net cash used in operating activities:		
Acquired in-process research and development	22,670	—
Stock-based compensation	5,343	5,971
Depreciation	56	36
Amortization of operating lease right-of-use asset	423	246
Amortization of debt discount	208	301
Amortization, net of premiums and discounts on investments	—	9
Loss on sales and disposals of property and equipment	84	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(84)	(449)
Accounts payable	(75)	(1,101)
Accrued expenses	69	(1,170)
Merger related costs paid	(1,003)	—
Operating lease liabilities	(417)	(245)
Taxes payable	(4)	(5)
Net cash used in operating activities	(17,482)	(18,240)
Cash flows from investing activities:		
Proceeds from maturities of marketable securities	—	27,000
Cash acquired in merger transaction	2,145	—
Cash received from long-term deposits	—	42
Net cash provided by investing activities	2,145	27,042
Cash flows from financing activities:		
Proceeds from underwritten public offerings, net of issuance costs	47,718	—
Proceeds from debt financing obligation	-	797
Repayment of term loan principal	(2,500)	(2,083)
Payment for settlement of taxes upon vesting of restricted stock units	(237)	(119)
Proceeds from advances from collaboration partners	2,606	402
Proceeds from exercises of stock options	6	64
Net cash provided by (used in) financing activities	47,593	(939)
Increase (decrease) in cash, cash equivalents and restricted cash	32,256	7,863
Cash, cash equivalents and restricted cash at the beginning of the period	24,724	22,536
Cash, cash equivalents and restricted cash at the end of the period	$ 56,980	$ 30,399
Reconciliation of cash, cash equivalents and restricted cash to condensed consolidated balance sheets:		
Cash and cash equivalents	$ 56,734	$ 30,347
Restricted cash	246	52
Total cash, cash equivalents and restricted cash	$ 56,980	$ 30,399
Supplemental disclosure of cash flow activities:		
Issuance of common stock in merger transaction	$ 22,335	$ —
Cash paid for interest	$ 273	$ 481
Cash paid for income taxes	$ 2	$ 5

See accompanying notes to unaudited condensed consolidated financial statements

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common stock				Treasury stock			
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income	Shares	Amount	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2020	40,157,187	$ 404	$ 183,250	$ —	(193,735)	$ (1,828)	$ (171,596)	$ 10,230
Vesting of restricted stock units	57,687	—	-	—	(23,883)	(94)	—	(94)
Stock-based compensation expense	—	—	1,308	—	—	—	—	1,308
Net loss	—	—	—	—	—	—	(8,694)	(8,694)
Balance at March 31, 2021	40,214,874	$ 404	$ 184,558	$ —	(217,618)	$ (1,922)	$ (180,290)	$ 2,750
Exercise of stock options	3,525	—	6	—	—	—	—	6
Vesting of restricted stock units	53,224	—	—	—	(43,970)	(143)	—	(143)
Stock-based compensation expense	—	—	4,035	—	—	—	—	4,035
Issuance of common stock in connection with merger	7,596,810	76	22,259	—	—	—	—	22,335
Issuance of shares upon public offering	38,333,334	383	47,335	—	—	—	—	47,718
Net loss	—	—	—	—	—	—	(36,058)	(36,058)
Balance at June 30, 2021	86,201,767	$ 863	$ 258,193	$ —	(261,588)	$ (2,065)	$ (216,348)	$ 40,643

ELOXX PHARMACEUTICALS, INC. AND SUBSIDIARIES

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common stock				Treasury stock			
	Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income	Shares	Amount	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2019	40,030,763	$ 402	$ 174,515	$ 18	(155,706)	$ (1,703)	$ (137,019)	$ 36,213
Exercise of stock options	10,636	—	64	—	—	—	—	64
Vesting of restricted stock units	84,055	1	(1)	—	(34,874)	(116)	—	(116)
Stock-based compensation expense	—	—	3,995	—	—	—	—	3,995
Change in unrealized gain on investments	—	—	—	47	—	—	—	47
Net loss	—	—	—	—	—	—	(13,946)	(13,946)
Balance at March 31, 2020	40,125,454	$ 403	$ 178,573	$ 65	(190,580)	$ (1,819)	$ (150,965)	$ 26,257
Vesting of restricted stock units	9,836	—	—	—	(1,036)	(3)	—	(3)
Stock-based compensation expense	—	—	1,976	—	—	—	—	1,976
Change in unrealized gain (loss) on investments	—	—	—	(52)	—	—	—	(52)
Net loss	—	—	—	—	—	—	(7,887)	(7,887)
Balance at June 30, 2020	40,135,290	$ 403	$ 180,549	$ 13	(191,616)	$ (1,822)	$ (158,852)	$ 20,291

See accompanying notes to unaudited condensed consolidated financial statements

1. Nature of the Business

Eloxx Pharmaceuticals, Inc., together with its subsidiaries (collectively "Eloxx" or the "Company"), is a clinical-stage biopharmaceutical company developing novel ribonucleic acid (RNA)-modulating drug candidates, each designed to be a eukaryotic ribosomal selective glycoside (ERSG), for the treatment of rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt the stability of the impacted messenger RNA (mRNA) and the protein synthesis from that mRNA. On April 1, 2021, the Company acquired Zikani Therapeutics, Inc. ("Zikani"), a preclinical stage biopharmaceutical company engaged in the science of ribosome modulation, leveraging its innovative TURBO-ZM™ chemistry technology platform to develop novel ribosome modulating agents (RMAs) as potential therapeutics for people with limited treatment options. The TURBO-ZM™ platform is designed to enable rapid synthesis of novel compounds that can be optimized to modulate the ribosome in a disease specific manner. Zikani is in pre-clinical development, with a plan to target rare diseases including genetic diseases and cancers caused by nonsense mutations. For more information see Note 15.

The Company is headquartered in Watertown, Massachusetts, with an additional office in Rehovot, Israel.

Liquidity and Going Concern

The Company has a history of net losses and negative cash flows from operating activities since its inception and, as of June 30, 2021, had an accumulated deficit of $216.3 million. The Company expects to continue to incur net losses and use cash in its operations for the foreseeable future. The Company has not generated revenue from the sale of any product or service and does not expect to generate significant revenue unless it obtains marketing approval for and commercializes one or more of its product candidates currently in development. Successful transition to profitable operations is dependent upon achieving a level of revenue adequate to support the Company's cost structure.

The Company has financed its operations primarily from the sale of equity securities and, to a lesser extent, loans and grants. The Company may never achieve profitability and, unless it does, the Company will need to continue raising additional capital to fund its operations. The Company believes that its cash and cash equivalents of $56.7 million at June 30, 2021 will enable it to meet anticipated cash needs required to maintain its current and planned operations through at least the next 12 months from the issuance of the financial statements for the quarter ended June 30, 2021.

Management intends to fund future operations through private or public debt or equity financing transactions and may seek additional capital through arrangements with strategic partners or from other sources. If the Company is unable to obtain adequate financing, it will evaluate options which may include reducing or deferring operating expenses, including curtailing its workforce and certain development programs, which would have a material adverse effect on the Company's operations and future prospects.

2. Basis of Presentation and Significant Accounting Policies

The Company has prepared the accompanying unaudited interim condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) promulgated by the Financial Accounting Standards Board (“FASB”).

The Company has reclassified certain items from the prior year’s condensed consolidated financial statements to conform to the current year’s presentation. Specifically, the Company allocated certain facilities and support costs between research and development expenses and general and administrative expenses that were previously reported within general and administrative expenses only. For the three and six months ended June 30, 2020, $0.2 million and $0.4 million, respectively, is reclassified from general and administrative expenses to research and development expenses, which resulted in general and administrative expenses decreasing from $4.0 million to $3.8 million and $9.3 million to $8.9 million, for the three and six months ended June 30, 2020, respectively, and research and development expenses increasing from $3.5 million to $3.7 million and $8.1 million to $8.5 million, for the three and six months ended June 30, 2020, respectively. This reclassification had no impact on previously reported total operating expenses, loss from operations, net loss, or net cash used in operating activities.

Certain information and footnote disclosures normally included in the Company’s annual consolidated 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 June 30, 2021 and 2020.

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 condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 12, 2021 (the “Annual Report”).

The significant accounting policies used in the preparation of these condensed consolidated financial statements are consistent with those described in the Company’s audited consolidated financial statements as of and for the year ended December 31, 2020, and the notes thereto, in the Company’s Annual Report.

Recent Accounting Pronouncements

Although the FASB has issued several ASUs for which adoption dates are pending, the Company does not expect any to have any impacts on its consolidated financial statements.

