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DELTA REPORT

10-Q

ELDN - ELEDON PHARMACEUTICALS, I

10-Q - SEPTEMBER 30, 2023 COMPARED TO 10-Q - JUNE 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	350
CHANGES	125
DELETIONS	108
ADDITIONS	117

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June September 30, 2023

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: 001-36620

ELEDON PHARMACEUTICALS, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**20-1000967**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
19900 MacArthur Blvd., Suite 550 Irvine, California	**92612**
(Address of principal executive offices)	**(Zip Code)**

(949) 238-8090

Registrant's telephone number, including area code

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

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Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ELDN	Nasdaq Capital 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, a 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

As of August 8, 2023 November 7, 2023 there were 23,545,130 24,198,130 shares of the Registrant's common stock outstanding.

Special Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. Any statements other than

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statements of historical or current fact in this Quarterly Report on Form 10-Q are forward looking statements. In some instances, you can identify forward-looking statements by the use of words such as "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," and similar expressions, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding:

- our product development plans, expectations for and the timing of commencement, enrollment, completion, data, and release of results of clinical trials for our product candidates;
- our estimates regarding expenses, capital requirements and needs for additional financing;
- our strategies with respect to our preclinical and clinical development programs;
- our plans, strategy and timing to obtain and maintain regulatory approvals of our product candidates;
- our review of strategic alternatives and the outcome of such review; and
- expectations about our future financial performance or condition.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including the factors listed under "Risk Factor Summary" below. These risks and uncertainties, as well as other risks and uncertainties that could cause the Company's actual results to differ significantly from the forward-looking statements contained herein, are described in greater detail in Part II, Item 1A. *Risk Factors* in this Quarterly Report on Form 10-Q.

Any forward-looking statements contained in this Quarterly Report on Form 10-Q speak only as of the date hereof and not as of any future date, and the Company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

The market data and certain other statistical information used in this Quarterly Report are based on independent industry publications, governmental publications, reports by market research firms or other independent sources. Some data are also based on our good faith estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information.

RISK FACTOR SUMMARY

The following summarizes the principal factors that make an investment in the Company speculative or risky, all of which are more fully described in Part II, Item 1A, *Risk Factors* in this Quarterly Report on Form 10-Q. This summary should be read in conjunction with the Risk Factors section and should not be relied upon as an exhaustive summary of the material risks facing our business. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-

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looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

- Our short operating history and the acquisition of Anelixis Therapeutics, Inc. in September 2020 may make it difficult to evaluate the success of our business to date and to assess our future viability.
- Our financial condition raises substantial doubt as to our ability to continue as a going concern. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.
- We have incurred significant operating losses since our inception and expect that we will continue to incur losses ove the next several years and may never achieve or maintain profitability.
- We will require additional funding to be able to complete the development of our lead drug candidate. If we are unab to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.
- Issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities as well as shares and warrants issued in connection with our recent Private Placement, could result in significant dilution and could cause our stock price to fall.
- Our product candidates are in the early stages of clinical development and may not be successfully developed. If we are unable to successfully develop and commercialize these or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed.
- Unfavorable global economic conditions could have a material adverse effect on our business.
- Adverse conditions in the financial markets, including bank failures, could adversely affect our liquidity and financial performance.
- Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the U.S. Food and Drug Administration (FDA) or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, c ultimately be unable to complete, the development, formulation and commercialization of our product candidates.
- The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the result of later-stage clinical trials, and there is a risk that additional nonclinical and/or clinical safety studies will be required the FDA or similar regulatory authorities outside the United States or that subsequent studies will not match results seen in prior studies.
- Delays or difficulties in the enrollment of patients in clinical trials could delay or prevent our receipt of necessary regulatory approvals and increase expenses for the development of our product candidates.
- If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.
- Our future success depends on our ability to retain executives and key employees and to attract, retain and motivat qualified personnel in the future.
- If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may b for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.
- Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

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- Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitiv information related to our business and have a material adverse effect on our reputation, business, financial conditi or results of operations.
- Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commerci success.
- If our current product candidates, or a future product candidate receives marketing approval and we, or others, late discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, the ability to market the product could be compromised.
- We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.
- Our reliance on third parties for the manufacture of our product candidates for nonclinical and clinical trials, and for eventual commercialization, increases the risk that we will not have sufficient quantities of our product candidates o products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.
- We depend on contract research organizations ("CROs") and other contracted third parties to perform nonclinical an clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.
- If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.
- The COVID-19 pandemic has adversely affected and it or other public health crises, including any future pandemics o epidemics, could in the future adversely affect our business operations, which could have a material adverse effect o our business.
- Our stock price could be volatile, and the market price of our common stock may drop unexpectedly.
- If we fail to establish and maintain proper and effective internal control over financial reporting, our operating result and our ability to operate our business could be harmed.
- Provisions in our corporate charter and under Delaware law could make an acquisition of the Company more difficul and may prevent attempts by our stockholders to replace or remove our current management.

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ELEDON PHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE SEPTEMBER 30, 2023

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
ASSETS				
Current assets:				
Cash and cash equivalents	$ 40,947	$ 56,409	$ 3,667	$ 56,409
Short-term investments	30,431	—	55,942	—
Prepaid expenses and other current assets	2,244	3,109	3,382	3,109
Total current assets	73,622	59,518	62,991	59,518
Operating lease asset, net	553	739	459	739
In-process research and development	32,386	32,386	32,386	32,386
Other assets	224	150	233	150

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Total assets	106,78 $ 5	$ 92,793	$ 96,069	$ 92,793
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$ 2,197	$ 2,200	$ 465	$ 2,200
Current operating lease liabilities	390	363	396	363
Accrued expenses and other liabilities	2,313	3,912	2,038	3,912
Total current liabilities	4,900	6,475	2,899	6,475
Deferred tax liabilities	1,752	1,752	1,752	1,752
Non-current operating lease liabilities	184	383	83	383
Total liabilities	6,836	8,610	4,734	8,610
Commitments and contingencies (Note 8)				
Stockholders' equity:				
Preferred stock, $0.001 par value, 5,000,000 shares authorized at June 30, 2023 and December 31, 2022:				
Series X_1 non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 and 117,970 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—		
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 and 6,204 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	—	—		
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 23,043,933 and 13,776,788 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	23	14		

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Preferred stock, $0.001 par value, 5,000,000 shares authorized at September 30, 2023 and December 31, 2022:				
Series X_1 non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 and 117,970 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively			—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 and 6,204 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively			—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 23,545,130 and 13,776,788 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively			24	14
Additional paid-in capital	323,142	287,034	324,876	287,034
Accumulated deficit	(223,216)	(202,865)	(233,565)	(202,865)
Total stockholders' equity	99,949	84,183	91,335	84,183
Total liabilities and stockholders' equity	$ 106,785	$ 92,793	$ 96,069	$ 92,793

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

(Unaudited)

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	For the Three Months Ended June 30,		For the Six Months Ended June 30,		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
Operating expenses								
Research and development	$ 7,201	$ 5,743	$ 15,314	$ 12,378	$ 7,931	$ 7,452	$ 23,245	$ 19,830
General and administrative	3,153	3,540	6,150	6,764	3,267	3,146	9,417	9,910
Total operating expenses	10,354	9,283	21,464	19,142	11,198	10,598	32,662	29,740
Loss from operations	(10,354)	(9,283)	(21,464)	(19,142)	(11,198)	(10,598)	(32,662)	(29,740)
Other income, net	775	36	1,113	31	849	127	1,962	158
Net loss and comprehensive loss	$ (9,579)	$ (9,247)	$ (20,351)	$ (19,111)	$ (10,349)	$ (10,471)	$ (30,700)	$ (29,582)
Net loss per share, basic and diluted	$ (0.40)	$ (0.65)	$ (1.06)	$ (1.34)	$ (0.35)	$ (0.73)	$ (1.35)	$ (2.07)
Weighted-average common shares outstanding, basic and diluted	24,006,549	14,265,905	19,173,080	14,299,969	29,974,400	14,265,905	22,813,085	14,289,929

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

(Unaudited)

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	Series X1 Non-Voting Convertible Preferred Stock		Series X Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2022	117,970	$ —	6,204	$ —	13,776,788	$ 14	$ 287,034	$ (202,865)	$ 84,183
Stock-based compensation	—	—	—	—	—	—	1,381	—	1,381
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(10,772)	(10,772)
Balance as of March 31, 2023	117,970	—	6,204	—	13,776,788	14	288,415	(213,637)	74,792

	Series X1 Non-Voting Convertible Preferred Stock		Series X Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2022	117,970	$ —	6,204	$ —	13,776,788	$ 14	$ 287,034	$ (202,865)	$ 84,183
Stock-based compensation	—	—	—	—	—	—	1,381	—	1,381
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(10,772)	(10,772)
Balance as of March 31, 2023	117,970	—	6,204	—	13,776,788	14	288,415	(213,637)	74,792

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Issuance of common stock and pre-funded warrants in connection with Securities Purchase Agreement, net of issuance costs	—	—	—	—	8,730,160	9	33,008	—	33,017	—	—	—	—	8,730,160	9	33,008	—	33,017
Issuance of common stock in connection with conversion of X non-voting convertible preferred stock	—	—	(1,782)	—	99,000	—	—	—	—	—	—	(1,782)	—	99,000	—	—	—	—

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Issuance of common stock in connection with conversion of X1 non-voting convertible preferred stock	(7,884)	—	—	—	437,977	—	(1)	—	(1)	(7,884)	—	—	—	437,977	—	(1)	—	(1)
Stock-based compensation	—	—	—	—	—	—	1,720	—	1,720	—	—	—	—	—	—	1,720	—	1,720
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(9,579)	(9,579)	—	—	—	—	—	—	—	(9,579)	(9,579)
Balance as of June 30, 2023	110,086	$ —	4,422	$ —	23,043,933	$ 23	$ 323,142	$ (223,216)	$ 99,949	110,086	—	4,422	—	23,043,933	23	323,142	(223,216)	99,949
Issuance of common stock in connection with exercise of pre-funded warrants										—	—	—	—	501,197	1	—	—	1

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Stock-based compensation	—	—	—	—	—	—	1,73 4	—	1,73 4
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(10,34 9)	(10,34 9)
Balance as of September 30, 2023	11,08 6	$ —	4,42 2	$ —	23,45 ,1 30	$ 24	32,4,87 $ 6	(2 33,5 $ 65)	91 ,3 $ 35

	Series X1 Non-Voting Convertible Preferred Stock		Series X Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity	Series X1 Non-Voting Convertible Preferred Stock		Series X Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount				Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2021	10,08 0	$ —	6,20 4	$ —	14,306 ,788	$ 14	$ 0	$ (1,998)	$ 16,305	10,08 0	$ —	6,20 4	$ —	14,306 ,788	$ 14	$ 0	$ (1,998)	$ 16,305

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Cancellation of common stock in connection with exchange for X1 non-voting convertible preferred stock	9,900	—	—	—	(550,000)	—	1	—	1	9,900	—	—	—	(550,000)	—	1	—	1
Stock-based compensation	—	—	—	—	—	—	2,186	—	2,186	—	—	—	—	—	—	2,186	—	2,186
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(9,864)	(9,864)	—	—	—	—	—	—	—	(9,864)	(9,864)
Balance as of March 31, 2022	117,970	—	6,204	—	13,756,888	14	28,107	(124,763)	15,631,978	117,970	—	6,204	—	13,756,888	14	28,107	(124,763)	15,631,978
Stock-based compensation	-	—	—	—	—	—	2,308	—	2,308	-	—	—	—	—	—	2,308	—	2,308
Net loss and other comprehensive loss	-	—	—	—	—	—	—	(9,247)	(9,247)	-	—	—	—	—	—	—	(9,247)	(9,247)

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Balance as of June 30, 2022	117,976,020	$ —	4	$ —	13,756,888	$ 14	28,375	$ (10)	$ 14,937	117,976,020	$ —	4	$ —	13,756,888	$ 14	28,375	$ (10)	$ 14,937
Stock-based compensation	-	—	—	—	—	—	2,185	—	2,185	-	—	—	—	—	—	2,185	—	2,185
Net loss and other comprehensive loss	-	—	—	—	—	—	—	(10,047)	(10,047)	-	—	—	—	—	—	—	(10,047)	(10,047)
Balance as of September 30, 2022	117,976,020	$ —	4	$ —	13,756,888	$ 14	28,560	$ (10,481)	$ 14,093	117,976,020	$ —	4	$ —	13,756,888	$ 14	28,560	$ (10,481)	$ 14,093

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	For the Six Months Ended June 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Cash flows used in operating activities:				
Net loss	$ (20,351)	$ (19,111)	$ (30,700)	$ (29,582)
Adjustments to reconcile net loss to net cash used in operating activities:				

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Amortization of operating lease asset	186	187	280	280
Accretion on investment discounts	(97)	—	(579)	—
Stock-based compensation	3,101	4,494	4,835	6,679
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	791	1,282	(356)	2,082
Accounts payable, accrued expenses and other liabilities	(1,603)	(1,042)	(3,609)	1,871
Operating lease liabilities	(172)	(183)	(267)	(274)
Net cash used in operating activities	(18,145)	(14,373)	(30,396)	(18,944)
Cash flows from investing activities:				
Purchase of available-for-sale short-term investments	(30,334)	—	(60,363)	—
Proceeds from maturities of available-for-sale short-term investments			5,000	—
Net cash used in investing activities	(30,334)	—	(55,363)	—
Cash flows from financing activities:				
Proceeds from issuances of common stock and pre-funded warrants, net	33,017	—	33,017	—
Net cash provided by financing activities	33,017	—	33,017	—
Net change in cash and cash equivalents	(15,462)	(14,373)	(52,742)	(18,944)
Cash and cash equivalents at beginning of period	56,409	84,833	56,409	84,833
Cash and cash equivalents at end of period	$ 40,947	$ 70,460	$ 3,667	$ 65,889
Supplemental disclosure of non-cash investing and financing activities				
Non-cash activities:				
Common stock exchanged for X and X_1 non-voting convertible preferred stock	$ 1	$ 1	$ 1	$ 1
Increase in operating lease asset and liability due to lease modification			$ —	$ 344

See accompanying notes to unaudited condensed consolidated financial statements.

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ELEDON PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Description of Business

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company using its immunology expertise in targeting the CD40 Ligand ("CD40L", also called "CD154") pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat amyotrophic lateral sclerosis ("ALS"). The Company's lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for the CD40 Ligand, a well-validated biological target that we believe has broad therapeutic potential. Unless otherwise indicated, references to the terms "Eledon," "our," "us," "we," or the "Company" refer to Eledon Pharmaceuticals, Inc. and its wholly owned subsidiaries, on a consolidated basis.

On September 14, 2020, Eledon acquired Anelixis Therapeutics, Inc. ("Anelixis"), a privately held clinical stage biotechnology company developing a next generation anti-CD40L antibody as a potential treatment for organ and cellular transplantation, autoimmune diseases, and neurodegenerative diseases. The Company maintains its corporate headquarters in Irvine, California and has research and development facilities in Burlington, Massachusetts.

Note 2. Going Concern and Management's Plans

The accompanying condensed consolidated financial statements have been prepared under the assumption the Company will continue to operate as a going concern, which contemplates the realization of assets and the settlement of liabilities in the normal course of business. The condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

The Company had a net loss of $20.4 30.7 million for the six nine months ended June 30, 2023 September 30, 2023 and an accumulated deficit of $223.2 233.6 million as of June 30, 2023 September 30, 2023, as a result of incurring losses since its inception. The Company expects to continue to incur net losses into the foreseeable future in connection with its ongoing activities, particularly as the Company expands its clinical program with tegoprubart, continues the research and development of, and seeks marketing approval for, its product candidates. In addition, if the Company obtains marketing approval for any of its product candidates, the Company expects to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. The Company has financed operations primarily by net proceeds from the sale of preferred and common stock and warrants.

On April 28, 2023, the Company entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional and accredited investors (the "Purchasers"), pursuant to which the Company agreed to issue and sell to the Purchasers in a private placement (the "Private Placement") shares of common stock and warrants in a series of three potential closings. On May 5, 2023, the initial closing occurred and the Company received $35.0 million, in exchange for 8,730,168 shares of common stock, pre-funded warrants to purchase 6,421,350 shares of common stock and additional

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common stock warrants to purchase 15,151,518 shares of common stock (or pre-funded warrants in lieu thereof). The Company may receive up to an additional $105.0 million in tranche financing in a second and a third closing, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $45.5 million assuming the exercise of all common stock warrants issued in the initial closing of the Private Placement. See Note 9. "Stockholders' Equity" for further information regarding the Private Placement. Due to the contingent nature of the exercise of the common stock warrants and the second and third closings of the Private Placement, accounting principles generally accepted in the United States of America ("GAAP") requires the Company to exclude them from its going concern analysis. If these events do not occur or the Company is unable to secure additional capital or is unable to do so on acceptable terms, it will be forced to significantly alter its business strategy, substantially curtail its current operations, or liquidate and cease operations altogether.

As of June 30, 2023 September 30, 2023, the Company had cash and cash equivalents and short-term investments of approximately $71.4 59.6 million. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future, the Company will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to, such resources is not assured. Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern.

Note 3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP and Article 8 of Regulation S-X requirements as set forth by the Securities and Exchange Commission ("SEC") for interim financial information and reflect all adjustments and disclosures, which are, in the opinion of management, of a normal and recurring nature, and considered necessary for a fair presentation of the financial information contained herein. Pursuant to these rules and regulations, the unaudited condensed consolidated financial statements do not include all information and notes necessary for a complete presentation of results of operations and comprehensive loss, financial position, and cash flows in conformity with GAAP.

The accompanying unaudited condensed consolidated financial statements and notes should be read in conjunction with the audited financial statements and accompanying notes of Eledon for the year ended December 31, 2022 included in the Annual Report on Form 10-K filed by the Company with the SEC on March 30, 2023. The results of operations and comprehensive loss for the three and six nine months ended June 30, 2023 September 30, 2023 are not necessarily indicative of results expected for the full fiscal year or any other future period.

Principles of Consolidation

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Eledon, a Delaware corporation, owns 100% of the issued and outstanding common stock or other ownership interest in Anelixis Therapeutics, LLC, a Delaware limited liability company, and Otic Pharma, Ltd., a private limited company organized under the laws of the State of Israel ("Otic"). Otic owns 100% of the issued and outstanding common stock or other ownership interest in its U.S. subsidiary, Otic Pharma, Inc.

The functional currency of the Company's foreign subsidiary is the U.S. Dollar; however, certain expenses, assets and liabilities are transacted at the local currency. These transactions are translated from the local currency into U.S. Dollars at exchange rates during or at the end of the reporting period. The activities of the Company's foreign subsidiary are not significant to the condensed consolidated financial statements.

All significant intercompany accounts and transactions among the entities have been eliminated from the condensed consolidated financial statements.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to stock-based compensation, accruals for liabilities, impairment of long-lived assets, and other matters that affect the consolidated financial statements and related disclosures. Actual results could differ materially from those estimates under different assumptions or conditions and the differences may be material to the consolidated financial statements.

Concentration of Credit Risk

Financial instruments which potentially subject the Company to significant concentration of credit risk consists of cash, cash equivalents and short-term investments. The Company maintains deposits in federally insured institutions in excess of federally insured limits and invests in short-term investments with the primary objective of seeking to preserve principal, achieve liquidity requirements and safeguard invested funds. We believe that the Company is not exposed to significant credit risk due to the financial position of the depository institution in which those deposits are held and the nature, including the credit ratings, of our cash equivalents and short-term investments, but we have not eliminated all credit risk.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less when purchased to be cash equivalents. Cash and cash equivalents include cash in readily available checking accounts, money market funds, U.S. government securities and U.S. government agency securities. The carrying amounts reported in the unaudited

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condensed consolidated balance sheets for cash and cash equivalents are valued at cost, which approximates their fair value due to the short-term maturities of these investments.

Risks and Uncertainties

As of June 30, 2023 September 30, 2023 and December 31, 2022, all of the Company's long-lived assets were located in the United States.

The Company's products will require approval from the U.S. Food and Drug Administration ("FDA") and foreign regulatory agencies before commercial sales can commence. There can be no assurance that its products will receive any of these required approvals. The denial or delay of such approvals may impact the Company's business in the future. In addition, after the approval by the FDA, there is still an ongoing risk of adverse events that did not appear during the product approval process.

The Company is subject to risks common to companies in the pharmaceutical industry, including, but not limited to, new technological innovations, clinical development risk, establishment of appropriate commercial partnerships, protection of proprietary technology, compliance with government and environmental regulations, uncertainty of market acceptance of products, product liability, the volatility of its stock price and the need to obtain additional financing.

Our The Company's facilities and equipment, including those of our the Company's suppliers and vendors, may be affected by natural or man-made disasters. Our The Company's administrative office is based in Irvine, California and we manage the Company manages all our its research and development activities through third parties that are located throughout the world. We have The Company has taken precautions to safeguard our its facilities, equipment and systems, including insurance, health and safety protocols, and off-site storage of computer data. However, our the Company's facilities and systems, as well as those of our its third-party suppliers and vendors, may be vulnerable to earthquakes, fire, storm, public health or similar emergencies, power loss, telecommunications failures, physical and software break-ins, software viruses and similar events which could cause substantial delays in our its operations, damage or destroy our its equipment or inventory, and cause us the Company to incur additional expenses and delay research and development activities. In addition, the insurance coverage we maintain the Company maintains may not be adequate to cover our its losses in any circumstance and may not continue to be available to use on acceptable terms, or at all.

Research and Development Expenses

Research and development expenses include personnel and facility-related expenses, outside contracted services including clinical trial costs, manufacturing and process development costs, research costs and other consulting services and non-cash stock-based compensation. Research and development costs are expensed as incurred. Amounts due under contracts with third parties may be either fixed fee or fee for service, and may include upfront payments, monthly payments and payments upon the completion of milestones or receipt of deliverables. Non-refundable advance payments under agreements are capitalized and expensed as the related goods are delivered or services are performed.

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The Company contracts with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to its vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. The Company's accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. These contracts may be terminated by the Company upon written notice and the Company is generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances the Company may be further responsible for termination fees and penalties. The Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior-period accrued estimates for clinical trial activities during the three and six nine months ended June 30, 2023 September 30, 2023.

Recently Adopted Accounting Pronouncements

No new accounting pronouncement issued or effective during the fiscal period had or is expected to have a material impact on the Company's condensed consolidated financial statements or disclosures.

Note 4. Short-Term Investments

The objectives of the Company's investment policy are to preserve principal, achieve liquidity requirements and safeguard invested funds. Short-term investments consist of U.S. government securities and U.S. government agency securities. The Company has classified these investments as available-for-sale securities, as the sale of such investments may be required prior to maturity to implement management strategies, and therefore has classified all investments with maturity dates beyond three months at the date of purchase as current assets in the accompanying unaudited condensed consolidated balance sheets. Any premium or discount arising at purchase is amortized and/or accreted to interest income as an adjustment to yield using the straight-line method over the life of the instrument. The amortized cost of available-for-sale securities is adjusted for amortization of premiums and accretion of discounts to maturity. Investments are reported at their estimated fair value. Unrealized gains and losses are included in accumulated other comprehensive loss as a component of stockholders' equity until realized.

The following is a summary of short-term investments, which were classified as available-for-sale securities as of June 30, 2023 September 30, 2023:

	June 30, 2023		September 30, 2023	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value

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U.S. government securities	$ 17,642	$ 17,642	$ 39,871	$ 39,871
U.S. government agency securities	12,789	$ 12,789	16,071	16,071
Total short-term investments	$ 30,431	$ 30,431	$ 55,942	$ 55,942

There were no short-term investments as of December 31, 2022. All of the Company's available-for-sale securities have a stated maturity of less than one year. There were no short-term investments as of December 31, 2022.

Note 5. Fair Value Measurements

Financial assets and liabilities are recorded at fair value.

The Company classifies fair value measurements using a three-level hierarchy that prioritizes the inputs used to measure fair value. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1—Quoted market prices (unadjusted) in active markets for identical assets and liabilities.
- Level 2—Observable inputs other than quoted market prices included in Level 1, such as quoted market prices fo markets that are not active or other inputs that are observable or can be corroborated by observable market dat
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities, including certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs. These fair values are obtained from independent pricing services which utilize Level 1 and Level 2 inputs.

The following summarizes the Company's financial instruments measured at fair value on a recurring basis as of June 30, 2023 September 30, 2023 and December 31, 2022. Included within cash and cash equivalents on the condensed consolidated balance sheet, sheets, but excluded from the fair value hierarchy table, are cash deposits held at financial institutions.

	June 30, 2023				September 30, 2023			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Assets:								
Cash equivalents:								

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Money market funds	5,14 $ 3	$ —	$ —	5,14 $ 3	$ 89	$ —	$ —	$ 89
U.S. government securities	—	32,8 43	—	32,8 43	—	1,99 7	—	1,99 7
U.S. government agency securities	—	993	—	993				
Total cash equivalents	5,14 $ 3	33,8 $ 36	$ —	38,9 $ 79	$ 89	1,99 $ 7	$ —	2,08 $ 6
Short-term investments:								
U.S. government securities	$ —	17,6 $ 42	$ —	17,6 $ 42	$ —	39,8 $ 71	$ —	39,8 $ 71
U.S. government agency securities	—	12,7 89	—	12,7 89	—	16,0 71	—	16,0 71
Total short-term investments	$ —	30,4 $ 31	$ —	30,4 $ 31	$ —	55,9 $ 42	$ —	55,9 $ 42
Total financial assets	5,14 $ 3	64,2 $ 67	$ —	69,4 $ 10	$ 89	57,9 $ 39	$ —	58,0 $ 28

	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 9,296	$ —	$ —	$ 9,296
U.S. government securities	—	—	—	—
U.S. government agency securities	—	—	—	—
Total cash equivalents	$ 9,296	$ —	$ —	$ 9,296

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Short-term investments:				
U.S. government securities	$ —	$ —	$ —	$ —
U.S. government agency securities	—	—	—	—
Total short-term investments	$ —	$ —	$ —	$ —
Total financial assets	$ 9,296	$ —	$ —	$ 9,296

	December 31, 2022			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents:				
Money market funds	$ 9,296	$ —	$ —	$ 9,296
Total cash equivalents	$ 9,296	$ —	$ —	$ 9,296
Total financial assets	$ 9,296	$ —	$ —	$ 9,296

Note 6. Prepaid Expenses and Other Current Assets

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

	June 30, 2023	**December 31, 2022**	**September 30, 2023**	**December 31, 2022**
Prepaid insurance	$ 315	$ 823	$ 95	$ 823
Prepaid clinical	1,445	2,115	3,022	2,115
Prepaid other	246	143	175	143
Other current assets	238	28	90	28
Total prepaid expenses and other current assets	$ 2,244	$ 3,109	$ 3,382	$ 3,109

Note 7. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

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	June 30, 2023	December 31, 2022	September 30, 2023	December 31, 2022
Accrued compensation and related expenses	$ 1,416	$ 1,909	$ 1,544	$ 1,909
Accrued clinical	826	1,826	366	1,826
Accrued professional services	33	65	61	65
Accrued other	38	112	67	112
Total accrued expenses and other liabilities	$ 2,313	$ 3,912	$ 2,038	$ 3,912

Note 8. Commitments and Contingencies

Operating Leases

The Company leases office space under various operating leases. Total rent expense for all operating leases in the accompanying condensed consolidated statements of operations and comprehensive loss was $0.1 million for each of the

three months ended June 30, 2023 September 30, 2023 and 2022 and $0.2 0.3 million for each of the six nine months ended June 30, 2023 September 30, 2023 and 2022.

The Company has an operating lease for 5,197 square feet of office space in Irvine, California. Effective January 1, 2023, the office lease was amended to extend the term of the lease through December 31, 2024.

On November 4, 2021, the Company entered into an operating lease for 6,138 square feet of office space in Burlington, Massachusetts, that expires on November 20, 2024.

The Company determines if a contract contains a lease at inception. Our office leases have a remaining term of approximately twenty-one months and do not include options to extend the leases for additional periods.

Operating lease assets and liabilities are recognized at the lease commencement date. Operating lease liabilities represent the present value of lease payments not yet paid. Operating lease assets represent our right to use an underlying asset and are based upon the operating lease liabilities as adjusted for prepayments or accrued lease payments, initial direct costs, lease incentives, and impairment of operating lease assets. To determine the present value of lease payments not yet paid, we estimate incremental secured borrowing rates corresponding to the maturities of the leases. As we have no outstanding debt nor committed credit facilities, secured or otherwise, we estimate this rate based on prevailing financial market conditions, comparable company and credit analysis, and management's judgment.

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Our leases contain rent escalations over the lease term. We recognize expense for these leases on a straight-line basis over the lease term. Additionally, tenant incentives used to fund leasehold improvements are recognized when earned and reduce our right-of-use asset related to the lease. These are amortized through the right-of-use asset as reductions of expense over the lease term. Our lease agreements do not contain any material residual value guarantees or material restrictive covenants.

While we do not currently have any lease agreement with lease and non-lease components, we elected to account for lease and non-lease components as separate components.