3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Research and development	$ 751	$ 631
Insurance	283	170
Other	545	368
Total	$ 1,579	$ 1,169

4. Property and Equipment

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

	June 30, 2021	December 31, 2020
Computers and software	$ 31	$ 124
Office furniture and equipment	28	164
Laboratory equipment	176	-
Leasehold improvements	65	158
	300	446
Less accumulated depreciation	(115)	(313)
Property and equipment, net	$ 185	$ 133

Depreciation expense was $40 thousand and $17 thousand for the three months ended June 30, 2021 and 2020, and $56 thousand and $36 thousand for the six months ended June 30, 2021 and 2020, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Research and development expenses	$ 1,499	$ 802
Payroll and other employee-related expenses	1,017	1,315
Professional services	686	415
Interest on debt	48	57
Other	52	39
Restructuring	—	258
Total	$ 3,302	$ 2,886

6. Debt

Term Loan

On January 30, 2019, the Company entered into a Loan and Security Agreement (the “Loan Agreement”) in the amount of $15.0 million with Silicon Valley Bank (“SVB”) and WestRiver Innovation Lending Fund VIII, L.P. (“WestRiver”, and together with SVB, the “Lenders”).

Outstanding principal on the loan accrues interest at a floating rate equal to the greater of (i) 5.25% per annum and (ii) the sum of 2.5% plus the prime rate, as published in The Wall Street Journal. Interest payments are payable monthly. On June 30, 2021, the interest rate was 5.75%. The Company commenced making payments on the outstanding principal balance of the loan on February 1, 2020, which is payable in 36 equal monthly installments and fully matures on January 1, 2023.

In conjunction with the initial loan advance, the Company issued warrants to the Lenders to purchase an aggregate of 40,834 shares of common stock at a price of $11.02 (subject to certain adjustments).

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

The Company granted first priority liens and a security interest in substantially all of the Company’s assets, excluding all of its intellectual property, which is subject to a negative pledge, and a pledge by the Company of the shares of one of its wholly-owned subsidiaries as collateral for the obligations thereunder. The Loan Agreement also contains customary covenants, including limitations on other indebtedness, liens, acquisitions, investments and dividends, and events of default, including payment defaults, breaches of covenants, a material impairment in the perfection or priority of the security interest in the collateral, and events relating to bankruptcy or insolvency.

As of June 30, 2021, the carrying value of the outstanding loan consists of $7.9 million in principal less an unamortized debt discount of $0.3 million. The debt issuance costs, the valuation of the warrants, and the final maturity payment of $0.9 million, have been recorded as a debt discount which are being accreted to interest expense through the maturity date of the loan. Interest expense relating to the loan for the three months ended June 30, 2021 and 2020 was $0.2 million and $0.3 million, respectively. Interest expense is calculated using the effective interest method and is inclusive of non-cash amortization of the debt discount. At June 30, 2021, the effective interest rate was 10.85%.

PPP Loan

In April 2020, the Company entered into a loan agreement with SVB under the U.S. Small Business Administration (the "SBA") Paycheck Protection Program (the "PPP") pursuant to the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act") and received loan proceeds of $0.8 million (the "PPP Loan"). The Company used the loan proceeds for payroll and other covered costs in accordance with the relevant terms and conditions of the CARES Act. The PPP Loan has a maturity date of April 21, 2022 and an interest rate of 1.0% per annum. Monthly payments of principal and interest are due beginning on September 21, 2021, although interest accrues from the issuance date. A PPP loan may be partially or entirely forgiven based on employee retention for the 24-week period starting on the loan date through October 2020, and the use of loan proceeds for payroll or other specified costs during the same period. Forgiveness is also based on the employer maintaining or restoring headcount and maintaining salary levels. Forgiveness is reduced if headcount declines or if salaries decrease. Any loan forgiveness will be made subject to SVB approval in accordance with SBA requirements.

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

	June 30, 2021
Remainder of 2021	$ 2,898
2022	5,398
2023	417
Total future principal payments	8,713
Less unamortized discount	(290)
Carrying value of long-term debt	8,423
Less current portion	(5,686)
Add final fee due at maturity in 2023	900
Long-term portion	$ 3,637

7. Legal and Other Contingencies

From time to time, the Company may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. The Company is currently unaware of any material pending legal proceedings to which it is a party or of which its property is the subject.

The Company accounts for its contingent liabilities in accordance with ASC Topic 450, "Contingencies".

During 2019, the Company received a funding award from the Cystic Fibrosis Foundation ("CFF") and entered into an agreement relating to the award, which agreement was amended in December 2020 providing for an additional award amount. Payment of award amounts are subject to the achievement of certain milestones in connection with the Company's cystic fibrosis development program. The Company will be required to repay amounts received from the CFF (or specified multiples of such amounts) in certain circumstances, including as royalties on net sales, and, in the event of a disposition of the underlying asset. The funding provided to the Company is accounted for as an advance from a collaboration partner within the scope of ASC Topic 730, "Research and Development." As of June 30, 2021, and December 31, 2020, the Company received payments of $3.4 million and $0.8 million, respectively, which are recorded as liabilities captioned 'Advances from collaboration partners' in the accompanying condensed consolidated financial statements.

During May 2021, the Company received an additional award from the CFF to help identify optimized oral RMAs for further development in the treatment of cystic fibrosis patients with nonsense mutations. Payment of award amounts are subject to the achievement of certain milestones in connection with the Company’s oral RMA cystic fibrosis development program. The Company will be required to repay amounts received from the CFF (or specified multiples of such amounts) in certain circumstances, including as royalties on net sales, and, in the event of a disposition of the underlying asset. As of June 30, 2021, the Company had not received any funds associated with this award.

8. Stockholders' Equity

Warrants

As of June 30, 2021 and December 31, 2020, 323,892 warrants to purchase common stock were outstanding, with a weighted average exercise price of $4.31 per share. The weighted average remaining contractual life at June 30, 2021 was 2.24 years.

9. Stock-based Compensation

Summary of Stock Option Activity

Transactions related to stock options awarded to employees and directors during the six months ended June 30, 2021 were as follows:

	Shares	Weighted average exercise price	Weighted average remaining contractual life (years)	Aggregate intrinsic value
Options outstanding at December 31, 2020	3,803,061	$ 10.16	8.20	$ 1,936,183
Granted	4,662,867	2.74		
Exercised	(3,525)	(1.59)		
Forfeited	(807,395)	(5.00)		
Options outstanding at June 30, 2021	7,655,008	$ 6.19	7.45	$ 1,346,198
Options exercisable at June 30, 2021	2,719,909	$ 11.49	3.78	$ 413,252

The aggregate intrinsic value represents the total intrinsic value (the difference between the fair value of the common stock as of June 30, 2021 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 June 30, 2021. This amount is impacted by changes in the fair value of the common stock.

Summary of Restricted Stock Unit Activity

Activity related to restricted stock units awarded to employees during the six months ended June 30, 2021 were as follows:

	Shares	Weighted average grant date fair value per share
Unvested at December 31, 2020	349,725	$ 4.67
Granted	542,679	$ 3.36
Vested	(178,762)	$ 4.71
Forfeited	(78,750)	3.97
Unvested at June 30, 2021	634,892	$ 3.63

Stock-based Compensation

Stock-based compensation relates, non-employee directors and non-employees, time-based restricted stock units granted and performance-based stock options and restricted stock units granted. In February 2020, the Board of Directors approved a leadership and organizational realignment, which accelerated the vesting of certain awards, resulting in additional stock-based compensation of $2.1 million, which was recorded in restructuring charges. In connection with the acquisition of Zikani, on April 1, 2021, Martijn Kleijwegt, Silvia Noiman and Gregory Williams resigned from the Board of Directors. The Company incurred a one-time non-cash stock compensation charge, relating to accelerated vesting of executive stock awards of $2.4 million. Total equity-based compensation expense related to all of the Company's stock-based awards was recognized as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 114	$ 262	$ 355	$ 481
General and administrative	3,921	1,714	4,988	3,366
Restructuring charges	—	—	—	2,124
Total stock-based compensation expense	$ 4,035	$ 1,976	$ 5,343	$ 5,971

10. Marketable Securities

Cash and cash equivalents at June 30, 2021 and December 31, 2020 had an amortized cost as well as fair value of $56.7 million and $24.7 million, respectively. As of June 30, 2021 and December 31, 2020, no credit losses were identified related to the cash equivalents or marketable securities.

11. Fair Value of Financial Instruments

At June 30, 2021 and December 31, 2020, the Company's financial assets valued based on Level 1 inputs consisted of cash and cash equivalents. During the three and six months ended June 30, 2021, the Company did not have any transfers of financial assets between levels, as defined in the significant accounting policies note in our Annual Report.

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

12. Other Expense, Net

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Interest and other expense	$ 319	$ 347	$ 579	$ 762
Interest and other income	—	(69)	—	(313)
Foreign currency exchange losses	10	12	30	22
Investment income	—	11	—	9
Total other expense, net	$ 329	$ 301	$ 609	$ 480

13. 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, are as follows (amounts in thousands, except share and per share data):

	Three Months Ended June 30, 2021	Three Months Ended June 30, 2020	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Numerator:				
Net loss	$ (36,058)	$ (7,887)	$ (44,752)	$ (21,833)
Denominator:				
Weighted average number of shares of common stock used in computing net loss per share, basic and diluted	66,389,865	40,129,304	53,357,401	40,101,789
Net loss per share, basic and diluted	$ (0.54)	$ (0.20)	$ (0.84)	$ (0.54)

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

	Six Months Ended June 30, 2021	Six Months Ended June 30, 2020
Options to purchase common stock	7,655,008	4,952,230
Restricted stock units	634,892	367,167
Warrants	323,892	323,894
Total potential common stock equivalents	8,613,792	5,643,291

14. Restructuring

In February 2020, the Company eliminated 13 full-time positions. This resulted in a charge of $4.0 million, including $2.1 million in stock-based compensation expense, with severance being paid over one year.

The accrued charges and associated payments for the three months ended June 30, 2021, are as follows (in thousands):

	Beginning Balance	Additions	Deductions	Ending Balance
Severance and related costs	$ 258	$ —	$ (258)	$ —
Total restructuring charges	$ 258	$ —	$ (258)	$ —

The accrued charges and associated payments for the three months ended June 30, 2020 are as follows (in thousands):

	Beginning Balance	Additions	Deductions	Ending Balance
Severance and related costs	$ —	$ 1,705	$ (747)	$ 958
Contract termination costs	—	165	(165)	—
Total restructuring charges	$ —	$ 1,870	$ (912)	$ 958

15. Merger Accounting

On April 1, 2021, the Company, acquired Zikani, pursuant to an Agreement and Plan of Merger (the "Merger Agreement"). Under the terms of the Merger Agreement, the Company issued 7,596,810 shares of common stock, $0.01 par value per share ("Eloxx Common Stock"), in exchange for all of the issued and outstanding equity interests of Zikani (the "Merger Consideration"). In addition, the Company issued 442,142 restricted stock units under the Eloxx Pharmaceuticals, Inc. 2018 Equity Incentive Plan (the "Equity Plan") to certain employees of Zikani in respect of each individual's prospective service as an officer, consultant or director of the Company.

The Company has been determined to be the acquiring company for accounting purposes and has concluded the merger represents an asset acquisition by the Company of Zikani. To determine the accounting for this transaction under U.S. GAAP, a company must assess whether an integrated set of assets and activities will be accounted for as an acquisition of a business or an asset acquisition. The guidance requires an initial screen test to determine if substantially all of the relative fair value of the gross assets acquired is concentrated in a single asset or group of similar non-financial assets. If that screen is met, the set is not a business. In connection with the acquisition of Zikani, substantially all of the consideration paid is allocable to the fair value of acquired in-process research and development ("IPR&D") and, as such, the acquisition is treated as an asset acquisition. Zikani's assets and liabilities have been initially recognized by allocating the accumulated cost of the acquisition based on their relative fair values, as estimated in good faith by management. The net assets acquired as of the transaction date has been combined with the assets, liabilities, and results of operations of the Company on consummation of the Merger. In accordance with ASC 730, Research and Development, the portion of the Merger Consideration allocated to the acquired IPR&D based on its relative fair value is included as an operating expense as there is no alternative future use.

The total consideration for the Merger is as follows (in thousands, except per share data):

Number of shares of Eloxx common stock issued to Zikani stockholders (1)		7,597
Actual closing price per share of Company common stock as reported on the Nasdaq Capital Market on April 1, 2021	$ 3.36	
Adjusted for a discount for lack of marketability ("DLOM") (1)	87.5%	$ 2.94
Estimated fair value of common stock consideration		22,335
Estimated transaction costs		1,003
Total preliminary estimated purchase price		$ 23,338

(1) The shares of common stock issued as merger consideration are unregistered and subject to trading restriction under Rule 144. The Company estimated the DLOM based on consideration of multiple valuation methods. A DLOM is applied to the Company's quoted common stock price to estimate the value of Eloxx common stock issued on a minority, non-marketable basis. The Eloxx Common Stock issued was offered and sold in transactions exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), in reliance on Section 4(a)(2) thereof and Regulation D thereunder.

The following table summarizes the preliminary allocation of the cost of the acquisition to the respective assets acquired and liabilities assumed, based on their relative fair values. The purchase price allocations were prepared on a preliminary basis and are subject to change as additional information becomes available concerning the fair value of the assets acquired and liabilities assumed. Any measurement period adjustments to the purchase price allocation will be made as soon as practicable but no later than one year from the date of acquisition.

Cash and cash equivalents	$ 1,954
Restricted cash	191
Prepaid expenses and other current assets	296
Operating lease right-of-use asset	1,810
Property and equipment, net (2)	192
Intangible assets (3)	467
Total Assets	4,910
Accounts payable	1,219
Accrued expenses	748
Current portion of operating lease liability	588
Operating lease liability	1,222
Total liabilities	3,777
Net assets acquired	1,133
In process research and development acquired (4)	22,205
Purchase price	23,338

(2) Zikani's property and equipment consists principally of laboratory and computer equipment, furniture and fixtures and leasehold improvements.

(3) Employee-related intangible assets relate to Zikani's assembled workforce acquired in the Merger.

(4) IPR&D represents the allocated consideration based on the estimated fair value of Zikani's IPR&D. In accordance with ASC 730, Research and Development, the fair value of IPR&D acquired in an asset acquisition with no alternative future use be allocated a portion of the consideration transferred and charged to expense at the acquisition date. The actual purchase price allocated to IPR&D may change, subject to finalization of the fair value estimates and the determination of final transaction costs. The final valuation of the IPR&D consideration could differ significantly from the current estimate.

In addition, the Company incurred and expensed costs directly related to the Merger totaling approximately $1.0 million, of which $0.8 million and $1.0 million was incurred in the three and six months ended June 30, 2021, and is included in general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

Since the closing date of the Merger, the results of Zikani's operations have been included in the Company's condensed consolidated financial statements.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes included elsewhere in this Quarterly Report, as well as the audited financial statements and the related notes thereto, and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks, uncertainties and other factors that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Please see the sections "Forward-Looking Statements," "Summary Risk Factors," and Part I, Item 1A. "Risk Factors" herein.

Company Overview

We are a clinical-stage biopharmaceutical company engaged in the science of ribosome modulation, leveraging both its innovative TURBO-ZM™ chemistry technology platform in an effort to develop novel Ribosome Modulating Agents (RMAs) and its library of Eukaryotic Ribosome Selective Glycosides (ERSGs), for the treatment of rare and ultra-rare premature stop codon diseases. Premature stop codons are point mutations that disrupt the stability of the impacted messenger RNA (mRNA) and the protein synthesis from that mRNA.

Our lead clinical program, ELX-02, is currently in Phase 2 clinical development for the treatment of cystic fibrosis (CF) in patients with diagnosed nonsense mutations and is being conducted at leading investigator sites in Europe, Israel and the United States. As of the end of June 2021, we believe that we have enrolled a sufficient number of patients to assess biological activity of ELX-02. We expect to present data from the first four treatment arms of the study in the fourth quarter of 2021. The Cystic Fibrosis Foundation ("CFF") is providing funding for a portion of this clinical trial program.

The FDA has granted orphan drug designation to ELX-02 for the treatment of nephropathic cystinosis, MPS I, Rett syndrome, and CF.

Acquisition of Zikani Therapeutics, Inc.

On April 1, 2021, the Company acquired Zikani Therapeutics, Inc. ("Zikani"), a company in preclinical development and engaged in the science of ribosome modulation, leveraging its innovative TURBO-ZM™ chemistry technology platform to develop novel Ribosome Modulating Agents (RMAs) as potential therapeutics for people with limited treatment options. The TURBO-ZM™ platform is designed to enable rapid synthesis of novel compounds that can be optimized to modulate the ribosome in a disease specific manner. The TURRBO-ZM™ synthetic chemistry platform can design oral novel macrolide-based small molecules that are potent oral modulators with favorable therapeutic indices. Macrolides are antibiotics that inhibit protein synthesis in bacteria.

We expect the combined company to emerge as a leader in the science of ribosome modulation through our complementary platforms and continued development of our library of RMAs and Eukaryotic Ribosome Selective Glycosides (ERSGs). ELX-02, is a small molecule drug candidate designed to restore production of full-length functional proteins. The investigational therapy has shown strong activity across a full range of mutations in CF preclinical models. In Phase 1 testing, ELX-02 was generally well tolerated and demonstrated high bioavailability with consistent pharmacokinetics across both single and multiple-dose studies. The Phase 2 trials are designed to validate the safety of ELX-02 and assess its biological activity.

With the strength of our ELX-02 program for CF, the acquisition of Zikani provides us with the opportunity to amplify the potential of our innovative science by developing a new class of therapies to treat diseases with limited to no treatment options. The CFF has agreed to provide funding for a portion of this research. Our preclinical programs are focused on select rare diseases including inherited diseases, cancer caused by nonsense mutations, kidney diseases, including autosomal dominant polycystic kidney disease, as well as rare ocular genetic disorders. In addition, we plan to file an IND in 2022 for what could potentially become the first oral therapy for protein restoration for patients with nonsense mutations in Recessive Dystrophic Epidermolysis Bullosa (RDEB) and Junctional Epidermolysis Bullosa (JEB). RDEB is an incurable, extremely painful and often fatal skin blistering condition caused by a lack of collagen type VII that is estimated to affect more than 3,000 people worldwide. JEB is the most severe form of EB, with most patients dying in infancy. By extending the application of ribosomal RNA modulation to the readthrough of nonsense mutations in tumor suppressor genes, we are also rapidly advancing preclinical research for familial adenomatous polyposis (FAP), an inherited pre-cancerous colorectal disease frequently caused by nonsense mutations in the adenomatous polyposis coli (APC) gene. We plan to target rare diseases including genetic diseases and cancers caused by nonsense mutations.