We have elected the short-term lease recognition exemption for all applicable classes of underlying assets. Short-term disclosures include only those leases with a term greater than one month and 12 months or less, and expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less, that do not include an option to purchase the underlying asset that we are reasonably certain to exercise, are not recorded on the condensed consolidated balance sheet.

The components of lease expense were as follows (in thousands):

	For the Six Months Ended June 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost(a)	$ 199	$ 203	$ 300	$ 303

(a) Includes variable operating lease expenses, which are immaterial

(a) Includes variable operating lease expenses, which are immaterial

(a) Includes variable operating lease expenses, which are immaterial

Other information related to leases was as follows (in thousands, except lease term and discount rate):

	For the Six Months Ended June 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Supplemental Cash Flows Information				
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	$ 181	$ 193	$ 279	$ 290
Remaining lease term				

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Operating leases	1.45 years	1.91 years	1.20 years	2.20 years
Discount rate				
Operating leases	2.49 %	3.00 %	2.48 %	2.49 %

Future payments under noncancelable operating leases having initial or remaining terms of one year or more are as follows for the succeeding fiscal year and thereafter (in thousands):

	June 30, 2023	September 30, 2023
2023 (remainder of)	$ 197	$ 99
2024	388	388
Total minimum lease payments	585	487
Less imputed interest	(11)	(8)
Present value of lease liabilities	574	479
Less current portion of operating lease liabilities	(390)	(396)
Non-current operating lease liabilities	$ 184	$ 83

Grants and Licenses

ALS Therapy Development Foundation, Inc. License Agreement

In May 2015, Anelixis executed a License Agreement (the "Agreement"), which is an exclusive patent rights agreement with ALS Therapy Development Foundation, Inc. ("ALS TDI") for certain patents and "know-how" of ALS TDI. This Agreement continues until the licensee terminates the agreement with ninety days written notice. The Agreement requires license fees payable to ALS TDI, subject to the achievement of certain milestones and other conditions.

The first and second milestones of the Agreement are the dosing of the first subjects in a first toxicity study in non-human primates and the dosing of the first patient in a Phase I Clinical Trial, respectively. Both of these milestones were achieved as of December 31, 2018 and 2017. The fee due for the achievement of these milestones was $1.0 million each. During 2018 and 2017, Anelixis issued $1.0 million worth of its common stock in lieu of making a cash payment. No milestones were achieved during either the six nine months ended June 30, 2023 September 30, 2023 or the year ended December 31, 2022.

The Agreement was amended and restated in February 2020, and a first amendment to the restated license agreement was executed in September 2020. As amended in September 2020, the remaining milestone payments for a first

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licensed product total $6.0 million. In the event that the Company develops a second licensed product, the Company is obligated to pay up to $2.5 million in additional milestone payments.

In addition to the milestone payments, the Company is required to pay ALS TDI an amended annual license maintenance fee of $0.1 million beginning on the earlier of January 1, 2022, the Company's first sublicense, or change in control, as defined in the Agreement. Beginning in 2022, the Company began paying the $0.1 million annual license maintenance fee to ALS TDI.

Furthermore, the Company shall pay ALS TDI fees based on reaching certain levels of annual net sales of any product produced with the patent rights. A royalty in the low single digits will be due on aggregate net sales. Upon the first calendar year of reaching $500.0 million in aggregate net sales, the Company shall pay ALS TDI a one-time milestone payment of $15.0 million. Upon the first calendar year of reaching $1.0 billion in aggregate net sales, the Company is obligated to pay ALS TDI a one-time milestone payment of $30.0 million.

Lonza Sales AG Inc. License Agreement

In September 2018, Anelixis executed a License Agreement (the "Lonza Agreement"), which is a manufacturing know-how rights agreement with Lonza Sales AG Inc. ("Lonza") for the use of certain processes and know-how related to the manufacture of tegoprubart. The Lonza Agreement continues until the later of the last Valid Claim (as defined therein) or ten years from the First Commercial Sale of tegoprubart, as defined and subject to the conditions therein. A royalty in the low single digits will be due on aggregate net sales of tegoprubart that is manufactured by Lonza or any other third-party or licensee.

eGenesis, Inc. Collaboration Agreement

In September 2022, and subsequently amended in January 2023, Eledon executed a collaborative research agreement with eGenesis, Inc. (the "eGenesis Agreement"), under which eGenesis will gain access to tegoprubart for eGenesis' ongoing preclinical research and development xenotransplant studies of human-compatible organs and cells for the treatment of organ failure. eGenesis will pay Eledon for supplies of tegoprubart based on the number of study days per animal needed for the

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eGenesis preclinical xenotransplant studies. The eGenesis agreement continues until September 2025, unless terminated earlier by either party.

Israeli Innovation Authority Grant

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From 2012 through 2015, the Company received grants in the amount of approximately $0.5 million from the Israeli Innovation Authority (previously the Office of Chief Scientist) of the Israeli Ministry of Economy and Industry designated for investments in research and development. The grants are linked to the U.S. Dollar and bear annual interest of LIBOR. The grants are to be repaid out of royalties from sales of the products developed by the Company from its investments in research and development. Because the Company has not yet earned revenues related to these investments and cannot estimate potential royalties, no liabilities related to these grants have been recorded as of each period presented. Repayment of the grant is contingent upon the successful completion of the Company's research and development programs and generating sales. The Company has no obligation to repay these grants if the research and development program fails, is unsuccessful or aborted or if no sales are generated. The Company has not yet generated sales as of June 30, 2023 September 30, 2023; therefore, no liability was recorded for the repayment in the accompanying condensed consolidated financial statements.

Legal Matters

The Company and its subsidiaries are not a party to or the subject of any claim or lawsuit that individually or in the aggregate is anticipated to have a material effect on the Company's results of operations, financial condition or cash flows.

Indemnifications

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves future claims that may be made against the Company but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future because of these indemnification obligations. No amounts associated with such indemnifications have been recorded to date.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated. There have been no contingent liabilities requiring accrual at June 30, 2023 September 30, 2023.

Note 9. Stockholders' Equity

2021 Equity Distribution Agreement

On March 31, 2021, the Company filed a registration statement on Form S-3 containing a prospectus and prospectus supplement under which the Company may offer and sell up to $75 million in shares of its common stock,

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from time to time, pursuant to an open market sale agreement with Jeffries Jefferies LLC and by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933 (the "ATM Program"). Pursuant to the "baby shelf rules" promulgated by the SEC, if the Company's public float is less than $75.0 million as of specified measurement periods, the number of shares of common stock that may be offered and sold by the Company under a Form S-3 registration statement, including pursuant to the ATM Program, in any twelve-month period is limited to an aggregate amount that does not exceed one-third of the Company's public float. As of June 30, 2023 September 30, 2023, the Company was permitted to sell up to $17.8 10.6 million of shares of common stock pursuant to the ATM Program under the SEC's "baby shelf" rules. The Company will remain subject to the "baby shelf rules" under the Form S-3 registration statement until such time as its public float exceeds $75.0 million. Through June 30, 2023 September 30, 2023, no shares of common stock have been sold under the ATM program. Under the Securities Purchase Agreement described below in this Note 9, the Company is restricted from selling shares under the ATM Program until the later of (i) 4 months from April 28, 2023 and (ii) ninety days after the registration statement filed pursuant to the Securities Purchase Agreement has been declared effective. The registration statement filed pursuant to the Securities Purchase Agreement was declared effective on June 2, 2023.

2022 Exchange Agreement

On January 11, 2022, the Company entered into an exchange agreement (the "Series X[1] Exchange Agreement") with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P., Biotechnology Value Trading Fund OS, L.P., MSI BVF SPV, L.L.C. (collectively, the "BVF Exchanging Stockholders"), pursuant to which the Series X[1] Exchanging Stockholders exchanged (the "Series X[1] Exchange") 550,000 shares of the Company's common stock for 9,899.99 shares of Series X[1] Non-Voting Convertible Preferred Stock.

2023 Securities Purchase Agreement

On April 28, 2023, the Company entered into the Securities Purchase Agreement with Purchasers, pursuant to which the Company agreed to issue and sell to the Purchasers in the Private Placement (i) in an initial closing, (a) an aggregate of 15,151,518 shares (the "Shares") of the Company's common stock, $0.001 par value per share, or pre-funded warrants in lieu thereof (the "Pre-Funded Warrants"), and (b) common stock warrants exercisable into an aggregate of 15,151,518 shares of common stock (or Pre-Funded Warrants in lieu thereof) (the "Common Warrants" and, together with the Pre-Funded Warrants, the "Warrants"); (ii) in a second closing, upon the satisfaction of specified conditions set forth in the Securities Purchase Agreement, an aggregate of 20,202,024 shares of common stock (or Pre-Funded Warrants); and (iii) in a third closing, upon the satisfaction of specified conditions set forth in the Securities Purchase Agreement, an aggregate of 25,252,530 shares of common stock (or Pre-Funded Warrants), in each case subject to customary adjustments as provided in the Securities Purchase Agreement, Pre-Funded Warrant or Common Warrant, as applicable. Each Common Warrant has an exercise price of $3.00 per share and expires five years after issuance. The Pre-Funded Warrants are exercisable immediately and until exercised in full, with an exercise price of $0.001 per share. The Shares, the Warrants, and the shares

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of common stock issuable upon the exercise of the Warrants, have not been registered under the Securities Act of 1933, as amended, and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act of 1933, as amended, and Rule 506(b) promulgated thereunder.

On May 5, 2023, the initial closing occurred and the Company received $35.0 million, or net proceeds of approximately $33.0 million after deducting offering costs, in exchange for 8,730,168 shares of common stock and Pre-Funded Warrants to purchase 6,421,350 shares of common stock. The Company may receive an additional $105.0 million upon sale of the shares to be issued in the second and third closings, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $45.5 million assuming the exercise of all Common Warrants issued in the initial closing of the Private Placement.

In connection with the Private Placement, the Company filed on May 18, 2023, a registration statement on Form S-3 ("Registration Statement") with the SEC to register for resale the Shares and the shares of common stock issuable upon the exercise of the Warrants. The Registration Statement became effective on June 2, 2023.

2023 Conversion Agreement of Non-Voting Convertible Preferred Stock

On May 16, 2023, Cormorant Global Healthcare Master Fund LP provided notice to convert (i) 1,782 shares of Series X Non-Voting Convertible Preferred Stock for 99,000 shares of common stock in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X Non-Voting Convertible Preferred Stock, and (ii) 7,883.586 shares of Series X[1] Non-Voting Convertible Preferred Stock for 437,977 shares of common stock in accordance with the Certificate of Designation of Preferences, Rights and Limitations of the Series X[1] Non-Voting Convertible Preferred Stock. The conversion was completed on May 23, 2023.

2023 Exercise of Pre-Funded Warrants

On July 10, 2023, Armistice Capital Master Fund Ltd. (the "Exercising Stockholder"), exercised Pre-Funded Warrants to purchase 501,197 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the Securities Purchase Agreement. On July 14, 2023, the Company issued 501,197 shares of common stock to the Exercising Stockholder in accordance with such exercise.

Common Stock Warrants

As of June 30, 2023 September 30, 2023, there were 22,718,499 22,217,302 warrants exercisable into common stock (rounding for fractional shares and subject to beneficial ownership blockers).

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	Roll Forward of Warrant Activity				Roll Forward of Warrant Activity			
	Private placement warrants	Pre-funded warrants	Warrants exchanged for Series X_1 preferred stock	Total	Private placement warrants	Pre-funded warrants	Warrants exchanged for Series X_1 preferred stock	Total
Balance as of December 31, 2022	337,822	509,117	298,692	1,145,631	337,822	509,117	298,692	1,145,631
		6,421,350		21,572,800		6,421,350		21,572,800
	15,151,518	1,350		72,868	15,151,518	1,350		72,868
Issued		0	—			0	—	
Exercised	—	—	—	—	—	(501,197)	—	(501,197)
Cancelled/Expired	—	—	—	—	—	—	—	—
Balance as of June 30, 2023	15,489,340	6,930,467	298,692	22,718,299				
Balance as of September 30, 2023					15,489,340	6,429,270	298,692	22,217,302

Preferred Stock Warrants

As of June 30, 2023 September 30, 2023, there were 50,207.419 warrants exercisable into Series X^1 Preferred Stock, which are convertible into 2,789,301 shares of common stock (rounding for fractional shares and subject to beneficial ownership conversion blockers).

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	Roll Forward of Series X1 Convertible Preferred Warrant Activity
	Total
Balance as of December 31, 2022	50,207.419
Assumed and replaced Issued	—
Exercised	—
Cancelled/Expired	—
Balance as of June 30, 2023 September 30, 2023	50,207.419

Note 10. Stock-based Compensation

The Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value.

The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical industry. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options ordinary vesting period and the contractual term. For stock options granted to the Company's board of directors (the "Board"), the Company determined the expected life assumption using the simplified method as the starting point with an average period of twelve (12) months added to take into account for the extended range of time of 12 to 18 months vested stock options granted to Board members may be exercised upon termination. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Restricted Stock Units ("RSUs") are measured and recognized based on the quoted market price of our common stock on the date of grant.

In March 2020, the Board approved an increase of 28,816 shares issuable under the 2014 Stock Incentive Plan (the "2014 Plan") and 7,204 shares issuable under the 2014 Employee Stock Purchase Plan (the "ESPP").

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On December 18, 2020, the Company held a special meeting of its stockholders (the "Special Meeting"), whereby the Company's stockholders approved the 2020 Long Term Incentive Plan (the "2020 Plan"). The aggregate number of shares of

stock initially available for issuance under the 2020 Plan was 4,860,000 shares of common stock, which represented approximately 15% of the total issued and outstanding shares of the Company's common stock as of the record date of the Special Meeting (calculated on an as-converted basis and without regard to the potential application of beneficial ownership conversion limitations on the Preferred Stock) and may be increased by the number of shares under the 2014 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by the Company.

On June 21, 2023, the Company held its Annual Meeting of Stockholders (the "Annual Meeting"). At the Annual Meeting, the Company's stockholders approved an amendment to the 2020 Plan. The 2020 Plan, as amended, (i) reflects an increase in the limit on the aggregate number of shares of the Company's common stock that may be delivered pursuant to all awards granted under the 2020 Incentive Plan by an additional 9,600,000 shares so that the new aggregate share limit under the 2020 Plan is 14,460,000 shares, and (ii) extends the date through which the Company may grant new awards under the 2020 Plan from November 15, 2030 to April 26, 2033.

On May 1, 2023, the Company issued stock option awards to its employees with both time-based and performance-based vesting requirements, with 1,292,172 of the granted stock options subject to the Company's customary time-based vesting schedule. The remaining 5,168,685 stock options granted are subject to both customary time-based vesting requirements and performance-based vesting requirements that are based on the same clinical development milestones applicable to the second and third closings of the Private Placement as specified in the Securities Purchase Agreement. No specified clinical development milestones were achieved during the six nine months ended June 30, 2023 September 30, 2023.