Nonsense mutations cause approximately 10-12 percent of rare inherited diseases. ELX-02 along with the TURBO-ZMTM library of compounds are anticipated to significantly expand to include the treatment of many other rare diseases and certain cancers.

Under the terms of the Agreement and Plan of Merger (the "Merger Agreement"), the Company issued 7,596,810 shares of common stock in exchange for all of the issued and outstanding equity interests of Zikani. (the "Merger Consideration").

COVID-19

The ongoing COVID-19 pandemic and the measures that we, our employees, consultants, suppliers, contract research organizations ("CROs"), and other partners or governments may take in response to the pandemic may significantly disrupt our business operations. We are working to ensure that we can operate with minimal disruption, and mitigate the impact of the pandemic on the health and safety of our employees and the patients and healthcare professionals that participate in our clinical trials. However, given the significant uncertainty regarding the ongoing impact of the COVID-19 pandemic, there remains a risk that we or our employees, contractors, suppliers, and other partners may be prevented or prohibited from conducting business activities for indefinite periods of time, for example due to a substantial percentage of personnel contracting the virus or due to government-mandated restrictions.

While the pandemic has not to date had a material adverse impact on our financial condition, and we have not had to furlough any employees, our clinical trials were temporarily paused. Both Phase 2 clinical trials have resumed, and we believe that we have enrolled a sufficient number of patients to assess biological activity of ELX-02. We continue to monitor our operations, states of affairs in the regions in which we and our business partners operate and conduct research and clinical trial activities, and applicable government recommendations.

Results of Operations

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

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
	2021	2020	$	%	2021	2020	$	%
Operating expenses:								
Research and development	$ 5,704	$ 3,738	$ 1,966	53 %	$ 9,777	$ 8,505	$ 1,272	15 %
General and administrative	7,355	3,848	3,507	91 %	11,696	8,854	2,842	32 %
Acquired in-process research and development	22,670	—	22,670	—	22,670	—	22,670	—
Restructuring charges	—	—	—	—	—	3,994	(3,994)	—
Total operating expenses	35,729	7,586	28,143	371 %	44,143	21,353	22,790	107 %
Loss from operations	(35,729)	(7,586)	(28,143)	371 %	(44,143)	(21,353)	(22,790)	107 %
Other expense, net	329	301	28	9 %	609	480	129	27 %
Net loss	$ (36,058)	$ (7,887)	$ (28,171)	357 %	$ (44,752)	$ (21,833)	$ (22,919)	105 %

Research and development expense

Research and development expenses were $5.7 million for the three months ended June 30, 2021, compared to $3.7 million for the same period in 2020, an increase of $2.0 million. The increase was primarily related to a $1.8 million increase in expenses related to subcontractors, consultants and advisors in connection with continued development of ELX-02 due to the impact of the COVID-19 pandemic on the corresponding prior year period expense, an increase in salaries and other personnel related costs of $0.3 million partially offset by a $0.1 million decrease in stock-based compensation expense.

Research and development expenses were $9.8 million for the six months ended June 30, 2021 compared to $8.5 million for the same period in 2020, an increase of $1.3 million. The increase was primarily related to a $1.50 million increase in expenses related to subcontractors, consultants and advisors in connection with continued development of ELX-02 due to the impact of the COVID-19 pandemic on the corresponding prior year period expense, partially offset by a decrease in salaries and other personnel related costs of $0.1 million, and a $0.1 million decrease in stock-based compensation expense.

General and administrative expenses

General and administrative expenses were $7.4 million for the three months ended June 30, 2021, compared to $3.8 million for the same period in 2020, an increase of $3.5 million. The increase was primarily related to a $2.2 million increase in stock-based compensation expense, a $1.2 million increase in in salaries and other personnel related costs related to the merger with Zikani, as well as an increase of $0.1 million increase in expenses attributable principally to infrastructure related costs including legal, accounting and other professional fees.

General and administrative expenses were $11.7 million for the six months ended June 30, 2021, compared to $8.9 million for the same period in 2020, an increase of $2.8 million. The increase was primarily related to a $1.6 million increase in stock-based compensation expense, a $1.0 million increase in in salaries and other personnel related costs related to the merger with Zikani, as well as an increase of $0.2 million increase in expenses attributable principally to infrastructure related costs including legal, accounting and other professional fees.

Acquired in-process research and development

Acquired in-process research and development ("IPR&D") expense of $22.7 million for the six months ended June 30, 2021 consists of the estimated fair value of the assets acquired and consideration given in connection with the acquisition of the Zikani's IPR&D. As the assets acquired were in the research and development phase and were determined to not have any alternative future use, it was expensed as acquired IPR&D. There was no such expense for the six months ended June 30, 2020.

Restructuring charges

Restructuring charges of $4.0 million for the six months ended June 30, 2020 resulted from the leadership and organizational realignment during the first quarter of 2020. The total included $1.9 million related to contract termination and employee separation costs, primarily severance and benefits, and $2.1 million of stock-based compensation, relating to accelerated vesting of stock awards. There were no similar charges during the six months ended June 30, 2021.

Other expense, net

We recorded $0.3 million in other expense, net for each of the three months ended June 30, 2021, and 2020. We recorded $0.6 million in other expense, net for the six months ended June 30, 2021, compared to $0.5 million for the same period in 2020. The increase in other expense, net was primarily due to lower interest income.

Liquidity and Capital Resources

Liquidity is the ability of a company to generate funds to support its current and future operations, satisfy its obligations, and otherwise operate on an ongoing basis. Significant factors in the management of liquidity are funds generated by operations, levels of accounts receivable and accounts payable and capital expenditures. We have not generated revenue from sales of any product or service.

We have incurred significant operating losses to date and have not generated revenue from sales of any products or services. Our net losses were $44.8 million and $7.9 million for the six months ended June 30, 2021, and 2020. As of June 30, 2021, we had an accumulated deficit of $216.3 million. Further, we expect to incur additional costs related to our acquisition of Zikani. We have financed our operations primarily through the issuance of equity instruments, and to a lesser extent, from loans and grants. We have devoted substantially all of our financial resources and efforts to the development of our product candidates. We expect that it may be several 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 operating losses for the foreseeable future. A successful transition to profitable operations is dependent upon achieving a level of revenue adequate to support our cost structure. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses may increase if, and as, we:

- advance ELX-02 and/or other product candidates further into clinical development;
- experience any additional delays in enrollment and completion of our clinical trials due to the COVID-19 pandemic;
- continue the preclinical development of our research programs and advance candidates into clinical trials;
- pursue regulatory authorization to conduct clinical trials of additional product candidates;
- seek marketing approvals for our product candidates;
- 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;
- acquire or in-license other product candidates and technologies; and
- operate as a public company.

We may never achieve profitability and until we do, we will continue to need to raise additional cash to fund our operations. Our cash and cash equivalents are highly liquid investments with original maturities of one year or less at the date of purchase and consist of cash in operating accounts and secured investments, primarily money market funds.

We believe that our cash and cash equivalents of $56.7 million at June 30, 2021, will enable us to meet anticipated cash needs required to maintain our current and planned operations through at least the next 12 months from the issuance of this Report.

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

Principal Financing Activities

In April 2020, we entered into a loan agreement with Silicon Valley Bank (“SVB”) under the U.S. Small Business Administration (the “SBA”) Paycheck Protection Program (the “PPP”) pursuant to the Coronavirus Aid, Relief and Economic Security Act of 2020 (the “CARES Act”) and received loan proceeds of $0.8 million (the “PPP Loan”). We used the loan proceeds for payroll and other covered costs in accordance with the relevant terms and conditions of the CARES Act. The PPP Loan has a maturity date of April 21, 2022 and an interest rate of 1.0% per annum. Monthly payments of principal and interest are due beginning on September 21, 2021, although interest accrues from the issuance date. A PPP loan may be partially or entirely forgiven based on employee retention for the 24-week period starting on the loan date through October 2020, and the use of loan proceeds for payroll or other specified costs during the same period. Forgiveness is also based on the employer maintaining or restoring headcount and maintaining salary levels. Forgiveness is reduced if headcount declines or if salaries decrease. Any loan forgiveness will be made subject to SVB approval in accordance with SBA requirements.

On May 13, 2021, we completed an underwritten public offering of 38,333,334 shares of common stock at a price of $1.35 per share and received gross proceeds of approximately $51.8 million, before deducting underwriting discounts and commissions of $3.1 million and offering expenses of $0.8 million.

Cash Flows

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

	Six Months Ended June 30,	
	2021	**2020**
Net cash used in operating activities	$ (17,482)	$ (18,240)
Net cash provided by investing activities	2,145	27,042
Net cash provided by (used in) financing activities	47,593	(939)

Our operating activities used cash of $17.5 million and $18.2 million during the six months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021, net cash used in operating activities resulted primarily from our net loss of $44.8 million and changes in working capital of $0.3 million, partially offset by total non-cash charges of $28.5 million. Non-cash charges primarily related to $22.7 million of acquired in-process research and development, $5.3 million of stock-based compensation, $0.3 million of amortization of lease assets, and $0.2 million of debt discount amortization. Changes in working capital were primarily related to decreases of $0.1 million in prepaid expenses, $0.2 million in operating lease liabilities, and $1.0 million of merger related costs. For the six months ended June 30, 2020, net cash used in operating activities resulted primarily from our net loss of $(21.8) million and total changes in working capital of $(3.0) million partially offset by total non-cash charges of $6.6 million. Non-cash charges primarily related to $6.0 million of stock-based compensation, $0.3 million of amortization of lease assets, and $0.3 million of debt discount amortization. Changes in working capital were primarily related to decreases of $1.2 million in accrued expenses, $1.1 million in accounts payable and $0.3 million in operating lease liabilities, and in increase of $0.4 million in prepaid expenses and other current assets.

Our investing activities provided cash of $2.1 million and $27.0 million during the six months ended June 30, 2021 and 2020, respectively. For the six months ended June 30, 2021, cash provided in investing activities was primarily related to $2.1 million of cash acquired as part of the merger. For the six months ended June 30, 2020, cash provided in investing activities was primarily related to $27.0 million of proceeds from the maturity of marketable securities.

Our financing activities provided cash of $47.6 million during the six months ended June 30, 2021 and used cash of $0.9 million during the six months ended June 30, 2020. For the six months ended June 30, 2021, net cash provided by financing activities consisted primarily of net proceeds of $47.7 million from our public offering of common stock in May 2021, $2.6 million in advances received from collaboration partners, offset by $2.5 million in term loan principal repayments and $0.2 million related to the settlement of taxes upon vesting of restricted stock units. For the six months ended June 30, 2020, net cash used in financing activities consisted primarily of $2.1 million in term loan principal repayments, offset by $0.8 million received from the PPP Loan and $0.4 million in advances received from collaboration partners.

Off-balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Use of Estimates

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

The critical accounting policies that we believe impact significant judgments and estimates used in the preparation of our condensed consolidated financial statements presented in this Report are described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report. There have been no material changes to our critical accounting policies through June 30, 2021 from those discussed in our Annual Report filed with the SEC on March 12, 2021.

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

Limitations on Effectiveness of Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act 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.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect that there are resource constraints and the management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and interim Chief Financial Officer, evaluated, as of the end of the period covered by this Report, the effectiveness of our disclosure controls and procedures. Based on that evaluation, our Chief Executive Officer and interim Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2021.

As discussed in Note 15 of our financial statements included elsewhere in this Report, we acquired Zikani on April 1, 2021. We are in the process of evaluating the internal controls of Zikani, and, as permitted for newly acquired businesses, the internal control over financial reporting of Zikani was excluded from the evaluation of the effectiveness of our disclosure controls and procedures as of June 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls over financial reporting (as defined in Rules 13a-15(f) and 15(d)-15(f) under the Exchange Act) during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. As noted above, we acquired Zikani on April 1, 2021. We are in the process of reviewing the internal control structure of Zikani and, if necessary, will make appropriate changes as we continue to integrate Zikani into our Company.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

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. 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.

Item 1A. Risk Factors

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

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

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

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

Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for, and successfully commercializing ELX-02 and any future product candidates, either alone or with third parties. The success of ELX-02 and any other product candidates will depend on several factors, including the following:

- our ability to continue our business operations and product candidate research and development, and adapt to any changes in the regulatory approval process, manufacturing supply or clinical trial requirements and timing due to the ongoing COVID-19 pandemic;
- successful completion of preclinical studies;
- receipt of authorization to proceed under investigational new drug applications ("INDs") and similar filings outside the United States for our planned clinical trials or future clinical trials;
- successful patient enrollment in and completion of clinical trials;
- safety and efficacy data for our product candidates that are satisfactory to the FDA, European Medicines Agency ("EMA"), or any other comparable foreign regulatory authority for marketing approval;
- receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- completion of any required post-marketing approval commitments to applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved;
- establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients, the medical community and third-party payors;
- obtaining and maintaining third-party coverage and adequate reimbursement; and
- maintaining a continued acceptable safety profile of our products following any approval.

Many of these factors are beyond our control, and it is possible that we may never obtain regulatory approval for ELX-02 or any other product candidates even if we expend substantial time and resources seeking their development and approval. If we do not achieve regulatory approval in a timely manner or at all, we could experience significant delays or an inability to commercialize our current or future product candidates, which would materially adversely affect our business.

The success of our business, including our ability to finance our Company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and any eventual commercialization of the product candidates we develop. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating cost-effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production in accordance with current Good Manufacturing Practices ("cGMP") or similar regulatory requirements outside the United States, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenue from product sales. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

Preclinical and clinical drug development is a lengthy and expensive process, with an uncertain outcome. Our preclinical and clinical programs may experience delays or may never advance, which would adversely affect ability to obtain regulatory approvals or commercialize our product candidates on a timely basis or at all, which could have an adverse effect on our business

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 of our product candidates in humans to the satisfaction of the FDA, EMA and other applicable regulatory agencies in the jurisdictions in which we intend to market our product candidates. Clinical testing is expensive, time-consuming, and subject to uncertainty. Of the large number of drugs in development, only a small percentage successfully complete clinical testing and an even smaller portion obtain FDA or similar foreign regulatory authority approval 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.

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

Further, we may experience delays in clinical trials of our product candidates. We do not know whether ongoing clinical trials will be completed on schedule or at all, or whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. We also cannot be sure that submission of an IND or similar application will result in the FDA, or other regulatory authority allowing clinical trials to begin in a timely manner, if at all. Moreover, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Clinical trials can be delayed for a variety of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- reaching a consensus with regulatory authorities on study design or implementation of the clinical trials;
- failure in obtaining regulatory authorization to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations ("CROs"), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining institutional review board ("IRB"), or ethics committee approval at each clinical trial site;
- identifying, recruiting and training suitable clinical investigators;
- manufacturing, testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials;

- insufficient or inadequate supply or quality of product candidates or other materials necessary for use in clinical trials;
- recruiting, screening and enrolling suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a clinical trial;
- adding new clinical trial sites;
- failure by our CROs, other third parties or us to adhere to clinical trial protocols;
- failure to perform in accordance with the FDA's good clinical practice requirements ("GCPs"), or similar regulatory guidelines in other countries;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits, or occurrence of adverse events in clinical trials of the same class of agents conducted by other companies;
- changes in regulatory requirements or guidance that require amending or submitting new clinical trial protocols;
- changes to the standard of care on which a clinical development plan was based, which may require new or additional studies or clinical trials;
- selection of clinical endpoints that require prolonged periods of observation or analyses of resulting data;
- costs of clinical trials of our product candidates being greater than we anticipate;
- clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon development of such product candidates;
- transfer of manufacturing processes to larger-scale facilities operated by a contract manufacturing organization ("CMO") and delays or failure by our CMOs or us to make any necessary changes to such manufacturing processes;
- third parties being unwilling or unable to satisfy their contractual obligations to us; or
- unforeseen factors beyond our control, including public health concerns such as the COVID-19 pandemic.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, on March 25, 2020, we announced that enrollment in our clinical trials had been paused temporarily in response to the COVID-19 pandemic. On June 17, 2020, we announced that enrollment in our Phase 2 clinical trial in cystic fibrosis had resumed in Israel and Europe and, on August 12, 2020, we announced that enrollment had resumed in the Unites States. COVID-19 is continuing to evolve and we continue to work closely with our clinical trial sites and investigators to ensure that patient enrollment will continue as quickly as is feasible in a safe environment for our patients. While we believe that we have enrolled a sufficient number of patients to assess biological activity of ELX-02, and expect to present data from the first four treatment arms of the study in the fourth quarter of this year, we cannot provide assurances as to whether we will incur significant additional costs, expend additional resources or be subject to additional regulatory requirements, including COVID-19 related disruptions, any of which may have a material adverse impact on our financial condition and results of operations.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical trial or by the FDA or any other regulatory authority, or if the IRBs or ethics committees of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

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

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

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

- The U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under any U.S. federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, including stock options. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Any arrangements with prescribers must be for bona fide services and compensated at fair market value.

- The U.S. federal civil and criminal false claims laws, including without limitation, the civil False Claims Act, which can be enforced by private citizens on behalf of the U.S. federal government through civil whistleblower or qui tam actions, and the federal civil monetary penalties law which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the U.S. federal government. Pharmaceutical manufacturers can cause false claims to be presented to the U.S. federal government by, among other things, engaging in impermissible marketing practices, such as the off-label promotion of a product for an indication for which it has not received FDA approval. Further, pharmaceutical manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and 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.