The 2014 Plan was closed to new grants following the initial approval of the 2020 Plan, and therefore, there were no shares reserved for issuance under the 2014 Plan as of June 30, 2023 September 30, 2023. The number of shares reserved for issuance under the 2020 Plan and ESPP was 2,995,096 3,281,333 and 24,077 shares, respectively, as of June 30, 2023 September 30, 2023.

Total stock-based compensation expense was recognized in our condensed consolidated statements of operations and comprehensive loss as follows (in thousands):

For the Three Months Ended June 30,		For the Six Months Ended June 30,		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
2023	2022	2023	2022	2023	2022	2023	2022

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Research and development	$ 455	$ 924	$ 852	1,80 $ 4	$ 321	$ 873	1,17 $ 3	2,67 $ 7
General and administrative	1,26 5	1,38 4	2,2 49	2,69 0	1,41 3	1,31 2	3,66 2	4,00 2
Total stock-based compensation	1,72 $ 0	2,30 $ 8	3,1 $ 01	4,49 $ 4	1,73 $ 4	2,18 $ 5	4,83 $ 5	6,67 $ 9

Note 11. Net Loss Per Share

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding for the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share calculation, incentive stock options, restricted stock units and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position. Basic weighted average shares outstanding for the three and six nine months ended June 30, 2023 September 30, 2023 include 6,930,467 6,429,270 shares underlying pre-funded warrants to purchase common shares. As the shares underlying these pre-funded warrants can be issued for little consideration (an exercise price per share equal to $0.001 per share), these shares are deemed to be issued for purposes of basic earnings per share.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,		For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022	2023	2022	2023	2022
	(In thousands, except share and per share data)				(In thousands, except share and per share data)			
Net loss used in the calculation of basic and diluted loss per share	$ (9,579)	$ (9,247)	$ (20,351)	$ (19,111)	$ (10,349)	$ (10,471)	$ (30,700)	$ (29,582)

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Net loss per share, basic and diluted	$ (0.40)	$ (0.65)	$ (1.06)	$ (1.34)	$ (0.35)	$ (0.73)	$ (1.35)	$ (2.07)
Weighted-average number of common shares, basic and diluted	24,006,549	14,265,905	19,173,080	14,299,969	29,974,400	14,265,905	22,813,085	14,289,729

The computation of diluted earnings per share excludes incentive stock options, restricted stock units and warrants that are anti-dilutive. The following table provides a summary as of June 30, 2023 September 30, 2023 and 2022 of common share equivalents that were excluded because their inclusion would have been anti-dilutive.

	For the Six Months Ended June 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock options outstanding	6,686,360	5,194,353		
Stock options outstanding and other equity awards			15,119,434	5,096,085
Common and preferred warrants outstanding	18,577,332	3,127,121	18,577,332	3,127,121
Total	25,263,692	8,321,474	33,696,766	8,223,206

Note 12. Subsequent Events

On July 10, 2023 November 3, 2023, Armistice Capital Master Fund Ltd. (the "Exercising Stockholder"), exercised Pre-Funded Warrants to purchase 501,197 653,000 shares of common stock at an exercise price of $0.001 per share, which were issued in conjunction with the Securities Purchase Agreement. On July 14, 2023 November 6, 2023, the Company issued 501,197 653,000 shares of common stock to the Exercising Stockholder in accordance with such exercise.

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

The unaudited interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read together with our audited financial statements and accompanying notes for the year ended December 31, 2022 included in the Annual Report on Form 10-K filed by the Company with the Securities and

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Exchange Commission (the "SEC") on March 30, 2023. In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Please see Part II, Item 1A. *Risk Factors* in this Quarterly Report on Form 10-Q for a discussion of certain risk factors applicable to our business, financial condition, and results of operations. Operating results are not necessarily indicative of results that may occur for the full fiscal year or any other future period. See also "Special Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q. Unless otherwise indicated, references to the terms "Eledon", the "Company", "we", "our", and "us" refer to Eledon Pharmaceuticals, Inc.

ABOUT ELEDON PHARMACEUTICALS

Overview

Eledon Pharmaceuticals, Inc. ("Eledon" we", "us", "our" "Eledon" or the "Company") is a clinical stage biotechnology company using its immunology expertise in targeting the CD40 Ligand ("CD40L", also called "CD154") pathway to develop therapies to protect transplanted organs and prevent rejection, and to treat amyotrophic lateral sclerosis ("ALS"). The Company's Our lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for the CD40 Ligand, a well-validated biological target that we believe has broad therapeutic potential.

In September 2020, we acquired Anelixis Therapeutics, Inc. ("Anelixis"), the company that owned and controlled the intellectual property related to tegoprubart.

Tegoprubart is engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated CD4+ T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as macrophages and dendritic cells, as well as B cells. By blocking CD40L and not the CD40 receptor, tegoprubart inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti-CD40 receptor approaches. Blocking CD40L also increases polarization of CD4+ lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may play a therapeutic role in autoimmune diseases and in the prevention of allograft rejection after solid organ transplantation.

Tegoprubart is designed to negate the risk of thrombolytic events seen in the first generation of anti-CD40L antibodies by introducing structural modifications that have been shown in preclinical models to eliminate binding to the Fcγ receptors associated with platelet activation without altering the binding of tegoprubart to CD40L. In non-human primate studies, dosing of tegoprubart up to 200 mg/kg per week for 26 weeks, demonstrated no adverse events regarding coagulation, platelet activation or thromboembolism.

Our business strategy is to optimize the clinical and commercial value of tegoprubart and become a global biopharmaceutical company with a focused immunology franchise. Our original strategy was to develop tegoprubart in up to four indications: ALS, prevention of kidney allograft rejection, prevention of islet cell allograft rejection, and IgA Nephropathy ("IgAN"). We selected our indications based on preclinical and clinical data that was generated with either

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tegoprubart or historical anti-CD40L molecules. In January 2023, we announced our decision to prioritize resources on our kidney transplantation programs, discontinue the islet cell transplantation program, and deprioritize the IgAN program. We also remain committed to further progressing ALS clinical development and are working with key stakeholders on potential next steps to do so. However, as described below, we are unable to continue our clinical development of tegoprubart for people with ALS without additional financing.

Kidney transplantation: prevention of allograft rejection

In January 2023, we announced plans to prioritize and focus resources on its kidney transplantation programs. Kidney transplantation is the most common type of solid organ transplantation in the United States with an estimated 240,000 Americans living with a transplanted kidney. In 2019, an estimated 24,000 kidneys were transplanted, of which up to 15% were re-transplants in persons that had already received at least one other kidney. Over 90,000 people in the U.S. typically wait 3-5 years for a kidney transplant and in 2014, nearly 5,000 Americans died waiting for a kidney with another nearly 4,000 becoming too sick to receive a transplant.

Calcineurin inhibitors ("CNI"s) are a critical component of many immunosuppressive regimens to prevent acute and long-term kidney transplant rejection. However, chronic exposure to certain CNIs including tacrolimus is associated with new onset diabetes due to pancreatic beta cell toxicity, nephrotoxicity and cardiotoxicity. Over time, these CNI side effects may significantly damage transplanted kidneys or result in a requirement for reduced exposures to CNIs and a resulting potential decrease in the ability to prevent long-term rejection.

Tegoprubart seeks to address challenges associated with current immunosuppressive transplantation regimens using CNI-based therapies. The ability to prevent acute and chronic transplant rejection without the need for CNIs has the potential to transform the clinical management of preventing graft rejection by mitigating the adverse events associated with CNIs and improving long-term graft survival, thus potentially decreasing the need for repeat kidney transplants and making those organs available for use by other patients on the wait list.

We have received regulatory approvals in Canada, the United Kingdom and Australia, for a Phase 1b clinical trial of tegoprubart, in up to 12 subjects, replacing tacrolimus as an immunosuppressive regimen component in patients undergoing de novo kidney transplantation. Each participant will receive rabbit antithymocyte globulin (ATG) induction and a maintenance regimen consisting of tegoprubart, mycophenolate mofetil, and corticosteroids. The primary endpoint of the study is safety. Other endpoints include characterizing the pharmacokinetic profile of tegoprubart, the incidence of biopsy proven rejection, and eGFR. The first subject in the Phase 1b study was dosed in July 2022. We reported interim safety and efficacy results from the Phase 1b clinical trial in March 2023, and provided updated data in November 2023. At the time of the November 2023 update, results from 11 participants in the Phase 1b trial demonstrated that tegoprubart was generally safe and well-tolerated in patients undergoing kidney transplantation. There were no cases of

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hyperglycemia, new onset diabetes, tremor, or cytomegalovirus infection commonly seen with tacrolimus. One participant experienced a mild T cell mediated rejection (Banff score 1a) on day 99. This patient was treated for the rejection and remains in the study. There were no cases of graft loss or death. Aggregate mean estimated glomerular filtration rate (eGFR) – a measure of kidney function – was above 70 mL/min/1.73m2 at all reported time points after day 90. Historical studies have reported average eGFRs generally in the low 50 mL/min/1.73m2 range during the first year after kidney transplant using standard of care. One participant completed the study with an eGFR of 91 at one year (day 374) and is now enrolled in our Phase 2 open-label extension (OLE) study, which will evaluate the long-term safety, pharmacokinetics, and efficacy of tegoprubart in participants who have completed one year of treatment in either the ongoing Phase 1b or Phase 2 BESTOW study.

In July 2022, we received Investigational New Drug (IND) application clearance from the FDA for a controlled, Phase 2 BESTOW trial of tegoprubart for the prevention of transplant rejection in persons receiving a kidney transplant. The Phase 2 BESTOW study will be is a multi-center, two-arm, active comparator clinical study, and will enroll 120 participants undergoing kidney transplantation in the United States and other countries to evaluate the safety, pharmacokinetics, and efficacy of tegoprubart compared to the calcineurin inhibitor tacrolimus. The study's primary objective is to assess graft function as measured by estimated glomerular filtration rate (eGFR) at 12 months post-transplant in participants treated with tegoprubart compared to tacrolimus. Better graft function as assessed by eGFR has been associated with improved long-term patient and graft survival. Secondary objectives will include graft survival, biopsy-proven acute rejection, and the incidence of new onset diabetes mellitus after transplant. The Phase 2 BESTOW study will run is running in parallel to the ongoing Phase 1b clinical trial of tegoprubart in kidney transplantation. We expect to initiate patient enrollment The first subject in the third quarter of Phase 2 BESTOW study was dosed in August 2023.

Amyotrophic Lateral Sclerosis

ALS is a progressive, paralytic disorder characterized by degeneration of motor neurons in the brain and spinal cord. In the U.S., the incidence is estimated at approximately 5,000 cases per year with a prevalence of approximately 30,000 cases overall. Despite 3 approved drugs, in most cases, death from respiratory failure occurs between 3 to 5 years from diagnosis, with 50% of patients living at least 3 years from diagnosis and only 20% of patients living at least 5 years from diagnosis.

While the exact pathogenic mechanism of ALS is still not fully understood, there is strong evidence indicating that neuroinflammation plays an important role in the disease's pathogenesis. Neuroinflammation in ALS is characterized by the infiltration of lymphocytes and macrophages into the central nervous system, and the activation of microglia and reactive astrocytes. Reactive astrocytes and microglia as well as infiltrating lymphocytes, dendritic cells, monocytes, macrophages and immune complexes have been identified in cerebrospinal fluid and neural tissues in both animal models of ALS and at autopsy in ALS patients.

Tegoprubart is designed to block CD40L binding to CD40, thereby potentially inhibiting neuroinflammatory pathways leading to disease progression in ALS. In vitro proof-of-concept studies have shown that tegoprubart binds to CD40L in human cells and blocks CD40L binding on antigen presenting cells and activated T cells. The potential for

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therapeutic benefit of CD40L blockage in treating ALS has been demonstrated in a SOD1 mouse model of ALS, where a murine anti-CD40L antibody, MR1, prolonged survival and delayed the onset of neurological disease progression. These pathophysiological manifestations are believed to be due to reduced immune cell infiltration of macrophages into skeletal muscle and their destroying denervated nerves. The plasticity of the nervous system to repair itself in the absence of this immune cell attack is believed to result in improved neuromuscular junction occupancy and improved muscle function. Blocking CD40L signaling also prevents pro-inflammatory polarization of lymphocytes, reduced neuroinflammation and improved motor neuron survival in rodent ALS models.

In 2018, the FDA granted orphan drug designation to tegoprubart for ALS. In 2019, we completed a single ascending dose Phase 1 study of tegoprubart in healthy volunteers and people with ALS. In this study, the doses of tegoprubart studied were well tolerated in healthy subjects and adults with ALS. Tegoprubart demonstrated low anti-drug antibody responses that were not dose related, linear dose proportionality across the dose ranges, and a half-life of up to 26 days.

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In October 2020, we initiated a Phase 2a, open-label, multi-center study to evaluate the safety and tolerability of multiple doses of tegoprubart in adult subjects with ALS. Fifty-four subjects with ALS were enrolled into the study in the United States and Canada at 13 ALS treatment sites. Ascending doses of tegoprubart were administered as IV infusions to four sequentially enrolling cohorts. The first two cohorts consisted of nine participants, and the last two cohorts of 18 participants each. All enrolled subjects received six infusions of tegoprubart over a 12 week period. Blood samples for target engagement, and exploratory biomarkers for inflammation and neurodegeneration were taken and analyzed. Participant-focused clinical outcomes were also assessed. In May 2022, we completed the Phase 2a study and released positive topline results. Tegoprubart successfully met the primary endpoints of safety and tolerability. Fifty of the fifty-four subjects completed all six study infusions, and adverse events were typical of an ALS patient population. Tegoprubart was well-tolerated, and no drug-related serious adverse events were observed. No new safety signals emerged. Anti-drug antibodies (ADAs) were present in less than 5 percent of samples. All ADAs were of low titer and did not impact tegoprubart drug levels. Tegoprubart target engagement was demonstrated in all dose cohorts with increasing target engagement in a dose-dependent manner, plateauing at the 4 and 8 mg / kg dosing levels using CD40L and CXCL13 biomarkers related to T cell and B cell function, respectively. Tegoprubart exposure decreased inflammatory biomarker levels, in a dose dependent manner, in 20 of 32 pro-inflammatory proteins. Pro-inflammatory biomarkers reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10.

We are seeking to further progress ALS clinical development and plan to work with key stakeholders on potential next steps to do so. However, we will be unable to continue our clinical development of tegoprubart for people with ALS without additional financing specific for our ALS program, and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all.

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IgA Nephropathy

In January 2023, we announced the deprioritization of our IgAN program. IgAN is the leading cause of chronic glomerulonephritis, a state of inflammation producing damage to the filtering part of the kidney. Disease manifestation and clinical presentation involves renal dysfunction characterized by proteinuria with a slow relentless course. Approximately 30%-40% of persons living with IgAN ultimately reach end stage renal disease (ESRD). The standard of care for ESRD is dialysis or kidney transplant, which represents a significant economic burden as well as a major impact on a patient's quality of life. With an estimated prevalence of approximately 150,000 persons in the United States, IgAN is one of the most common autoimmune glomerulonephropathies. In the United States, oral budesonide Tarpeyo was approved for use in IgAN by the FDA in December 2021 and Kinpeygo received conditional approval by the European Medicines Agency ("EMA") in July 2022.

The pathophysiology of IgAN has been well characterized, and based on its mechanism of action, tegoprubart has the potential to impact the disease process both upstream, at the source of the immune complexes, and downstream in the kidney itself, where it may reduce inflammation in the glomeruli. By disrupting multiple steps in the IgAN's pathophysiology, tegoprubart has the potential to affect the clinical course of the disease and improve outcomes for patients. The inhibition of CD40L has been shown to be effective in models of multiple glomerulonephritides, as measured by a reduction in proteinuria and were associated with a decrease in immune cell infiltrate into the glomeruli.

In August 2022, we received IND clearance from the FDA to evaluate tegoprubart for the treatment of IgAN. The global study was a 96-week open-label, dose ranging trial, and included both a high dose and a low dose cohort. The primary endpoint was change in urinary protein:creatinine ratio at week twenty-four. Secondary endpoints included change in estimated Glomerular Filtration Rate (eGFR) at week 96 as well as safety and tolerability. The first subject was dosed in May

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2022. We reported safety data from the high dose cohort in March 2023. All IgAN clinical activities and related spend will be discontinued in the third fourth quarter 2023.

Collaboration Agreement with eGenesis for Xenotransplantation Studies

In January 2023, we entered into a collaborative research agreement with eGenesis, Inc. ("eGenesis"), under which eGenesis gained access to tegoprubart, for preclinical xenotransplantation studies in support of eGenesis' kidney, heart and islet cell programs.

Financing Activities

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On April 28, 2023, we entered into a Securities Purchase Agreement (the "Securities Purchase Agreement") with certain institutional and accredited investors (the "Purchasers"), pursuant to which we agreed to issue and sell to the Purchasers in a private placement (the "Private Placement") (i) in an initial closing, (a) an aggregate of 15,151,518 shares (the "Shares") of our common stock, $0.001 par value per share, or pre-funded warrants in lieu thereof (the "Pre-Funded Warrants"), and (b) common stock warrants exercisable into an aggregate of 15,151,518 shares of common stock (or Pre-Funded Warrants in lieu thereof) (the "Common Warrants" and, together with the Pre-Funded Warrants, the "Warrants"); (ii) in a second closing, upon the satisfaction of specified conditions set forth in the Securities Purchase Agreement, an aggregate of 20,202,024 shares of common stock (or Pre-Funded Warrants); and (iii) in a third closing, upon the satisfaction of specified conditions set forth in the Securities Purchase Agreement, an aggregate of 25,252,530 shares of common stock (or Pre-Funded Warrants), in each case subject to customary adjustments as provided in the Securities Purchase Agreement, Pre-Funded Warrant or Common Warrant, as applicable. Each Common Warrant has an exercise price of $3.00 per share and expires five years after issuance. The Pre-Funded Warrants are exercisable immediately and until exercised in full, with an exercise price of $0.001 per share. The Shares, the Warrants, and the shares of common stock issuable upon the exercise of the Warrants, have not been registered under the Securities Act of 1933, as amended, and were offered pursuant to the exemption from registration provided in Section 4(a)(2) under the Securities Act of 1933, as amended, and Rule 506(b) promulgated thereunder.

On May 5, 2023, the initial closing occurred and we received $35.0 million, or net proceeds of approximately $33.0 million after deducting offering costs, in exchange for 8,730,168 shares of common stock and Pre-Funded Warrants to purchase 6,421,350 shares of common stock. We may receive an additional $105.0 million upon sale of the shares to be issued in the second and third closings, subject to achieving specified milestones and volume weighted average share price levels and trading volume conditions, and an additional $45.5 million assuming the exercise of all Common Warrants issued in the initial closing of the Private Placement.

In connection with the Private Placement, the Company filed on May 18, 2023, a registration statement on Form S-3 ("Registration Statement") with the SEC to register for resale the Shares and the shares of common stock issuable upon the exercise of the Warrants. The Registration Statement became effective on June 2, 2023.

Market Trends and Uncertainties

The global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, rising interest rates and uncertainty about economic stability. Likewise, the current conflict between conflicts in Ukraine and Russia has the Middle East have created extreme volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or

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commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business.

For example, the second and third closings of the Securities Purchase Agreement are subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions. There can be no assurances that the milestones will be satisfied and if we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

Any of the foregoing items could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted. See Item 1A, "Risk Factors" for additional information.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities as of the date of the

financial statements. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be 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. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no significant and material changes in our critical accounting policies and significant judgments and estimates during the six nine months ended June 30, 2023 September 30, 2023, as compared to those disclosed in the Annual Report on Form 10-K for the year ended December 31, 2022, filed by the Company with the SEC on March 30, 2023.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended June 30, 2023 September 30, 2023 and 2022

The following table provides comparative unaudited results of operations for the three months ended June 30, 2023 September 30, 2023 and 2022 (in thousands):

For the Three Months Ended June 30,	For the Three Months Ended September 30,

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	2023	2022	$ Variance	2023	2022	$ Variance
Operating expenses:						
Research and development	$ 7,201	$ 5,743	$ 1,458	$ 7,931	$ 7,452	$ 479
General and administrative	3,153	3,540	(387)	3,267	3,146	121
Total operating expenses	10,354	9,283	1,071	11,198	10,598	600
Loss from operations	(10,354)	(9,283)	(1,071)	(11,198)	(10,598)	(600)
Other income, net	775	36	739	849	127	722
Net loss	$ (9,579)	$ (9,247)	$ (332)	$ (10,349)	$ (10,471)	$ 122

Research and Development Expenses

Research and development expenses increased $1.5 million $0.5 million, to $7.2 million $7.9 million for the three months ended June 30, 2023 September 30, 2023, as compared to $5.7 million $7.5 million for the three months ended June 30, 2022 September 30, 2022. The increase in research and development expenses was primarily due to higher clinical development expenses, primarily with payments to external contract research organizations of $1.5 million, manufacturing costs of $0.2 million and driven by an increase in personnel costs expenses related to the production of $0.4 million, due to increased headcount. clinical trial materials of $0.8 million. The increase was partially offset by decreases a decrease in consulting employee compensation and benefits primarily driven by lower non-cash stock-based compensation expenses of $0.2 million and stock-based compensation a decrease in clinical development expenses with external contract research organizations of $0.4 million $0.1 million.

General and Administrative Expenses

General and administrative expenses decreased $0.4 million increased $0.1 million to $3.2 million $3.3 million for the three months ended June 30, 2023 September 30, 2023, as compared to $3.5 million $3.1 million for the three months ended June 30, 2022 September 30, 2022. The decrease increase in general and administrative expenses was primarily related to lower professional service costs. driven by an increase in employee compensation and benefits primarily driven by higher non-cash stock-based compensation expenses of $0.1 million.

Other Income, Net

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The change in other income, net was primarily due to an increase in interest income associated with higher interest rates on our cash and cash equivalents and short-term investments for the three months ended June 30, 2023 September 30, 2023.

Comparison of the Six Nine Months Ended June 30, 2023 September 30, 2023 and 2022

The following table provides comparative unaudited results of operations for the six nine months ended June 30, 2023 September 30, 2023 and 2022 (in thousands):

	For the Six Months Ended June 30,			For the Nine Months Ended September 30,		
	2023	2022	$ Variance	2023	2022	$ Variance
Operating expenses:						
Research and development	$ 15,314	$ 12,378	$ 2,936	$ 23,245	$ 19,830	$ 3,415
General and administrative	6,150	6,764	(614)	9,417	9,910	(493)
Total operating expenses	21,464	19,142	2,322	32,662	29,740	2,922
Loss from operations	(21,464)	(19,142)	(2,322)	(32,662)	(29,740)	(2,922)
Other income, net	1,113	31	1,082	1,962	158	1,804
Net loss	$ (20,351)	$ (19,111)	$ (1,240)	$ (30,700)	$ (29,582)	$ (1,118)

Research and Development Expenses

Research and development expenses increased $2.9 million $3.4 million, to $15.3 million $23.2 million for the six nine months ended June 30, 2023 September 30, 2023, as compared to $12.4 million $19.8 million for the six nine months ended June 30, 2022 September 30, 2022. The increase in research and development expenses was primarily due to higher driven by an increase in clinical development expenses primarily with payments to external contract research organizations of $3.6 million, $3.1 million and an increase in personnel costs expenses related to the production of $0.6 million, due to increased headcount, and general operating costs clinical trial materials of $0.2 million $1.1 million. The increase was

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partially offset by decreases in stock-based compensation of $0.9 million, a decrease in consulting expenses of $0.5 million $0.4 million and manufacturing costs a decrease in employee compensation and benefits primarily driven by lower non-cash stock-based compensation expenses of $0.1 million $0.4 million.

General and Administrative Expenses

General and administrative expenses decreased $0.6 million $0.5 million to $6.2 million $9.4 million for the six nine months ended June 30, 2023 September 30, 2023, as compared to $6.8 million $9.9 million for the six nine months ended June 30, 2022 September 30, 2022. The decrease in general and administrative expenses was primarily related to lower driven by a decrease in professional service costs expenses of $0.4 million and by a decrease in employee compensation and benefits primarily driven by lower non-cash stock-based compensation expenses of $0.4 million $0.1 million. The decrease was partially offset by an increase in personnel costs.

Other Income, Net

The change in other income, net was primarily due to an increase in interest income associated with higher interest rates on our cash and cash equivalents and short-term investments for the six nine months ended June 30, 2023 September 30, 2023.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

We do not have any approved products for commercial sale and have never generated revenue from product sales and have incurred significant net losses since our inception and expect to continue to incur net operating losses for the foreseeable future. We do not expect to receive any revenue from any product candidates that we develop unless and until we obtain regulatory approval and commercialize our product candidates or enter into collaborative arrangements with third parties. We currently have no credit facility or committed sources of capital.

As of June 30, 2023 September 30, 2023, the Company had cash and cash equivalents and short-term investments of approximately $71.4 million $59.6 million. To date, our operations have been financed primarily by net proceeds from the sale of preferred and common stock, the sale of warrants, and the issuance of convertible promissory notes. Additionally, in view of the Company's expectation to incur significant losses for the foreseeable future it will be required to raise additional capital resources in order to fund its operations, although the availability of, and the Company's access to, such resources is not assured. Accordingly, management believes that there is substantial doubt regarding the Company's ability to continue operating as a going concern. We have based this estimate on assumptions that may prove to be incorrect, and we could utilize our available resources sooner than we currently expect. In addition, we may receive up to an additional $105.0 million in tranche financing in a second and a third closing of the Private Placement, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $45.5 million assuming the exercise of all Common Warrants issued in the initial closing of the Private Placement. There is no assurance that the milestones required for the second and third closings will be satisfied or

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that the Common Warrants will be exercised. If these events do not occur or we are unable to secure additional capital or to do so on acceptable terms, we will

be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. Further, from time to time, our operating plans may change, and we may need additional funds to meet operational needs for clinical studies sooner than planned or to fund additional clinical studies. For example, we do not currently have sufficient liquidity to fund the continued clinical development of tegoprubart for people with ALS without additional financing, notwithstanding the positive topline results of our Phase 2a study of tegoprubart for adult subjects with ALS. We will continue to monitor our liquidity position in light of various financing alternatives and may pursue additional financing or other alternatives to allow us to continue our product development. However, there can be no assurance such financing or other alternatives will be available to us on acceptable terms, or at all.

Material Cash Requirements

Our primary use of cash is to fund operating expenses, which consist of clinical research and development expenses, manufacturing expenses, legal and compliance expenses, compensation and related expenses, and general overhead costs. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses. As of June 30, 2023 September 30, 2023, there have been no changes in our material cash requirements from known contractual and other obligations, including commitments for capital expenditures, as disclosed under "Liquidity and Capital Resources—Material Cash Requirements" in Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K.

We expect our expenses to increase in connection with our ongoing activities, particularly as we expand our clinical program with tegoprubart, continue the research and development of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

We will continue to require additional financing in order to advance our drug product through clinical development, to manufacture, obtain regulatory approval for and to commercialize our product candidates, to develop, acquire or in-license other potential product candidates, and to fund operations for the foreseeable future. Therefore, we will seek to raise additional capital through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. The ability to raise substantial additional capital will depend on many factors, including:

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials of tegoprubart, including as such activities may be adversely impacted by global events or macroeconomic conditions;
- the impact of global macroeconomic trends and uncertainties, which have recently experienced extreme volatility ar

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disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines i economic growth, increases in unemployment rates, increases in inflation rates, rising interest rates and uncertainty about economic stability;

- the number and scope of indications we decide to pursue for tegoprubart development;
- the cost, timing and outcome of regulatory review of any biologics license application, or BLA, we may submit for tegoprubart;
- the costs and timing of manufacturing for tegoprubart, if approved;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of tegoprubart;
- the costs associated with being a public company;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing tegoprubart, if approved for commercial sale.

Conditions in the financial and credit markets may also limit the availability of funding or increase the cost of funding. As a result of any of the foregoing factors, adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. As a result of the shares of our common stock issued in the initial closing or that may be issuable in the second or third closings of the Private Placement or upon the exercise of the Pre-Funded Warrants or the Common Warrants, our stockholders' ownership interests will be diluted. To the extent that we raise additional capital through the sale of additional equity or convertible debt securities in the future, our stockholders' ownership interests may be further diluted, and the terms of these securities may also include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise funds through collaborations, licenses and other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. Please see Part II, Item 1A. Risk Factors in this Quarterly Report on Form 10-Q for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

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On March 31, 2021,we filed a registration statement on Form S-3 containing a prospectus and prospectus supplement under which the Company may offer and sell up to $75.0 million in shares of its common stock, from time to time, pursuant to an open market sale agreement with Jeffries Jefferies LLC and by any method deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933 (the "ATM Program"). Pursuant to the "baby shelf rules" promulgated by the SEC, if the Company's public float is less than $75.0 million as of specified measurement periods, the number of shares of common stock that may be offered and sold by the Company under a Form S-3 registration statement, including pursuant to the ATM Program, in any twelve-month period is limited to an aggregate amount that does not exceed one-third of the Company's public float. As of June 30, 2023 September 30, 2023, the Company was permitted to sell up to $17.8 million $10.6 million of shares of common stock pursuant to the ATM Program under the SEC's "baby shelf" rules. The Company will remain subject to the "baby shelf " rules under the Form S-3 registration statement until such time as its public float exceeds $75.0 million. Through June 30, 2023 September 30, 2023, no shares of common stock have been sold under the ATM program. Under the Securities Purchase Agreement described in Note 9, the Company is restricted from selling shares under the ATM Program until the later of (i) 4 months from April 28, 2023 and (ii) ninety days after the registration statement filed pursuant to the Securities Purchase Agreement has been declared effective. The registration statement filed pursuant to the Securities Purchase Agreement was declared effective on June 2, 2023.

Cash Flows

The following table provides a summary of our net cash flow activity for six the nine months ended June 30, 2023 September 30, 2023 and 2022 (in thousands):

	For the Six Months Ended June 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Net cash used in operating activities	$ (18,145)	$ (14,373)	$ (30,396)	$ (18,944)
Net cash used in investing activities	(30,334)	—	(55,363)	—
Net cash provided by financing activities	33,017	—	33,017	—
Net change in cash and cash equivalents	$ (15,462)	$ (14,373)	$ (52,742)	$ (18,944)

Operating Activities

Net cash used in For the nine months ended September 30, 2023, operating activities for the six months ended June 30, 2023 used $30.4 million of cash, which primarily consisted primarily of our net loss of $20.4 million, partially offset by $30.7 million. Operating activities include adjustments for certain non-cash items consisting charges including $4.8 million of stock-based compensation, and amortization $0.3 million of operating lease assets totaling $3.3 million, amortization, partially offset by accretion of investment discounts of $0.1 million $0.6 million. Operating activities also include Net operating assets and liabilities changed by $4.2 million, primarily driven by a decrease in accounts payable

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and accrued expenses of $1.6 million $3.6 million, a decrease in operating lease liability of $0.2 million $0.3 million and an increase in prepaid expenses and other assets of $0.3 million.

For the nine months ended September 30, 2022, partially offset operating activities used $18.9 million of cash, which primarily consisted of our net loss of $29.6 million. Operating activities include adjustments for certain non-cash charges including $6.7 million of stock-based compensation and $0.3 million of operating lease amortization. Net operating assets and liabilities changed by $3.7 million, primarily driven by a decrease in prepaid expenses and other assets of $0.8 million.

Net cash used $2.1 million, a decrease in operating activities for the six months ended June 30, 2022 consisted primarily lease liability of our net loss $0.3 million and an increase in accounts payable and accrued expenses of $19.1 million, partially offset by non-cash items consisting primarily of stock-based compensation and amortization of

operating lease assets totaling $4.7 million. There was no impact to net cash as a result of changes in operating assets and liabilities for the six months ended June 30, 2022 $1.9 million.

Investing Activities

Net cash used in investing activities for the six nine months ended June 30, 2023 September 30, 2023 was $30.3 million, consisting primarily $55.4 million. We purchased $60.4 million of purchases short-term investments, which was partially offset by the maturing of available-for-sale $5.0 million of our short-term investments. investments during the period. There was no cash provided by or used in the investing activities for the six nine months ended June 30, 2022 September 30, 2022.

Financing Activities

Net cash provided by financing activities for the six nine months ended June 30, 2023 September 30, 2023 consisted of the Private Placement, totaling $33.0 million in net proceeds from the sale of 8.7 million shares of common stock and 6.4 million pre-funded warrants to purchase common stock. There was no cash provided by or used in financing activities for the six nine months ended June 30, 2022 September 30, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Per §229.305 of Regulation S-K, the Company, designated a Smaller Reporting Company as defined in §229.10(f)(1) of Regulation S-K, is not required to provide the disclosure required by this Item.

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Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2023 September 30, 2023, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, management concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of June 30, 2023 September 30, 2023.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) during the quarter ended June 30, 2023 September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

Neither we nor any of our subsidiaries is a party to, and none of their respective property is the subject of, any material legal proceeding, although we are from time-to-time party to legal proceedings that arise in the ordinary course of our business.

Item 1A. Risk Factors

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Quarterly Report on Form 10-Q and in our other public filings. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we

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may make from time to time. You should consider all of the risk factors described in our public filings when evaluating our business.

Unless otherwise indicated, references to the terms "Eledon", the "Company", "we", "our", and "us" refer to Eledon Pharmaceuticals, Inc.

Risks Related to Our Operations

Our short operating history and the Anelixis acquisition may make it difficult to evaluate the success of our business to date and to assess our future viability.

We are a clinical stage biopharmaceutical company. Our ongoing operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing technology, identifying potential product candidates and pursuing nonclinical and clinical trials. We have not yet demonstrated our ability to successfully manufacture drug product in large enough quantities and with stability to support additional clinical trials, execute pivotal clinical trials, obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. It can take many years to develop a new medicine from the time it is discovered to when it is available for treating patients. Consequently, any predictions made about our future success or viability based on our short operating history to date may not be as accurate as they could be if we had a longer operating history. In addition, as a result of the acquisition of Anelixis and our decision to discontinue our islet cell transplantation program and deprioritize the IgAN program, our future business, prospects, financial position and operating results could be significantly different than those in historical periods or previously projected by our management.

In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. To successfully market any of our current or future product candidates, we will need to transition from a company with a clinical development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As a result of the Private Placement described in Part I, Item 2, *Management's Discussion and Analysis of Financial Condition and Results of Operations,* we may receive up to an additional $105.0 million in tranche financing in a second and a third closing of the Private Placement, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $45.5 million assuming the exercise of all Common Warrants issued in the initial closing of the Private Placement. Due to the contingent nature of the Common Warrants and the second and third closings of the Private Placement, GAAP requires the Company to exclude them from its going concern analysis. Accordingly, based on recurring losses from operations incurred since inception, the expectation of continued operating losses, and the need to raise additional capital to finance our future operations, we determined

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that there is substantial doubt about our ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. Additionally, our independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2022, an explanatory paragraph that there is substantial doubt as to our ability to continue as a going concern. There is no assurance that the milestones required to complete the second and third closings of the Private Placement will be satisfied, that the Common Warrants will be exercised or that other funding will be available to

us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. The reaction of investors to the inclusion of a going concern statement by our auditors and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or enter into partnerships. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

We have incurred significant operating losses since our inception and expect that we will continue to incur losses over the next several years and may never achieve or maintain profitability.

We have incurred significant annual net operating losses in every year since our inception. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other general and administrative expenses related to our ongoing operations. If tegoprubart or any future product candidates we develop are not successfully developed and approved, we may never generate any revenue from sales of products. The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company's net loss for the six nine months ended June 30, 2023 September 30, 2023 is $20.4 million $30.7 million. As of June 30, 2023 September 30, 2023, the Company had cash and cash equivalents and short-term investments of $71.4 million $59.6 million, working capital of $68.7 million $60.1 million and an accumulated deficit of $223.2 million $233.6 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We expect it will be several years, if ever, before we have a product candidate ready for commercialization. We have financed our operations to date primarily through the sale of preferred and common stock, the sale of warrants, and the issuance of convertible promissory notes and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our net losses may fluctuate significantly from quarter to quarter and year to year and will depend, in part, on the rate at which we incur expenses and our ability to generate revenue. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We anticipate that we will continue to incur significant expenses as we:

- conduct nonclinical and clinical development of our product candidates or any future product candidate;

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- seek to identify and acquire additional product candidates;
- acquire or in-license other products and technologies;
- enter into collaboration arrangements with regards to product discovery or development;
- develop manufacturing processes;
- seek marketing approvals for any of our product candidates that successfully complete clinical trials;
- establish a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional personnel;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- operate as a public company.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant market potential. This will require us to be successful in a range of challenging activities, including completing clinical trials of our product candidates, obtaining marketing approval for these product candidates and manufacturing, marketing and selling those products for which we obtain marketing approval. We may never succeed in these activities, including if we do not have available financial resources to allow us to pursue clinical trials and other clinical development activities, and, even if we are successful, we may never generate revenues that are significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the Company, could impair our ability to raise capital, maintain our nonclinical and clinical development efforts, and expand our business or continue our operations and may require us to raise additional capital that may dilute the ownership interest of common stockholders. A decline in the value of the Company could also cause stockholders to lose all or part of their investment.

We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

Our financial statements have been prepared on a going concern basis, which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. As a result of the Private Placement described in Part I, Item 2, *Management's Discussion and Analysis of Financial Condition and Results of Operations*, we may also receive up to an additional $105.0 million in tranche financing in a second and a third closing of the Private Placement, subject to achieving specified clinical development milestones and volume weighted average share price levels and trading volume conditions, and an additional $45.5 million assuming the exercise of all

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Common Warrants issued in the initial closing of the Private Placement. There is no assurance that the milestones required to complete the second and third closings of the Private Placement will be satisfied or that the Common Warrants will be exercised. We can also provide no assurance that other funding will be available to us, will be obtained on terms favorable to us or will provide us with sufficient funds to meet our objectives. If we are unable to raise such capital, or if we are unable to do so on acceptable terms, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether. For example, we are currently unable to continue our clinical development of tegoprubart for people with ALS without additional financing, and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all.

Our funding needs may fluctuate significantly based on a number of factors, such as:

- the scope, progress, results and costs of formulation development and manufacture of drug product to support nonclinical and clinical development of our product candidates;
- the extent to which we enter into additional collaboration arrangements regarding product discovery or developme or acquire or in-license products or technologies;
- our ability to establish additional collaborations with favorable terms, if at all;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, f any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting formulation development, nonclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, 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, we will need to continue to rely on additional financing to achieve our business objectives. Even if we generate positive clinical data or are able to successfully commercialize one or more of our product candidates, additional financing may not be available to us on acceptable terms, or at all.

In addition to the dilution of our current stockholders' ownership as a result of the Private Placement, we currently have a significant number of securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price. Future issuances of our common stock, including common stock that may be issuable pursuant to outstanding warrants or other convertible securities, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

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As of June 30, 2023 September 30, 2023, there were 23,043,933 23,545,130 shares of our common stock outstanding. As a result of the first closing of the of Private Placement on May 5, 2023, we issued 8,720,168 8,730,168 shares of our common stock, Pre-Funded Warrants to purchase 6,421,350 shares of common stock and Common Warrants to purchase 15,151,518 shares of our common stock to the Purchasers therein. Additionally, up to 20,202,024 and 25,252,530 shares of common stock or Pre-Funded Warrants may be issued in a second and third closing of the Private Placement, respectively, subject to our achievement of certain milestones and conditions (which may be waived). The issuance of the common stock in the first closing of the Private Placement diluted the ownership interests of our existing stockholders, and the issuance of shares of common stock upon

exercise of the Pre-Funded Warrants or the Common Warrants issued in the initial closing of the Private Placement or any additional shares of common stock that may be issued, including pursuant to the exercise of additional Pre-Funded Warrants, in the second or third closings of the Private Placement, would result in significant additional dilution to our current stockholders, which could adversely affect the price of our common stock and the terms on which we could raise additional capital. If we sell additional shares of common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Our product candidates are in the early stages of clinical development and may not be successfully developed. If we are unable to successfully develop and commercialize these or any other product candidate, or if we experience significant delays in doing so, our business will be materially harmed.

We currently do not have any products that have gained regulatory approval. We have invested substantially all of our efforts and financial resources in the development of our lead drug candidate tegoprubart, including funding nonclinical studies, clinical trials, drug formulation and the manufacturing of clinical trial materials. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of one or more drug candidates. As a result, our business is substantially depending on our ability to successfully complete the development of and obtain approval for one of our potential future additional product candidates.

We have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical area. For example, to execute our business plan, we will need to successfully:

- obtain additional financing in order to advance our drug product through clinical development, and to manufacture obtain regulatory approval for and commercialize our product candidates;
- execute formulation, manufacturing, clinical, and nonclinical development activities;
- manufacture drug product at commercial scale;

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- establish and confirm commercially acceptable stability (shelf-life) of our drug products;
- in-license or acquire other product candidates and advance them through clinical development;
- obtain required regulatory approvals for the development and commercialization of tegoprubart or other product candidates;
- maintain, leverage, and expand our intellectual property portfolio;
- build and maintain robust sales, distribution and marketing capabilities, either on our own or in collaboration with strategic partners;
- gain market acceptance for any approved and marketed drug products;
- obtain and maintain adequate product pricing and reimbursement;
- develop and maintain any strategic relationships we elect to enter; and
- manage our spending as costs and expenses increase due to product manufacturing, nonclinical development, clinic trials, regulatory approvals, post-marketing commitments, and commercialization.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop and commercialize our or other product candidates, and our business will suffer.

The COVID-19 pandemic has adversely affected and it or other public health crises, including and future pandemics or epidemics could in the future adversely affect our business operations, which could have a material adverse effect on our business.

Our business and operations, including but not limited to ongoing or planned research and development activities, have been and may continue to be adversely affected by the COVID-19 pandemic, which has also caused significant disruption in the operations of third parties upon whom we rely. Other future public health crises, including any future pandemics or epidemics could have a similar impact on our business.

We have experienced, and may in the future experience disruptions as a result of the COVID-19 pandemic or from another public health crisis, including any future pandemic or epidemic, that could severely impact our operations and development activities, including, but not limited to:

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;
- delays in manufacturing of our drug candidates due to increased competition for manufacturing capacity as a result the pandemic;
- limitations in employee resources that would otherwise be focused on the conduct of our development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

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- refusal of the FDA to accept data from clinical trials in affected geographies;
- delays in procuring drug substance and/or in manufacturing drug product due to limitations in employee resources forced furloughs at our contract manufacturing organizations;
- delays in initiation of future clinical trials, including delays in receiving authorization from local regulatory authorities initiate such clinical trials; and
- delays or disturbances in enrollment and trial execution, for example, because clinical trial sites may be unable to operate normally, or patients may elect to forego visits to medical facilities or undertake voluntary medical procedures.

Any of the foregoing factors, or other effects of the COVID-19 pandemic or another public health crisis, including any future pandemic or epidemic, could materially affect our business, possibly to a significant degree. The severity and duration of any such impacts cannot be predicted.

Unfavorable global economic conditions could adversely affect our business, financial condition and results of operations

The global economy, including the financial and credit markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates, rising interest rates and uncertainty about economic stability. Likewise, the current conflict between conflicts in Ukraine and Russia has the Middle East have created extreme volatility in the global capital markets and global economic consequences, including disruptions of the global supply chain and energy markets. A severe or prolonged economic downturn or continued volatility in the financial and credit markets could negatively impact our ability to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all. The severity and duration of any such impacts cannot be predicted. Any such failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies or cause us to delay our clinical development plans, research and development programs or commercialization efforts, out-license intellectual property rights to our product candidates or sell unsecured assets, or a combination of the above. Any of these actions could materially harm our business. For example, we do not currently have sufficient liquidity to fund the continued clinical development of tegoprubart for people with ALS without additional financing, notwithstanding the positive topline results of our Phase 2a study of tegoprubart for adult subjects with ALS. In addition, if we are unable to raise capital, we will be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

In addition, inflation has recently increased throughout the U.S. economy. As a result of inflation, we have experienced and may continue to experience cost increases, including costs of clinical trials and research and development of our product candidates, production costs, the price of labor, administration and other costs of doing business. Although we may continue to take measures to mitigate the impact of this inflation, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Further, in an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets

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faster than forecasted. If this happens, we may need to raise more capital to fund our operations than expected, and such capital may not be available in sufficient amounts or on reasonable terms, if at all.

Adverse conditions in the financial markets, including bank failures, could adversely affect our liquidity and financial performance.

We currently maintain domestic cash deposits, for short term operating requirements, in Federal Deposit Insurance Corporation ("FDIC") insured banks, which exceed the FDIC insurance limits. Our additional cash and cash equivalents are held in accounts managed by third-party financial institutions and consist of primarily of cash invested in money market funds and government bonds. Bank failures, events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to widespread demands for customer withdrawals and liquidity constraints that may result in market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank failed and was taken into receivership by the FDIC. At that time, we maintained deposits amounting to approximately 78% of our total cash at Silicon Valley Bank. On March 26, 2023, the assets, deposits and loans of Silicon Valley Bank were acquired by First-Citizens Bank & Trust Company. In response to the failure of Silicon Valley Bank, we diversified our cash deposits into money market funds, U.S. treasuries and U.S. government agency securities and, as of the date of this report, our total cash maintained in FDIC insured banking accounts is less than 3% of our total cash and cash equivalents and short-term investments. The failure of a bank, or other adverse conditions in the financial or credit markets impacting financial institutions at which we maintain balances, could adversely impact our liquidity and financial performance. There can be no assurance that our deposits in excess of the FDIC or other comparable insurance limits will be backstopped by the U.S. or any applicable foreign government in the future or that any bank or financial institution with which we do business will be able to obtain needed liquidity from other banks, government institutions or by acquisition in the event of a future failure or liquidity crisis. Additionally, our cash investments outside of FDIC insured bank accounts are subject to general credit, liquidity, market, and interest rate risks. If the carrying value of an investment exceeds the fair value, and the decline in fair value is deemed to be other-than-temporary, we are required to write down the value of the investment, which could materially harm our results of operations and financial condition and could limit our access to liquidity.

Drug development involves a lengthy and expensive process with an uncertain outcome, including failure to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the formulation and commercialization of our product candidates.

Given the early stage of development for our product candidates, the risk of failure is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must conduct nonclinical trials, and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans.

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Formulation and device development, nonclinical and clinical testing are all expensive activities, difficult to design and implement, and can take years to complete. Failure can occur at any time during the development program, including during the clinical trial process. Further, the results of nonclinical studies and early clinical trials of our product candidates, as well as earlier generation formulations may not be predictive of the results of later-stage clinical trials. Interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical and clinical trials have nonetheless failed to obtain marketing approval of their products. There is a risk that additional nonclinical and/or clinical safety studies will be required by the FDA or similar regulatory authorities outside the United States and/or that subsequent studies will not match results seen in prior studies. It is impossible to predict when or if any of our product candidates will prove effective, safe and well-tolerated in humans or will receive regulatory approval.

We may experience delays in our clinical trials, and we do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. There can be no assurance that the FDA or equivalent foreign regulatory bodies will approve investigational new drug applications and allow us to start clinical trials for any of our product candidates in the future, including for islet cell transplant. Once a clinical trial has commenced, there is also no assurance that the FDA or equivalent foreign regulatory body will not put any of our product candidates on clinical hold. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design tha we want to execute;
- delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

- delays in reaching, or failure to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- delays in completing formulation development and manufacturing as a prerequisite to commencing clinical work;
- inability, delay, or failure in identifying and maintaining a sufficient number of trial sites, many of which may already engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our

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contract research organizations ("CROs") and other third parties;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulato may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trial at a higher rate than we anticipate;
- we may experience delays or difficulties in the enrollment of patients that our product candidates are designed to target;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have difficulty partnering with experienced CROs and study sites that can identify patients that our product candidates are designed to target and run our clinical trials effectively;
- regulators or IRBs may require that we or our investigators suspend or terminate clinical research for various reason including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; or
- there may be changes in governmental regulations or administrative actions. In addition, our development and commercialization activities could be harmed or delayed by a shutdown of the U.S. government, including the FDA. F example, a prolonged shutdown may significantly delay the FDA's ability to timely review and process any submissions we may file or cause other regulatory delays, which could materially and adversely affect our business.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- be subject to additional post-marketing restrictions and/or testing requirements; or
- have the product removed from the market after obtaining marketing approval.

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Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our nonclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant nonclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or may allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented and expenses for the development of our product candidates could increase.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to demonstrate safety and efficacy. We do not know whether the ongoing or planned clinical trials will enroll subjects in a timely fashion, require redesign of essential trial elements or be completed on its projected schedule. In addition, competitors may have ongoing clinical trials for product candidates that treat related or the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether.

Patient enrollment is affected by other factors including:

- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in othe clinical trial programs, including some that may be for the same disease indication;
- the patient referral practices of physicians;
- the proximity and availability of clinical trial sites for prospective patients;
- ambiguous or negative interim results of our clinical trials, or results that are inconsistent with earlier results;
- feedback from regulatory authorities, IRBs, ethics committees ("ECs"), or data safety monitoring boards, or results from earlier stage or concurrent nonclinical and clinical trials, that might require modifications to the protocol;
- decisions by regulatory authorities, IRBs, ECs, or the Company, or recommendations by data safety monitoring boards, to suspend or terminate clinical trials at any time for safety issues or for any other reason; and
- unacceptable risk-benefit profile or unforeseen safety issues or adverse effects.

Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of the Company to decline and limit our ability to obtain additional financing.

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Our ability to conduct clinical trials in some jurisdictions outside of the United States may be adversely affected.

We currently have clinical trial sites in regions outside the United States, including Asia, the European Union and the United Kingdom, and we will continue to conduct future clinical trials in these markets. Our ability to conduct clinical trials at sites located outside the United States is subject to numerous risks unique to conducting business in jurisdictions outside the United States, including:

- difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites;
- different local standards for the conduct of clinical trials;
- difficulty in complying with various and complex import laws and regulations when shipping drugs to certain countries;
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments;

- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries;
- instability in economic or political conditions, including inflation, recession and actual or anticipated military conflicts social upheaval or political uncertainty;
- foreign exchange fluctuations;
- cultural differences in medical practice and clinical research; and
- changes in country or regional regulatory requirements.

Additionally, Russia's February 2022 invasion of The ongoing conflict in Ukraine and the resulting imposition of economic and other sanctions by the United States, European Union and many other nations on Russia, individuals in Russia, Russian businesses and the Russian central bank, or any escalation of tensions in the region, could have a broader impact that expands into other countries. The ongoing conflict in the Middle East could have similar impacts. Although the length and impact of any military action and expansion of the conflict into other countries are highly unpredictable, if the either conflict spreads or has effects on additional countries, outside Ukraine and Russia, we may experience disruptions or delays in our plans to conduct clinical trial activities in affected regions outside the United States.

If serious adverse events or unacceptable side effects are identified during the development of our product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidates are associated with undesirable effects in nonclinical or clinical trials or have characteristics that are unexpected, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent,

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less severe or more acceptable from a risk-benefit perspective. Any occurrences of clinically significant adverse events with our product candidates may harm our business, financial condition and prospects significantly.

Tegoprubart is an early□product candidate, and the side effect profile in humans has not been fully established. Currently unknown, drug-related side effects may be identified through ongoing and future clinical trials and, as such, these possible drug-related side effects could affect patient recruitment, the ability of enrolled subjects to complete the trial, or result in potential product liability claims.

Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate qualified personnel in the future.

We are highly dependent on the product development, clinical and business development expertise of the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executives and key employees, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. Our recent decision to discontinue the islet cell transplantation program and deprioritize the IgAN program and uncertainties regarding our financial condition may increase the likelihood that employees depart in the foreseeable future.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel is critical to our success. Due to the small size of the Company and the limited number of employees, each of our executives and key employees serves in a critical role. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating drug product, nonclinical development, clinical development, regulatory strategy, and commercial strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to provide services to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Risks Related to Regulatory Approval of Our Product Candidates and Other Legal Compliance Matters

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If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, or the approvals may be for a narrow indication, we may not be able to commercialize our product candidates, and our ability to generate revenue may be materially impaired.

Our product candidates must be approved by the FDA pursuant to a new drug application in the United States and by other regulatory authorities outside the United States prior to commercialization in the respective regions. The process of obtaining marketing approvals, both in the United States and outside the United States, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate. We have not received approval to market any of our product candidates from regulatory authorities in any country. We have no experience in filing and supporting the applications necessary to gain marketing approvals for our products and may engage third-party consultants to assist in this process. Securing marketing approval requires the submission of extensive nonclinical and clinical data, and other supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product formulation and manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical, clinical or other data. In addition, varying interpretations of the data obtained from nonclinical and clinical trials could delay, limit or prevent marketing approval of a product candidate. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application.

Any marketing approval we ultimately obtain may be for fewer or more limited indications than requested or subject to restrictions or post-approval commitments that render the approved product not commercially viable or its market potential significantly impaired. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

In order to market and sell our products in the EU and other international jurisdictions outside of the United States, we or our third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may require additional nonclinical, clinical or health outcome data. In addition, the time required to obtain approval may differ substantially amongst international jurisdictions. The regulatory approval process outside the United States generally includes all the risks associated with obtaining FDA approval. In addition to regulatory approval, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially

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impaired.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

Our product candidates and the activities associated with their development and commercialization, including their testing, manufacture, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation that are specific to those defined by regulatory authorities in the countries where the product is approved. In the United States and other countries that follow the International Conference on Harmonization, these requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, including periodic inspections by the FDA and other regulatory authorities, requirements regarding the distribution of samples to physicians and recordkeeping.

The FDA, or other regulatory authorities, may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products and if we promote our products beyond their approved indications, we may be subject to enforcement action for off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers, or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;

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- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the EU's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Legislation regulating the pharmaceutical and healthcare industries may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes intended to contain healthcare costs and modify the regulation of drug and biologic products. These and other regulatory changes could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

For example, on August 16, 2022, the U.S. government enacted the Inflation Reduction Act of 2022, which, among other things, includes policies that are designed to have a direct impact on drug prices and reduce drug spending by the federal government, which shall take effect in 2023. The Inflation Reduction Act requires drug manufacturers to pay rebates to Medicare if they increase prices faster than inflation for certain drugs used by Medicare beneficiaries. The mechanics of the rebate calculation would mimic those of the Medicaid rebate, but the expansion of inflation-based rebates may further complicate pricing strategies. The Inflation Reduction Act of 2022 or other similar legislation could have the effect of reducing the prices we can charge and reimbursement we receive for our products, thereby reducing our profitability.

We expect that additional state and federal healthcare reform measures and regulations will be adopted in the future. Any of these measures and regulations could limit the amounts that federal and state governments will pay for healthcare products and services, result in reduced demand for our product candidates or additional pricing pressures and affect our product development, testing, marketing approvals and post-market activities.

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Laws, restrictions, and other regulatory measures are also imposed by healthcare laws and regulations in international jurisdictions and in those jurisdictions we face the same issues as in the United States regarding difficulty and cost for us to obtain marketing approval and commercialization of our product candidates and which may affect the prices we may obtain.

In some countries, particularly the countries of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our business operations and relationships with healthcare providers, physicians, third-party payers, and customers will be subject to applicable anti-kickback, fraud and abuse and other broadly applicable healthcare laws, which could expose us to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payers will play a primary role in the recommendation and prescription of any product candidates for which we receive marketing approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute the products for which we receive marketing approval. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, federal and state healthcare laws are and will be applicable to our business. Such laws include, but are not limited to federal false claims, false statements and civil monetary penalties laws, including the federal civil False Claims Act ("FCA"), the federal Anti-Kickback Statute, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 ("HITECH"), the federal transparency requirements under the Physician Payments Sunshine Act, and analogous state, local or foreign law.

Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines,

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imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, that person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Laws, restrictions, and other regulatory measures are also imposed by anti-kickback, fraud and abuse, and other healthcare laws and regulations in international jurisdictions, and in those jurisdictions we face the same issues as in the United State regarding exposure to criminal sanctions, civil penalties, program exclusion, contractual damages, reputational harm, and diminished profits and future earnings.

We depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches,

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disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

European data collection is governed by restrictive regulations governing the collection, use, processing and cross-border transfer of personal information.

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We may collect, process, use or transfer personal information from individuals located in the European Economic Area in connection with our business, including in connection with conducting clinical trials in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the European Economic Area. The collection and use of personal health data in the European Economic Area is governed by the provisions of the General Data Protection Regulation ((EU) 2016/679) (the "GDPR"), along with other European Union and country-specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the European Economic Area, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals' requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact assessments and record-keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the European Economic Area and other states in the European Economic Area may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our nonclinical or clinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, we may fail to achieve the degree of market acceptance by physicians, patients, third-party payers and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, we may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers and others in the medical community. In addition, physicians, patients and third-party payers may prefer other novel products to ours. If our product candidates do not achieve an

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adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments;
- the ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement, including patient cost-sharing programs such a copays and deductibles;
- the ability to develop or partner with third-party collaborators to develop companion diagnostics;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If our current product candidates, or a future product candidate receives marketing approval and we, or others, later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, the ability to market the product could be compromised.

Clinical trials are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent beneficial effect of a product candidate that is greater than the actual positive effect in a broader patient population or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- the product may be required to be recalled or changes may be required to the way the product is administered;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the product;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- the creation of a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- additional restrictions may be imposed on the distribution or use of the product via a Risk Evaluation and Mitigation Strategy;

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- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business. The commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We currently have no marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues.

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. In order to commercialize any product candidates, we must build on a territory-by-territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we intend to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which will be expensive and time-consuming, will require significant attention of our executive officers to manage and may nonetheless fail to effectively market and sell our product candidates. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our products that we obtain approval to market. With respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are several large pharmaceutical and biotechnology

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companies that currently market and sell products or are pursuing the development of products for the treatment of the disease indications for which we are developing our product candidates. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a number of companies developing competing anti-CD40 and anti-CD40L therapeutics in clinical trials for transplant, autoimmune or central nervous system indications, including: Novartis, Sanofi, UCB, Amgen (post-acquisition of Horizon Therapeutics), Bristol Myers Squibb, and Kiniksa. All of these companies are larger than Eledon and have significantly greater resources to develop their drug candidates.

If approved, we expect that tegoprubart will face competition from numerous FDA-approved therapeutics for the prevention of transplant rejection, including PROGRAF®, ASTAGRAF XL®, ENVARSUS XR®, NULOJIX®, CELLCEPT®, MYFORTIC®, and numerous other branded and generic immunosuppressive agents. Multiple companies are working on islet cell and kidney transplant solutions that may ultimately potentially negate the need for immunosuppressive agents in these indications altogether.

If approved, we expect tegoprubart will face competition from other FDA-approved therapeutics for the treatment of lupus nephritis, focal segmental glomerulosclerosis or IgAN, including TARPEYO™, LUPKYNIS™ and BENLYSTA®, SPARSENTAN, and numerous other branded and generic medicines are already being used “off-label” to treat them.

We expect that tegoprubart will face competition from FDA-approved therapeutics for the treatment of ALS including RADICAVA®, RELYVRIO™, RILUZOLE, and numerous other branded and generic immunosuppressive agents. Multiple pharmaceutical and biotechnology companies, including but not limited to Biogen, Ionis Pharmaceuticals, Alexion Pharmaceuticals, Orion Pharma, Orphazyme, AZTherapies, Voyager Therapeutics, Apic Bio, Brainstorm Cell Therapeutics, and Cytokinetics, are also working on competing ALS pharmaceutical, gene therapy and cell therapy approaches.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products.

Generic products are currently available, with additional generic products expected to become available over the coming years, potentially creating pricing pressure. If our product candidates achieve marketing approval, we expect that they will be priced at a significant premium over competitive generic products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, conducting nonclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers

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and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payers is essential for most patients to be able to afford expensive treatments. Sales of our product candidates will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payers. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, as CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare. Private payers tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

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Moreover, increasing efforts by governmental and third-party payers, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. Increased expense is incurred to cover costs of health outcome focused research used to generate data necessary to justify the value of our products in order to secure reimbursement. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

In addition, many private payers contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that we may develop; injury to our reputation and significant negative media attention; withdrawal of clinical trial participants; significant costs to defend the related litigation; substantial monetary awards to trial participants or patients; loss of revenue; reduced resources of our management to pursue our business strategy; and the inability to commercialize any products that we may develop.

We currently hold $10.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $10.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks Related to Our Dependence on Third Parties

We contract with third parties for the manufacture of our product candidates for nonclinical and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not

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have sufficient quantities of our product candidates or products at an acceptable cost and quality, which could delay, prevent or impair our development or commercialization efforts.

We have utilized, and intend to continue utilizing, third parties to formulate, manufacture, package, and distribute clinical supplies of our drug candidates. We have no experience in manufacturing and do not have any manufacturing facilities. Currently, we rely on third parties for the manufacturing of drug substance and drug product for nonclinical and clinical activities. Our manufacturing vendors utilize proprietary cell culture media, cell lines, buffers, manufacturing equipment, manufacturing supplies, and storage buffers for the manufacturing of tegoprubart and other product candidates. These materials are custom-made and available from only a limited number of sources. Although we believe that our third-party suppliers maintain a significant supply of these materials and equipment on hand, any sustained disruption in this supply, could adversely affect our operations. We do not have any long-term agreements in place with our current suppliers. If we are required to change manufacturers, we may experience delays associated with finding an alternate manufacturer that is properly qualified to produce supplies of our products and product candidates in accordance with regulatory requirements and our specifications. Any delays or difficulties in obtaining or in manufacturing, packaging or distributing approved product candidates could negatively impact our clinical trials.

We expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of any other product candidates for which our collaborators or we obtain marketing approval. Despite drug substance and product risk management, this reliance on third parties presents a risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts. For example, these third parties experienced disruptions in their operations in conjunction with the COVID-19 pandemic. Any delay or performance failure on the part of our existing or future manufacturers of drug substance or drug products could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply. If suppliers cannot supply us with our requirements, we may be required to identify alternative manufacturers, which would lead us to incur added costs and delays in identifying and qualifying any such replacement.

Formulations and devices used in early studies are not final formulations and devices for commercialization. Additional changes may be required by the FDA or other regulatory authorities on specifications and storage conditions. These may require additional studies and may result in a delay in our clinical trials and commercialization activities.

We also expect to rely on other third parties to label, store, and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We may be unable to establish any 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:

- reliance on the third party for regulatory compliance and quality assurance;

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- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient f us.

The third parties we rely on for manufacturing and packaging are also subject to regulatory review, and any regulatory compliance problems with these third parties could significantly delay or disrupt our clinical or commercialization activities. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Additionally, macro-economic conditions may adversely affect these third parties, causing them to suffer liquidity or operational problems. If a key third-party vendor becomes insolvent or is forced to lay off workers assisting with our projects, our results and development timing could suffer.

Our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We depend on CROs and other contracted third parties to perform nonclinical and clinical testing and certain other research and development activities. As a result, the outcomes of the activities performed by these organizations will be, to a certain extent, beyond our control.

The nature of outsourcing a substantial portion of our business will require that we rely on CROs and other contractors to assist us with research and development, clinical testing activities, patient enrollment, data collection, and regulatory submissions to the FDA or other regulatory bodies. As a result, our success will depend partially on the success of these third parties in performing their responsibilities. Although we intend to pre-qualify our CROs and other contractors and we believe that the contractors selected will be fully capable of performing their contractual obligations, we cannot directly control the adequacy and timeliness of the resources and expertise that they apply to these activities. Additionally, macro-economic conditions may affect our development partners and vendors, which could adversely affect their ability to timely perform their tasks. If our contractors do not perform their obligations in an adequate and timely

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manner, the pace of clinical development, regulatory approval and commercialization of our drug candidates could be significantly delayed, and our prospects could be adversely affected.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology and products or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in relevant countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and internationally that are related to our novel technologies and product candidates. This patent portfolio includes issued patents and pending patent applications covering pharmaceutical compositions and methods of use.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions, and under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our discovery and nonclinical development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, India and China do not allow patents for methods of treating the human body. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the

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patent laws in the EU, the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

The risks described pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases, we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

The USPTO and various non-U.S. governmental patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In certain situations, non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

In addition, we have acquired rights to tegoprubart and other product candidates through a license agreement with The ALS Therapy Development Institute, and may in the future enter into other license agreements with third parties for other intellectual property rights or assets. These license agreements may impose various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our drug candidates than if we had developed the licensed technology internally.

In some cases, patent prosecution of our licensed technology may be controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We

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may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference or derivation proceedings before the USPTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If we were not able to obtain a license or are not able to obtain a license on commercially reasonable terms, our business could be harmed, possibly materially.

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If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Any NDAs or similar agreements entered into by the Company may not be with all relevant parties, or adequately protect the confidentiality of our trade secrets. Moreover, to the extent we enter into such agreements, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate them, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

We may be subject to claims of misappropriation of trade secrets from former employers of Company personnel.

Many of our employees and certain of our directors were previously employed at or affiliated with research foundations or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees and directors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or directors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or director's former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Common Stock

We expect our stock price to be volatile, and the market price of our common stock may drop unexpectedly.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biopharmaceutical, and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- uncertainties regarding our financial condition and our ability to raise sufficient capital to fund our ongoing operations;
- our ability to obtain regulatory approvals for our product candidates or other product candidates, and delays or failures to obtain such approvals;

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- failure of any of our product candidates, if approved, to achieve commercial success;
- issues in manufacturing our approved products, if any, or product candidates;
- the results of our current and any future clinical trials of our product candidates;
- the entry into, or termination of, key agreements, including key commercial partner agreements;
- the initiation of, material developments in, or conclusion of litigation to enforce or defend any of our intellectual property rights or defend against the intellectual property rights of others;
- announcements by commercial partners or competitors of new commercial products, clinical progress, or the lack thereof, significant contracts, commercial relationships, or capital commitments;
- the introduction of technological innovations or new therapies that compete with our potential products;
- the loss of key employees;
- changes in estimates or recommendations by securities analysts, if any, who cover our common stock;
- general and industry-specific economic conditions that may affect our research and development expenditures;
- changes in the structure of healthcare payment systems;
- period-to-period fluctuations in our financial results; and
- future issuances of shares of common stock.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we will have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP.

If we are unable to successfully maintain internal controls over financial reporting, the accuracy and timing of our financial reporting, and our stock price, may be adversely affected and we may be unable to maintain compliance with the applicable stock exchange listing requirements. Additionally, as we become a larger company, we will become subject to Section 404(b) of the Sarbanes-Oxley Act, which requires our independent auditors to document and test our internal controls. These additional requirements are costly, and our auditors may identify control deficiencies.

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Implementing any appropriate changes to our internal controls may distract the officers and employees of the Company, entail substantial costs to modify its existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of the internal controls of the Company, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase operating costs and harm the business. In addition, investors' perceptions that the internal controls of the Company are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm the stock price of the Company.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of the Company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our corporate charter and bylaws may discourage, delay or prevent a merger, acquisition or other change in control of the Company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by stockholders to replace or remove the current management by making it more difficult for stockholders to replace members of our Board. Among other things, these provisions:

- establish a classified Board such that not all members of the Board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board;
- limit the manner in which stockholders can remove directors from our Board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our Board to issue preferred stock without stockholder approval, which could be used to institute a "poisc pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of the Company's charter or bylaws.

We do not expect to pay any cash dividends in the foreseeable future.

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We expect to retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain, if any, for any stockholders for the foreseeable future.

Item 2. Unregistered Sales of Equity Securities, and Use of Proceeds. Proceeds and Issuer Purchases of Equity Securities.

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
2.1	Agreement and Plan of Merger, dated September 14, 2020, by and among Novus Therapeutics, Inc., Nautilus Merger Sub 1, Inc., Nautilus Merger Sub 2, LLC and Anelixis Therapeutics, Inc. (filed with the SEC as Exhibit 2.1 to the Company's Current Report on Form 8-K filed on September 15, 2020).
3.1	Restated Certificate of Incorporation of Novus Therapeutics, Inc., a Delaware corporation, dated September 22, 2014 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on September 26, 2014).
3.2	Certificate of Amendment to Certificate of Incorporation of Novus Therapeutics, Inc. (effecting, among other things a reverse stock-split), filed with the Secretary of the State of Delaware on May 9, 2017 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on May 15, 2017).

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3.3	Certificate of Amendment to Certificate of Incorporation of Novus Therapeutics, Inc. (effecting, among other things a change in the corporation's name to "Novus Therapeutics, Inc."), filed with the Secretary of the State of Delaware on May 9, 2017 (filed with the SEC as Exhibit 3.2 on the Company's Current Report on Form 8-K filed on May 15, 2017).
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of Novus Therapeutics, Inc., (effecting, among other things a reverse stock-split) effective as of October 5, 2020 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on October 6, 2020).
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of Novus Therapeutics, Inc., (effecting, among other things a change in the corporation's name to "Eledon Pharmaceuticals, Inc.") effective as of January 5, 2021 (filed with the SEC as Exhibit 3.1 on the Company's Current Report on Form 8-K filed on January 5, 2021).
3.6	Certificate of Designations of Series X Convertible Preferred Stock (filed with the SEC as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on February 19, 2020).
3.7	Certificate of Designations of Series X_1 Convertible Preferred Stock (filed with the SEC as Exhibit 3.1 to the Company's Current Report on Form 8-K filed on September 15, 2020).
3.8	Amended and Restated Bylaws of Eledon Pharmaceuticals, Inc. (filed with the SEC as Exhibit 3.2 to the Company's Current Report on Form 8-K filed on January 5, 2021).
4.1	Form of Pre-Funded Warrant to Purchase Common Stock (filed with the SEC as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on May 1, 2023).
4.2	Form of Tranche A Warrant to Purchase Common Stock or Pre-Funded Warrants (filed with the SEC as Exhibit 4.2 to the Company's Current Report on Form 8-K filed on May 1, 2023).
10.1 10.1†	Securities Purchase Form of Indemnification Agreement dated April 28, 2023 to be entered into with each of the directors and officers of Eledon (filed with the SEC as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on May 1, 2023).
10.2	Registration Rights Agreement, dated April 28, 2023 (filed with the SEC as Exhibit 10.2 to the Company's Current Report on Form 8-K filed on May 1, 2023).

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10.3	David-Alexandre Gros, M.D. Letter Agreement, dated April 27, 2023 (filed with the SEC as Exhibit 10.3 to the Company's Current Report on Form 8-K filed on May 1, 2023).

10.4	Steve Perrin, Ph.D. Letter Agreement, dated April 27, 2023 (filed with the SEC as Exhibit 10.4 to the Company's Current Report on Form 8-K filed on May 1, 2023).
10.5†	Eledon Pharmaceuticals, Inc. 2020 Long Term Incentive Plan, as amended (filed with the SEC as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on June 22, 2023 September 21, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of 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 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 Inline 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
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document

101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

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104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.

** Furnished herewith.

† Management contract or compensatory plan or arrangement.

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.

Eledon Pharmaceuticals, Inc.

Date: August 10, 2023 November 9, 2023 By: /s/ David-Alexandre C. Gros, M.D.

David-Alexandre C. Gros, M.D.
Chief Executive Officer and Director (Principal Executive Officer)

Date: August 10, 2023 November 9, 2023 By: /s/ Paul Little

Paul Little
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATIONS

I, David-Alexandre C. Gros, M.D., certify that:

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

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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 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 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 10, 2023 November 9, 2023

By: /s/ David-Alexandre C. Gros, M.D.

David-Alexandre C. Gros, M.D.
Chief Executive Officer
(Principal Executive Officer)

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Exhibit 31.2

CERTIFICATIONS

I, Paul Little, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Eledon 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 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 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):

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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 10, 2023 November 9, 2023

By: /s/ Paul Little

Paul Little

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Eledon Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2023 September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David-Alexandre C. Gros, M.D., Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 10, 2023 November 9, 2023

By: /s/ David-Alexandre C. Gros, M.D.

David-Alexandre C. Gros, M.D.

Chief Executive Officer

(Principal Executive Officer)

Exhibit 32.2

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CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Eledon Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2023 September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Paul Little, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: August 10, 2023 November 9, 2023

By: /s/ Paul Little

Paul Little
Chief Financial Officer
(Principal Financial and Accounting Officer)

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