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives, and similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations.

If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of noncompliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

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

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

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

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

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

- regulatory authorities may withdraw approvals of such product or impose restrictions on its distribution in the form of a new or modified risk evaluation and mitigation strategy;
- regulatory authorities may require additional labeling, such as additional warnings or contraindications, which may negatively impact sales;
- regulatory authorities may issue safety alerts, letters to healthcare providers, press releases or other communications containing warnings or other safety information about the product;
- we may be required to change the way the product is administered or to conduct additional clinical studies;
- we may be required to create a risk evaluation and mitigation strategy ("REMS") which could include a medication guide outlining the risks of such side effects for distribution to patients;
- we may be subject to fines, injunctions o the imposition of criminal penalties;
- 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, 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 cystic fibrosis caused by nonsense mutations;
- determination of dosing levels and corresponding effect analysis;
- unforeseen safety issues;
- lack of effectiveness during clinical trials;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators and IRBs to follow our clinical protocols;
- unforeseen factors beyond our control, including public health concerns such as the COVID-19 pandemic; and
- lack of sufficient funding to finance the clinical trials.

Even though we have received orphan drug designation from the FDA for ELX-02 for the treatment of cystic fibrosis, cystinosis, MPS I, and Rett syndrome, 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 Unites States and European Union ("EU"), may designate drugs for relatively small patient populations as orphan drugs in the U.S. and orphan medicinal products in the EU. Under the Orphan Drug Act, 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 in the U.S., or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan drug designation must be requested before submitting an NDA.

Similarly, in the EU, a medicinal product may receive orphan designation. This applies to products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition and either the condition affects no more than five in 10,000 persons in the EU when the application is made, or the product, without the benefits derived from orphan status, would unlikely generate sufficient return in the EU to justify the necessary investment. Moreover, in order to obtain orphan designation in the EU, it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition authorized for marketing in the EU, or if such a method exists, that the product will be of significant benefit to those affected by the condition. The applicable exclusivity period is ten years in the EU. The European exclusivity period can be reduced to six years, if, at the end of the fifth year a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

The FDA has granted orphan drug designation for ELX-02 for the treatment of cystic fibrosis, MPS I, Rett syndrome, and cystinosis. We may seek orphan drug designation for our other product candidates, and with respect to other indications. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a drug with an orphan drug designation subsequently receives the first FDA marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same indication for that time period. The applicable period is seven years in the U.S. Orphan drug exclusivity may be lost in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity, if the underlying NDA authorizing the sale of the drug is withdrawn, 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 drug candidate from competition because different drugs can be approved for the same condition. In addition, even after an orphan drug is approved, the applicable regulatory authority can subsequently approve the same or a similar drug from another sponsor 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. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of subjects. These trials and other trials we conduct may be subject to delays for a variety of reasons, including as a result of enrollment taking longer than anticipated, subject withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development. Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. The protocols for our clinical trials generally require that patients may not be enrolled in more than one clinical trial for the same indication, which will limit the pool of available subjects.

In addition to the rarity of some diseases, the eligibility criteria of our clinical studies will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure and that their disease is not too advanced. Specifically, some of the diseases that our product candidates are designed 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, potentially secure regulatory approval for, and if approved, successfully commercialize ELX-02.

We cannot guarantee that any of our programs will identify a sufficient number of patients to complete clinical development, pursue regulatory approval and market our product candidates, if approved. The combined number of patients in the U.S., Japan and Europe and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with ELX-02, or new patients may become increasingly difficult to identify, all of which would adversely affect our results of operations and our business. An inability to recruit and enroll a sufficient number of patients for any of our current or future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether, which could impact our ability to develop our product candidates and may have a material adverse effect on our business, results of operations and financial condition. Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

In addition, the ongoing COVID-19 pandemic has and may continue to adversely affect enrollment in our clinical trials. On March 25, 2020, we announced that enrollment in our clinical trials had been paused temporarily in response to the COVID-19 pandemic in order to avoid unnecessary exposure in at-risk populations, to maintain the integrity of our study data and to support global healthcare providers in their commitment to ensure patient safety. On June 17, 2020, enrollment in our Phase 2 clinical trial in cystic fibrosis had resumed in Israel and Europe and, on August 12, 2020 had resumed in the United States. COVID-19 is continuing to evolve and we continue to work closely with our clinical trial sites and investigators to ensure that patient enrollment will continue as quickly as is feasible in a safe environment for our patients. We also evaluated additional clinical sites in other countries where patient enrollment may be feasible , such as Australia and Canada. Additionally, significant additional costs as a result of this delay in enrollment or failure to complete enrollment in accordance with our objectives may have a material adverse impact on our financial condition and results of operations.

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, toxicologists and a small number of medical institutions and third-party contract research organizations to assist with our research efforts and conduct our preclinical and clinical trials and related activities. These collaborators, scientists, consultants and other third parties have provided, and we expect that they will continue to provide, valuable advice and services regarding our clinical development programs and product candidates. These collaborators, scientists, consultants and other third parties are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. We cannot control the amount or timing of resources that they devote to our preclinical and or clinical development programs and they may not assign as great a priority to our preclinical or clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. If outside collaborators fail to devote sufficient time and resources to our preclinical and clinical development programs, or if their performance is substandard, the authorization of INDs and clinical trial applications ("CTAs") and the approval of anticipated new drug applications ("NDAs") and other marketing applications, and our introduction of new drugs, if any, may be delayed or impeded, which could impair our clinical development programs and would have a material adverse effect on our business and results of operations. These collaborators may also have relationships with other commercial entities, some of whom may compete with us and we may be unable to prevent them from establishing competing businesses or developing competing products. The extent to which the COVID-19 pandemic and municipalities' efforts to combat it through temporary quarantines, containment zones and limitations on travel, as well as other restrictions, may create business disruptions within the organizations of our third-party researchers, scientists and consultants, as well as CROs, clinical trial sites and patient assistance groups, that result in the unavailability of personnel needed to successfully conduct and complete our clinical trials, may have a material adverse impact on our business and financial condition.

Interim, "topline" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all available data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine to be material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions or interpretations reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could negatively impact our business, operating results, prospects or financial condition.

The regulatory approval processes of the FDA and comparable regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of an NDA from the FDA. Similarly, in the EU, our product candidates can only be placed on the market after obtaining a marketing authorization.

Prior to obtaining approval to commercialize a product candidate in the United States, Europe or other jurisdictions, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or other regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA or other regulatory authority may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The FDA or any foreign regulatory authorities or bodies can delay, limit or deny approval of our drug product candidates or require us to conduct additional nonclinical or clinical testing or abandon a program for a variety of reasons, including the following:

- regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the applicable regulatory authority that a product candidate is safe or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by regulatory authorities for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be acceptable or sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States, the EU, or elsewhere, and we may be required to conduct additional clinical studies;
- the applicable foreign regulatory authority may disagree regarding the formulation, labeling and/or the specifications of our product candidates;
- applicable regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, including Phase 4 clinical trials, and/or the implementation of a REMS program, which may be required to assure safe use of the drug after approval. Regulatory authorities may also approve a product candidate for a more limited indication or patient population than we originally requested, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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.

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 pharmaceutical 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, for acquisitions and joint venture 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.

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 United States, a number of legislative and regulatory initiatives have focused on containing the cost of healthcare. The Patient Protection and Affordable Care Act, or PPACA, was enacted in March 2010. This law substantially changed the way healthcare is financed by both governmental and private insurers in the Unites States, 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, the Centers for Medicare and Medicaid Services issued final regulations to implement the changes to the Medicaid Drug Rebate Program under PPACA. 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. The issuance of regulations and coverage expansion by various governmental agencies relating to the Medicaid Drug Rebate Program will, upon commercialization of our drug product candidates, increase our costs and the complexity of compliance, will be time-consuming, and could have a material adverse effect on our results of operations.

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

Risks Related to Our Financial Position and Need for Additional Capital

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

We have a history of net losses and negative cash flows from operating activities since inception and, as of June 30, 2021, had an accumulated deficit of $216.3 million. We have financed our operations primarily through equity securities, and to a lesser extent from loans and grants. We have devoted substantially all of our financial resources and efforts to research and development. We expect that it will be several years, if ever, before we receive regulatory approval for commercialization of a product candidate. We expect to continue to incur significant expenses and 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 and/or other product candidates further into clinical development;
- continue to experience delays in enrollment and completion of our clinical trials due to the COVID-19 pandemic or otherwise;
- continue the preclinical development of our research programs and advance candidates into clinical trials;
- pursue regulatory authorization to conduct clinical trials of additional product candidates;
- seek marketing approvals for our product candidates;
- 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;
- 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 the company could also cause investors to lose all or part of their 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 sales, marketing, manufacturing and distribution of the approved product. Further, we expect to incur additional costs related to our acquisition of Zikani. Our future capital requirements will depend on many factors, including:

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

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

Accordingly, despite our prior public equity offerings and debt financing, 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. If we are unable to obtain adequate financing, we will evaluate options, which may include reducing or deferring operating expenses, including by downsizing our workforce and curtailing certain development programs, which could have a material adverse effect on our operations and financial results.

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, such as our public offering of shares in May 2021, or convertible debt securities, an investor's ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that may adversely affect an investor's 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.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors.

Risks Related to Our Business and Operations

Our stockholders may not realize a benefit from our acquisition of Zikani (the "Merger") commensurate with the ownership dilution they will experience in connection with the Merger.

If we are unable to realize the strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interest without receiving any commensurate benefit. Significant management attention and resources will be required to integrate the two companies and we may not manage these processes successfully. We are making substantial investments of resources to support this acquisition, which will result in significant ongoing operating expenses and may divert resources and management attention from other areas of our business. Delays in this process could adversely affect the combined company's business, financial results, financial condition and stock price. Even if we are able to integrate the business operations successfully, there can be no assurance that this integration will result in the realization of the full benefits of synergies, innovation and operational efficiencies that may be possible from this integration and that these benefits will be achieved within a reasonable period of time. It is also possible that undisclosed, contingent or other liabilities or problems in connection with the acquired company may arise in the future of which we were previously unaware. These undisclosed liabilities could have an adverse effect on our business, financial condition and prospects.

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

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

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

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

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

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

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

We could be subject to additional tax liabilities.

We are subject to federal, state and local taxes in the Unites 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.

Our business could be adversely affected by the effects of widespread public health epidemics and other factors beyond our control.

Public health epidemics or widespread outbreaks of contagious diseases could adversely impact our business. Any outbreak of contagious diseases, and other adverse public health developments, such as the recent novel strain of COVID-19, could impact our operations depending on future developments, which are highly uncertain, largely beyond our control and cannot be predicted with certainty. These uncertain factors include the duration of the outbreak, new information which may emerge concerning the severity of the disease and the actions to contain or treat its impact, could adversely impact our operations, including among others, conduct of our clinical trials, employee mobility and productiveness, temporary closure of facilities, including clinical trial sites, our manufacturing capabilities, and third party service providers such as CROs, any of which could have an adverse impact on our business and our financial results. The COVID-19 pandemic has also adversely affected the conduct of our clinical trials. For example, on March 25, 2020, we announced that enrollment in our clinical trials had been paused temporarily in response to the COVID-19 pandemic in order to avoid unnecessary exposure in at-risk populations, to maintain the integrity of our study data and to support global healthcare providers in their commitment to ensure patient safety. On June 17, 2020, we announced that enrollment in our Phase 2 clinical trial in cystic fibrosis had resumed in Israel and Europe, and on August 12, 2020, had resumed in the Unites States. As the COVID-19 pandemic continues in the United States and elsewhere, we may experience additional disruptions that could severely impact our business, preclinical studies and clinical trials.

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

We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the U.S., we may be subject to state security breach notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure and transmission of personal information.

Each of these laws is subject to varying interpretations by courts and government agencies, creating complex compliance issues for us. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA.

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

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

We are increasingly dependent on our information technology systems and infrastructure for our business. We collect, store, and transmit sensitive information including intellectual property, proprietary business information and personal information in connection with business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, “hacktivists,” patient groups, disgruntled current or former employees, and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance. We have also implemented information security measures to protect patients’ personal information against the risk of inappropriate and unauthorized external use and disclosure. The COVID-19 pandemic has caused us to modify our business practices, including permitting our employees to work from home. As a result, we are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data, which includes use of cloud technologies. This increased remote usage of information systems increases the risks that our business may be disrupted due to a variety of reasons, including security breaches, power outages, unavailability of employees, use of non-company secured equipment and increased phishing and hack activity. However, despite these measures, and due to the ever-changing information cyber-threat landscape, we may be subject to data breaches through cyber-attacks. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion. Like other companies in our industry, we have experienced attacks to our data and systems, including malware and computer viruses. If our systems failed or were breached or disrupted, patient and other data and information may become compromised, we could lose sales for approved products, if any, and suffer reputational damage and loss of confidence by patients, investors and business partners. Such incidents would result in notification obligations to affected individuals and government agencies, legal claims or proceedings, and liability under federal and state laws that protect the privacy and security of personal information. Any one of these events, or similar events occurring through one of our vendors that maintain such information on our behalf, could cause our business to be materially harmed and our results of operations to be adversely impacted.

We currently rely, and plan to rely on in the future, third parties to conduct and support our preclinical studies and clinical trials. If these third parties do not properly and successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We have utilized and plan to continue to utilize and depend upon independent investigators and collaborators, such as medical institutions, CROs, CMOs, consultants and strategic partners to conduct and support our preclinical studies and clinical trials. As a result, we will have less direct control over the conduct, timing and completion of these preclinical studies and clinical trials and the management of data developed. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with pharmaceutical product produced under cGMP regulations. Our failure or any failure by these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

We contract with third parties for the manufacture of our product candidates for preclinical studies and our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development, or if approved, eventual commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials. We do not have long-term supply agreements with these manufacturers. Furthermore, the raw materials for our product candidates are sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials. For example, the extent to which the COVID-19 pandemic impacts our ability to procure sufficient supplies for the development of our products and product candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of agreements at a time that is costly or inconvenient for us;
- the failure to comply with contractual obligations;
- the failure to comply with applicable regulatory requirements;
- the failure to manufacture our product candidates according to our specifications;
- clinical supplies not being delivered to clinical sites on time;
- disruptions to the operations of our third-party manufacturers or suppliers, testing facilities, or research sites caused by conditions unrelated to our business or operations, including unrelated regulatory action against or the bankruptcy of the manufacturer or supplier, testing facility, or research site, or the unavailability of essential personnel to conduct or complete our research or clinical trials, such as, for example, a result of the COVID-19 pandemic; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

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

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

The success of our business is dependent in large part on our continued ability to attract and retain our senior management, and other highly qualified personnel in our scientific, clinical, manufacturing and commercial organizations. Intense competition exists in the biopharmaceutical industry for these types of personnel. Our business is specialized and global and we must attract and retain highly qualified individuals across many geographies. We may not be able to continue to attract and retain the highly qualified personnel necessary for developing, manufacturing and commercializing our product candidates. If we are unsuccessful in our recruitment and retention efforts, or if our recruitment efforts take longer than anticipated, our business may be harmed. We may face difficulty in attracting and retaining key talent for a number of reasons, including management changes, the underperformance or discontinuation of one or more late-stage programs, recruitment by competitors or delays in the recruiting and hiring process as a result of the COVID-19 pandemic. We cannot ensure that we will be able to hire or retain the personnel necessary for our operations or that the loss of any such personnel will not have a material impact on our financial condition and results of operations.

We are highly dependent on principal members of our senior management. 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. 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.

We have experienced recent changes in management and other key personnel in critical functions across our organization, including in connection with the Merger. Changes in management and other key personnel have the potential to disrupt our business, and any such disruption could adversely affect our operations, programs, growth, financial condition or results of operations. In addition, new members of management may have different perspectives on programs and opportunities for our business, which may cause us to focus on new business opportunities or reduce or change emphasis on our existing business programs. Further, if members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to COVID-19, we may not be able to execute on our business strategy and/or our operations may be negatively impacted.

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 June 30, 2021, we owned or licensed 41 issued patents and 72 pending patent applications in the U.S. and abroad, not including U.S. provisional applications. However, with regard to the pending provisional applications, the filing of a patent application does not mean that we will be issued a patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a currently pending patent application may delay the approval of such patent application which could have a material adverse effect on our business, results of operations and financial condition. In addition, there are a number of factors that could cause our current or future issued patents to become invalid or unenforceable or that could cause our pending patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or lack of originality of the technology. Our competitive position and future revenue will depend in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our product candidates, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. However, we cannot predict:

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

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

Furthermore, the lives of our patents are limited. With regard to our lead compound ELX-02, patents that have issued or that may issue in the future from our primary composition of matter patent family are currently set to expire in 2031. We have pending patent families directed to specific methods of manufacturing ELX-02 and using ELX-02 to treat various ocular conditions, and any patents that may issue from these families would be expected to expire in 2038 and 2039, respectively. However, these applications may not issue, and even if they do issue the resultant patents may not provide adequate coverage to meaningfully block competitors from launching their products. We will likely pursue additional patent protection relating to ELX-02 in the future, including for example additional methods of use or manufacture, specific formulations, or combinations of ELX-02 with other therapeutic agents. However, as with our pending patent families, any applications we file in the future may not issue or may not result in adequate coverage to adequately protect our assets.

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

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

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

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

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

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

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

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

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement, which could significantly impede development and impair or block our ability to secure regulatory approval of any redesigned product or process;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our product candidates;
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

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

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

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

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

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

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

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

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

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful and have an adverse effect on the success of our business.

Competitors or other third parties may infringe, misappropriate or otherwise violate our patents or other intellectual property. If we or one of our licensors were to initiate legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States and in Europe, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness, lack of written description, or non-enablement. Third parties might allege unenforceability of our patents because during prosecution of the patent an individual connected with such prosecution withheld relevant information or made a misleading statement. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. The outcome of proceedings involving assertions of invalidity and unenforceability during patent litigation is unpredictable. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products and product candidates, which may allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or could require us to obtain license rights from the prevailing party in order to be able to manufacture or commercialize our products, product candidates or technologies without infringing third-party patent rights. Even if a defendant does not prevail on a legal assertion of invalidity or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others. Moreover, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize our product candidates. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon, misappropriating or otherwise violating our intellectual property rights. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. Our patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

We may be subject to third-party claims including infringement, interference or derivation proceedings, post-grant review and inter partes review before the USPTO or similar adversarial proceedings or litigation in other jurisdictions. Even if we believe such claims are without merit, a court could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize the applicable product or product candidates unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products, product candidates or technologies may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court to cover aspects of our products, product candidates or technologies, the holders of any such patents may be able to prohibit our commercialization of the applicable product or product candidate until such patent expires or is finally determined to be invalid or unenforceable or unless we obtained a license.

In addition, defending such claims would cause us to incur substantial expenses and, if successful, could cause us to pay substantial damages if we are found to be infringing a third party's patent rights. These damages potentially include royalties, increased damages (possibly treble damages) and attorneys' fees if we are found to have infringed such rights willfully. Further, if a patent infringement suit is brought against us, our development, manufacturing or sales activities relating to the product, product candidate or technology that is the subject of the suit may be delayed or terminated, as parties making claims against us may obtain injunctive or other equitable relief. As a result of patent infringement claims, or in order to avoid potential infringement claims, we may choose to seek, or be required to seek, a license from the third party, which may require payment of substantial royalties or fees, or require us to grant a cross-license under our intellectual property rights. These licenses may not be available on reasonable terms or at all. If we are unable to enter into a license on acceptable terms, we could be prevented from commercializing one or more of our products or product candidates, or forced to modify such products or product candidates, or to cease some aspect of our business operations, which could harm our business significantly. We might also be forced to redesign or modify our products, product candidates or technologies so that we no longer infringe the third-party intellectual property rights, which may result in significant cost or delay to us, or which redesign or modification could be impossible or technically infeasible.

Even if we were ultimately to prevail, any of these events could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, or prohibit us from manufacturing, importing, marketing or otherwise commercializing our products or product candidates. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have an adverse effect on our ability to compete in the marketplace and could have an adverse impact on our business and financial condition.

Risks Related to Our Regional Operations

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

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

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

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

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

Our research and development efforts were initially financed, in part, through royalty-bearing grants from the Israel Innovation Authority, or IIA. We received an aggregate of $2.6 million from the IIA for the development of our technologies. With respect to such grants we are required to pay certain royalties (including accrued 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.

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

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

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

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

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

General Risk Factors

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

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 (including the Merger), changes in financial or operational estimates or projections and the perceptions of our investors that we are not performing or meeting expectations. The market price of our common stock may decline as a result of the Merger for a number of reasons, including, our failure to achieve the perceived benefits of the Merger as rapidly or to the extent anticipated by financial or industry analysts, or investors react negatively to the Merger and its impact on our business and prospects. 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.

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.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002(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 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.

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

As of December 31, 2020, we had U.S. federal and state net operating loss carryforwards, or "NOL," of $108.9 million and $13.7 million, respectively, and federal research tax credit carryforwards of $3.6 million. Certain U.S. NOLs will begin to expire, beginning in 2021 through 2037, and research tax credits will expire beginning in 2026 through 2040. Included in these U.S. federal NOLs are $34.9 million of NOLs generated after January 1, 2018, which are not subject to expiration. Federal NOLs generated in 2018 and future years may be carried forward indefinitely but may not be carried back and are only eligible to offset up to a maximum of 80% of taxable income generated in a given year. It is uncertain if and to what extent various U.S. states will conform their NOL rules to the federal rules.

In general, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended, (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. 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 a material adverse effect on our consolidated financial statements. As of December 31, 2020, we had Israeli NOLs of $86.9 million, which carry forward indefinitely.

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, such as our public offering of shares in May 2021, 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 our 2018 Equity Incentive Plan, our management is authorized to grant stock options and other equity-based awards to our employees, directors and consultants. As of June 30, 2021, individuals held share awards to purchase or receive an aggregate of 8,614,506 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 6. Exhibits

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

		Incorporated by Reference			
Exhibit Number	Exhibit Description	Form	File No.	Exhibit	Filing Date
2.1†	Agreement and Plan of Merger, dated April 1, 2021, by and among Eloxx Pharmaceuticals, Inc., Delta Merger Sub Acquisition Corporation and Zikani Therapeutics, Inc.	8-K	001-31326	2.1	April 1, 2021
3.1	Amended and Restated Certificate of Incorporation of Senesco Technologies, Inc. filed with the State of Delaware on January 22, 2007	10-Q	001-31326	3.1	February 14, 2007
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Senesco Technologies, Inc. filed with the State of Delaware on December 13, 2007	10-Q	001-31326	3.1	February 14, 2008
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Senesco Technologies, Inc. filed with the State of Delaware on September 22, 2009	10-K	001-31326	3.3	September 28, 2009
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Senesco Technologies, Inc. filed with the State of Delaware on May 25, 2010	8-K	001-31326	3.1	May 28, 2010
3.5	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Senesco Technologies, Inc. filed with the State of Delaware on December 22, 2011	10-Q	001-31326	3.1	February 14, 2011
3.6	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Senesco Technologies, Inc. filed with the State of Delaware on April 1, 2013	10-Q	001-31326	3.1	May 15, 2013
3.7	Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on October 16, 2013	8-K	001-31326	3.1	October 21, 2013
3.8	Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on September 29, 2014	8-K	001-31326	3.1	October 3, 2014
3.9	Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on December 19, 2017	8-K	001-31326	3.1	December 22, 2017
3.10	Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, as filed with the Secretary of State of the State of Delaware on December 19, 2017	8-K	001-31326	3.2	December 22, 2017

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
3.11	Certificate of Designations to the Company's Certificate of Incorporation. (Series A)	8-K	001-31326	3.1	March 29, 2010
3.12	Certificate of Designations to the Company's Certificate of Incorporation. (0% Series C Convertible Preferred Stock)	8-K	001-31326	3.1	May 6, 2015
3.13	Amended and Restated Bylaws of Eloxx Pharmaceuticals, Inc.	8-K	001-31326	3.2	December 27, 2017
10.1	Employment Agreement, dated as of April 1, 2021, by and between Sumit Aggarwal and Eloxx Pharmaceuticals, Inc.	8-K	001-31326	10.1	April 1, 2021
10.2	Employment Agreement, dated as of April 1, 2021, by and between Vijay Modur and Eloxx Pharmaceuticals, Inc.	8-K	001-31326	10.2	April 1, 2021
10.3	Separation Agreement and General Release, dated as of April 1, 2021, by and between Gregory C. Williams and Eloxx Pharmaceuticals, Inc.	8-K	001-31326	10.3	April 1, 2021
10.4	Agreement and General Release, dated as of July 2, 2021, by and between Neil S. Belloff and Eloxx Pharmaceuticals, Inc.	8-K	001-31326	10.1	July 6, 2021
31.1*	Certification of the Company's Principal 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 Principal 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 Principal 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 Principal 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*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.				

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

† Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. Eloxx hereby agrees to furnish supplementally a copy of any of the omitted schedules upon request by the U.S. Securities and Exchange Commission.

* 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: August 16, 2021

by: /s/ Daniel E. Geffken

Daniel E. Geffken

Interim Chief Financial Officer

(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Sumit Aggarwal, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 16, 2021

/s/ Sumit Aggarwal

Sumit Aggarwal
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Daniel E. Geffken, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 16, 2021

/s/ Daniel E Geffken
Daniel E Geffken
Interim Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION[1]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted by §906 of the Sarbanes-Oxley Act of 2002, I, Sumit Aggarwal, Chief Executive Officer of Eloxx Pharmaceuticals, Inc. (the “Company”), hereby certify that, to the best of my knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 (the “Quarterly Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 16th day of August, 2021.

/s/ Sumit Aggarwal
Sumit Aggarwal
Chief Executive Officer
(Principal Executive Officer)

(1) This certification accompanies the Quarterly Report to which it relates, is not deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act and is not to be incorporated by reference into any filing of Eloxx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION[1]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted by §906 of the Sarbanes-Oxley Act of 2002, I, Daniel E. Geffken Interim Chief Financial Officer of Eloxx Pharmaceuticals, Inc. (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2021 (the "Quarterly Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

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

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 16th day of August, 2021.

/s/ Daniel E. Geffken
Daniel E. Geffken
Interim Chief Financial Officer
(Principal Financial Officer)

(1) This certification accompanies the Quarterly Report to which it relates, is not deemed filed with the Securities and Exchange Commission for purposes of Section 18 of the Exchange Act and is not to be incorporated by reference into any filing of Eloxx Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing.