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 30, 2022

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:

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 10, 2022, there were 13,756,788 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 in this Quarterly Report on Form 10-Q about the Company's future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, the review of strategic alternatives and the outcome of such review and other statements containing words such as "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "could," "may," and similar expressions, constitute forward-looking statements, 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; 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 important 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-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.
- 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.
- 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.
- The ongoing COVID-19 pandemic and actions taken in response to it may result in additional disruptions to our business operations, which could have a material adverse effect on our business.
- Unfavorable global economic conditions could have a material adverse effect on our business.
- 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.
- The results of nonclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, and there is a risk that additional nonclinical and/or clinical safety studies will be required by the U.S. Food and Drug Administration 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.
- We will require additional funding to be able to complete the development of our lead drug candidate. If we are unable to raise capital when needed, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.
- Our future success depends on our ability to retain executives and key employees and to attract, retain and motivate 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 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.
- 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.
- 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.
- 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 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.
- 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 or 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 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.
- 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 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 results 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 difficult and may prevent attempts by our stockholders to replace or remove our current management.

ELEDON PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED June 30, 2022

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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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 70,460	$ 84,833
Prepaid expenses and other current assets	2,328	3,513
Total current assets	72,788	88,346
Operating lease asset, net	581	768
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	303	400
Total assets	$ 154,706	$ 170,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,318	$ 1,813
Current operating lease liability	287	369
Accrued expenses and other liabilities	1,671	2,219
Total current liabilities	3,276	4,401
Deferred tax liability	1,752	1,752
Non-current operating lease liability	299	400
Total liabilities	5,327	6,553
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares authorized; 117,970 and 108,070 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares authorized; 6,204 shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 13,756,788 and 14,306,788 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	14	14
Additional paid-in capital	283,375	278,880
Accumulated deficit	(134,010)	(114,899)
Total stockholders' equity	149,379	163,995
Total liabilities and stockholders' equity	$ 154,706	$ 170,548

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)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	$ 5,743	$ 4,242	$ 12,378	$ 9,895
General and administrative	3,540	3,729	6,764	7,081
Total operating expenses	9,283	7,971	19,142	16,976
Loss from operations	(9,283)	(7,971)	(19,142)	(16,976)
Other income/(expense), net	36	(1)	31	4
Loss before income tax benefit	(9,247)	(7,972)	(19,111)	(16,972)
Income tax benefit	—	588	—	1,089
Net loss and comprehensive loss	$ (9,247)	$ (7,384)	$ (19,111)	$ (15,883)
Net loss per share, basic and diluted	$ (0.65)	$ (0.50)	$ (1.34)	$ (1.07)
Weighted-average common shares outstanding, basic and diluted	14,265,905	14,815,731	14,299,969	14,823,348

See accompanying notes to unaudited condensed consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Series X[1] Non-Voting Convertible Preferred Stock		Series X Non-Voting Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount			
Balance as of December 31, 2021	108,070	$ —	6,204	$ —	14,306,788	$ 14	$ 278,880	$ (114,899)	$ 163,995
Cancellation of common stock in connection with exchange for X[1] non-voting convertible preferred stock	9,900	—	—	—	(550,000)	—	1	—	1
Stock-based compensation	—	—	—	—	—	—	4,494	—	4,494
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(19,111)	(19,111)
Balance as of June 30, 2022	117,970	$ —	6,204	$ —	13,756,788	$ 14	$ 283,375	$ (134,010)	$ 149,379
Balance as of March 31, 2022	117,970	$ —	6,204	$ —	13,756,788	$ 14	$ 281,067	$ (124,763)	$ 156,318
Stock-based compensation	—	—	—	—	—	—	2,308	—	2,308
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(9,247)	(9,247)
Balance as of June 30, 2022	117,970	$ —	6,204	$ —	13,756,788	$ 14	$ 283,375	$ (134,010)	$ 149,379
Balance as of December 31, 2020	108,070	$ —	—	$ —	15,160,397	$ 15	$ 270,974	$ (80,393)	$ 190,596
Cancellation of common stock in connection with exchange for preferred stock	—	—	6,204	—	(344,666)	—	—	—	—
Cancellation of common stock in connection with exchange for warrants	—	—	—	—	(509,117)	(1)	1	—	—
Stock-based compensation	—	—	—	—	—	—	3,808	—	3,808
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(15,883)	(15,883)
Balance as of June 30 2021	108,070	$ —	6,204	$ —	14,306,614	$ 14	$ 274,783	$ (96,276)	$ 178,521
Balance as of March 31, 2021	108,070	$ —	6,204	$ —	14,306,614	$ 14	$ 272,749	$ (88,892)	$ 183,871
Stock-based compensation	—	—	—	—	—	—	2,034	—	2,034
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(7,384)	(7,384)
Balance as of June 30 2021	108,070	$ —	6,204	$ —	14,306,614	$ 14	$ 274,783	$ (96,276)	$ 178,521

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,	
	2022	**2021**
Operating activities		
Net loss	$ (19,111)	$ (15,883)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of operating lease asset	187	90
Stock-based compensation	4,494	3,808
Deferred tax liabilities	—	(1,089)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	1,282	(53)
Accounts payable and accrued expenses	(1,042)	609
Operating lease liability	(183)	(94)
Net cash used in operating activities	(14,373)	(12,612)
Financing activities		
Offering costs in connection with PIPE transaction	—	(450)
Net cash used in financing activities	—	(450)
Net change in cash and cash equivalents	(14,373)	(13,062)
Cash and cash equivalents at beginning of period	84,833	114,195
Cash and cash equivalents at end of period	$ 70,460	$ 101,133
Supplemental disclosure of non-cash investing and financing activities		
Common stock exchanged for X^1 preferred stock	$ 1	$ —
Common stock exchanged for warrants	$ —	$ 1
Increase in operating lease asset and liability due to lease modification	$ —	$ 219

See accompanying notes to unaudited condensed consolidated financial statements.

Note 1. Description of Business

Eledon Pharmaceuticals, Inc. (formerly Novus Therapeutics, Inc.) is a clinical stage biopharmaceutical company focused on developing life-changing, targeted medicines for persons living with an autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis ("ALS"). 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.

The Company's lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 ligand, a well-validated biological target with broad therapeutic potential.

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 has continued to maintain its corporate headquarters in Southern California and has research and development facilities in the Boston, Massachusetts area.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("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, 2021 included in the Annual Report on Form 10-K filed by the Company with the SEC on March 24, 2022. The results of operations and comprehensive loss for the three and six months ended June 30, 2022 are not necessarily indicative of results expected for the full fiscal year or any other future period.

Principles of Consolidation

Eledon, a Delaware corporation, owns 100% of the issued and outstanding common stock or other ownership interest in Anelixis Therapeutics, LLC, a Delaware corporation, 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.

Liquidity and Financial Condition

The Company has experienced recurring net losses and negative cash flows from operating activities since its inception. The Company recorded a net loss of $9.2 million and $19.1 million for the three and six months ended June 30, 2022, respectively. As of June 30, 2022, the Company had cash and cash equivalents of $70.5 million, working capital of $69.5 million and an accumulated deficit of $134.0 million. Due to continuing research and development activities, the Company expects to continue to incur net losses into the foreseeable future. In order to continue these activities, the Company will need to raise additional funds through public or private debt and equity financings or strategic collaboration and licensing arrangements. The Company's ability to raise additional capital in the equity and debt markets is dependent on a number of factors, including, but not limited to, the market demand for the Company's common stock, which itself is subject to a number of development and business risks and uncertainties, as well as the uncertainty that the Company would be able to raise such additional capital at a price or on terms that are favorable to the Company. If the Company issues equity or convertible debt securities to raise additional funding, its existing stockholders may experience dilution, it may incur significant financing costs, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of its existing stockholders. If the Company issues debt securities to raise additional funding, it would incur additional debt service obligations, it could become subject to additional restrictions limiting its ability to operate its business, and it may be required to further encumber its assets.

At the time of issuance of the condensed consolidated financial statements for the three and six months ended June 30, 2022, the Company's management performed an analysis and concluded that the Company had sufficient cash resources to meet its anticipated cash needs through at least the next 12 months from the date of issuance of the accompanying 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, including goodwill, 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.

Cash and Cash Equivalents

Cash represents cash deposits held at financial institutions. The Company considers all liquid investments purchased with an original maturity of three months or less and that can be liquidated without prior notice or penalty to be cash equivalents. The carrying value of cash equivalents approximates their fair value due to the short-term maturities of these instruments. Cash equivalents are held for the purpose of meeting short-term liquidity requirements, rather than for investment purposes. The Company had $9.2 million of cash equivalents at June 30, 2022 and December 31, 2021.

Concentration of Credit Risk and Other Risks and Uncertainties

As of June 30, 2022 and December 31, 2021, all of the Company's long-lived assets were located in the United States.

Financial instruments that are subject to concentration of credit risk consist primarily of cash equivalents. The Company's policy is to invest cash in institutional money market funds to limit the amount of credit exposure. At times, the Company maintains cash equivalents in short-term money market funds and it has not experienced any losses on its cash equivalents.

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 facilities and equipment, including those of our suppliers and vendors, may be affected by natural or man-made disasters. Our administrative office is based in Irvine, California and we manage all our research and development activities through third parties that are located throughout the world. We have taken precautions to safeguard our facilities, equipment and systems, including insurance, health and safety protocols, and off-site storage of computer data. However, our facilities and systems, as well as those of our third-party suppliers and vendors, may be vulnerable to earthquakes, fire, storm, health emergencies, including the ongoing COVID-19 pandemic or other future health crises, power loss, telecommunications failures, physical and software break-ins, software viruses and similar events which could cause substantial delays in our operations, damage or destroy our equipment or inventory, and cause us to incur additional expenses and delay research and development activities. In addition, the insurance coverage we maintain may not be adequate to cover our losses in any circumstance and may not continue to be available to use on acceptable terms, or at all.

Reportable Segments

Operating segments under GAAP are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the Chief Operating Decision Maker ("CODM"), or decision-making group, in deciding how to allocate resources and in assessing performance. The CODM is the Company's Chief Executive Officer and the Company has determined that it operates in one business segment, which is the development of products for therapeutic medicines selectively targeting critical pathways associated with the underlying molecular pathogenesis for patients with severe inflammation and autoimmune diseases.

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.

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, as well as reasonable shutdown costs. 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 months ended June 30, 2022.

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, preferred stock, convertible notes and accrued interest, stock options, warrants and restricted stock units ("RSUs") 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 months ended June 30, 2022 include 509,117 shares underlying warrants to purchase common shares. As the shares underlying these 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,	
	2022	2021	2022	2021
	(In thousands, except share and per share data)			
Net loss used in the calculation of basic and diluted loss per share	$ (9,247)	$ (7,384)	$ (19,111)	$ (15,883)
Net loss per share, basic and diluted	$ (0.65)	$ (0.50)	$ (1.34)	$ (1.07)
Weighted-average number of common shares, basic and diluted	14,265,905	14,815,731	14,299,969	14,823,348

The computation of diluted earnings per share excludes stock options, warrants, and RSUs that are anti-dilutive. As of June 30, 2022 and 2021, common share equivalents of 8,321,473 shares and 654,231 shares were anti-dilutive, respectively.

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 that 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, it 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 members of 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.

RSUs and performance-based RSUs ("PRSUs") 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").

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. Based on projected utilization rates, the Board currently intends that the initial shares under the 2020 Plan will be sufficient to fund the Company's equity compensation needs for approximately three years from the date of the Special Meeting.

The 2014 Plan was closed to new grants following the approval of the 2020 Plan, and therefore, there were no shares reserved for issuance under the 2014 Plan as of June 30, 2022. The number of shares reserved for issuance under the 2020 Plan and ESPP was 3,095,131 and 24,077 shares, respectively, as of June 30, 2022.

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 3. Prepaid Expenses and Other Current Assets

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

	June 30, 2022	December 31, 2021
Prepaid insurance	$ 698	$ 1,344
Prepaid clinical	1,373	2,039
Prepaid other	225	96
Other current assets	32	34
Total prepaid expenses and other current assets	$ 2,328	$ 3,513

Note 4. Accrued Expenses and Other Liabilities

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

	June 30, 2022	December 31, 2021
Accrued compensation and related expenses	$ 1,061	$ 1,411
Accrued severance	—	104
Accrued clinical	472	454
Accrued professional services	125	167
Accrued other	13	83
Total accrued expenses and other liabilities	$ 1,671	$ 2,219

Note 5. Commitments and Contingencies

Operating Leases

The Company leases office space under various operating leases. Total rental expense for all operating leases in the accompanying condensed consolidated statements of operations and comprehensive loss was $0.1 million for the three months ended June 30, 2022 and 2021, and $0.2 million and $0.1 million for the six months ended June 30, 2022 and 2021, respectively.

The Company has an operating lease for 5,197 square feet of office space in Irvine, California, which expires on December 31, 2022.

On November 4, 2021, the Company entered into an operating lease for approximately 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 ranging from nine months to less than three years 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.

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:

	For the Six Months Ended June 30,	
	2022	2021
Operating lease cost[(a)]	$ 203	$ 98

[(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,	
	2022	2021
Supplemental Cash Flows Information		
Cash paid for amounts included in the measurement of lease liability:		
Operating cash flows from operating lease	$ 193	$ 97
Remaining lease term		
Operating lease	1.91 years	1.5 years
Discount rate		
Operating lease	3.00%	3.18%

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, 2022
2022 (remainder of)	$ 194
2023	212
2024	200
Total minimum lease payments	606
Less imputed interest	(20)
Present value of lease liabilities	586
Less current portion of operating lease liability	(287)
Non-current operating lease liability	$ 299

Grants and Licenses

ALS Therapy Development Foundation, Inc. License Agreement

In May 2015, Anelixis executed a License Agreement (the "ALS 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 ALS Agreement continues until the licensee terminates the agreement with ninety days written notice. The ALS 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 ALS 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 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 months ended June 30, 2022 or the year ended December 31, 2021.

The ALS 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 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 ALS Agreement.

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.

Israeli Innovation Authority Grant

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, 2022; therefore, no liability was recorded for the repayment in the accompanying condensed consolidated financial statements.

Legal Matters

The Company is involved in various lawsuits and claims arising in the ordinary course of business, including actions with respect to intellectual property, employment, and contractual matters. In connection with these matters, the Company assesses, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the financial statements if it is believed to be probable that a loss has been incurred and the amount of the loss can be reasonably estimated. Because litigation is inherently unpredictable and unfavorable results could occur, assessing

contingencies is highly subjective and requires judgments about future events. The Company regularly reviews outstanding legal matters to determine the adequacy of the liabilities accrued and related disclosures. The amount of ultimate loss may differ from these estimates. Each matter presents its own unique circumstances, and prior litigation does not necessarily provide a reliable basis on which to predict the outcome, or range of outcomes, in any individual proceeding. Because of the uncertainties related to the occurrence, amount, and range of loss on any pending litigation or claim, the Company does not consider a liability probable and is currently unable to predict their ultimate outcome, and, with respect to any pending litigation or claim where no liability has been accrued, to make a meaningful estimate of the reasonably possible loss or range of loss that could result from an unfavorable outcome. In the event that opposing litigants in outstanding litigation proceedings or claims ultimately succeed at trial and any subsequent appeals on their claims, any potential loss or charges in excess of any established accruals, individually or in the aggregate, could have a material adverse effect on the Company's business, financial condition, results of operations, and/or cash flows in the period in which the unfavorable outcome occurs or becomes probable, and potentially in future periods.

Legal Proceedings

We are not currently a party to any material legal proceedings. We may, however, in the ordinary course of business face various claims brought by third parties or government regulators and we may, from time to time, make claims or take legal actions to assert our rights, including claims relating to our directors, officers, stockholders, intellectual property rights, employment matters and the safety or efficacy of our products.

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, 2022.

Note 6. Stockholders' Equity

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, from time to time, pursuant to an open market sale agreement with Jeffries 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, 2022, due to the SEC's "baby shelf rules," the Company was permitted to sell up to $14.5 million of shares of common stock pursuant to the ATM Program. 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, 2022, no shares of common stock have been sold under the ATM program.

Common Stock Warrants

As of June 30, 2022, there were 1,145,631 warrants exercisable into common stock (after rounding for fractional shares and subject to beneficial ownership blockers).

	Roll Forward of Warrant Activity					
	Registered direct warrants, placement agent	Private placement warrants	Private placement warrants, placement agent	Warrants exchanged for common stock	Warrants exchanged for Series X^1 preferred stock	Total
Balance as of December 31, 2021	$ 9,581	$ 319,064	$ 9,177	$ 509,117	$ 298,692	$ 1,145,631
Issued	—	—	—	—	—	—
Exercised	—	—	—	—	—	—
Cancelled/Expired	—	—	—	—	—	—
Balance as of June 30, 2022	9,581	319,064	9,177	509,117	298,692	1,145,631

Exchange Agreements

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 Preferred Stock.

Preferred Stock Warrants

As of June 30, 2022, there were 50,207.419 warrants exercisable into Series X^1 Preferred Stock, which are convertible into 2,789,301 shares of common stock (after rounding for fractional shares and subject to beneficial ownership conversion blockers).

	Roll Forward of Series X^1 Convertible Preferred Warrant Activity
	Total
Balance as of December 31, 2021	50,207.419
Assumed and replaced	—
Exercised	—
Cancelled/Expired	—
Balance as of June 30, 2022	50,207.419

Stock-Based Compensation

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,	
	2022	2021	2022	2021
Research and development	$ 924	$ 785	$ 1,804	$ 1,470
General and administrative	1,384	1,249	2,690	2,338
Total stock-based compensation	$ 2,308	$ 2,034	$ 4,494	$ 3,808

Note 7. Subsequent Events

The Company has evaluated events subsequent to June 30, 2022 through the filing date of this Quarterly Report on Form 10-Q. Any material subsequent events that occurred during this time have been properly recognized or disclosed in the condensed consolidated financial statements and accompanying notes.

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, 2021 included in the Annual Report on Form 10-K filed by the Company with the Securities and Exchange Commission (the "SEC") on March 24, 2022. 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* 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. References to the term "Tokai" refer to Tokai Pharmaceuticals, Inc., the legal predecessor of the Company.

ABOUT ELEDON PHARMACEUTICALS

Overview

Eledon Pharmaceuticals, Inc. ("Eledon" or the "Company") is a clinical stage biopharmaceutical company focused on developing life-changing, targeted medicines for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with amyotrophic lateral sclerosis ("ALS"). The Company's lead compound in development is tegoprubart, an IgG1, anti-CD40L antibody with high affinity for CD40 Ligand ("CD40L", also called "CD154"), a well-validated biological target that we believe has broad therapeutic potential.

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 for autoimmune diseases and in the transplant setting.

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.

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

Our business strategy is to optimize the clinical and commercial value of tegoprubart and become a global biopharmaceutical company with a focused autoimmune franchise. We plan 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 our molecule or historical anti-CD40L molecules.

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 2 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 APCs and activated T cells. The potential for 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 clinical 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 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.

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 bi-weekly infusions of tegoprubart over the study 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. 32 different inflammatory biomarkers were detectable in the study population, including TNF-α, MCP1, EN-RAGE, C-Reactive Protein (CRP), and IL-6. IL-1b was not detected in the study patient population. Statistically significant dose-dependent reductions were observed in 23 of these biomarkers, including TNF-α, MCP1, EN-RAGE, and CRP. Pro-inflammatory biomarkers significantly reduced included biomarkers also associated with IgA nephropathy and kidney transplant rejection, such as IgA, IgE, IgM, C3, CXCL9, and CXCL10. While the study was neither primarily designed nor powered to assess the effect of tegoprubart on ALS Functional Rating Scale (“ALSFRS”), both target engagement and level of pro-inflammatory biomarker reduction were associated with a trend in the slowing of disease progression as measured by ALSFRS slope. The Company is committed to further progressing ALS clinical development, and plans to work with key opinion leaders, our patient community, and regulators 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, and we can provide no assurances that we will be able to obtain financing on acceptable terms or at all.

Kidney transplantation: prevention of allograft rejection

Kidney transplantation is the most common type of solid organ transplantation in the United States with an estimated 227,000 Americans living with a transplanted kidney. In 2019, an estimated 23,000 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. are waiting 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 nephrotoxicity, cardiotoxicity, new onset diabetes due to pancreatic Beta cell toxicity and an increase in both opportunistic infections and malignancies. 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.

In July 2021, the Company received a No Objection Letter (NOL) from Health Canada 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. In December 2021, the Company received regulatory approval from the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom to add additional sites to the Phase 1b clinical trial. No subjects have been enrolled in the Phase 1b study as of June 30, 2022.

Islet cell transplantation: prevention of allograft rejection

Type 1 diabetes is a T cell mediated autoimmune disease with progressive loss of insulin producing pancreatic beta cells and affects over one million persons in the U.S. Of these individuals, an estimated 70,000 people have a particularly hard to control type 1 diabetes called Brittle Diabetes ("BT1D") which is in part characterized by large swings in blood glucose levels and impaired awareness of hypoglycemia. Impaired awareness of hypoglycemia for people with type 1 diabetes is associated with severe hypoglycemic events which can lead to significant symptoms and even death. Pancreatic islet cell transplantation may be a therapeutic option for type 1 diabetes because it can restore physiological insulin secretion, minimize the risk of hypoglycemic unawareness, and reduce the risk of death due to severe hypoglycemia. The advances made in this field over the past decade have improved patient outcomes.

A number of issues are believed to continue to hamper the overall success of islet cell transplantation and to need to be addressed in order for there to be widespread clinical acceptance. These include the acute loss of transplanted islets with current immunosuppressive treatments, particularly those with CNI-based therapies, due to islet cell toxicity and alloreactive immunologic responses to transplanted islets. Over time, the progressive loss of islet cells and decline in islet cell function often leads to the need for multiple transplant procedures in order for BTID patients to have optimal response to blood glucose levels and possibly achieve insulin independence. We believe that treatment with tegoprubart will address the challenges associated with current islet cell transplantation immunosuppressive regimens using CNI-based therapies, by replacing the CNIs with tegoprubart. CD40L blockade may abolish many effector mechanisms of inflammation, prevent, and intervene in the progression of autoimmunity, and instill transplant tolerance without causing harm to islet cells.

Historical studies in nonhuman primate models of islet cell transplantation have demonstrated that treatment with anti-CD40L antibodies induces long term islet cell function and graft survival, even as a monotherapy. Tegoprubart has shown pre-clinical, proof-of-concept efficacy in a non-human primate model of type 1 diabetes, where animals undergoing islet cell transplantation maintained glucose control and sustained levels of C-peptide with chronic tegoprubart treatment for up to a year. Compared to combination immunosuppressive therapy including CNIs, tegoprubart monotherapy was more effective in preventing long term islet cell rejection, associated with better graft function, and showed an improved safety profile.

In November 2020, the Company received clearance from Health Canada to proceed with the initiation of a Phase 2a clinical trial of tegoprubart for people with type 1 diabetes undergoing islet cell transplantation. In November 2021, the Company received investigational new drug ("IND") clearance from the FDA for a Phase 2a clinical trial of tegoprubart for up to six people with type 1 diabetes undergoing islet cell transplantation in the United States. No subjects have been enrolled in the Phase 2a study as of June 30, 2022.

IgA Nephropathy

IgAN is the leading cause of 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 patients 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. There are currently no European Medicines Agency ("EMA") approved treatments for IgAN, although in the United States budesonide was approved for use in IgAN by the FDA in December 2021.

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

Through June 30, 2022, the Company received regulatory clearances to initiate a phase 2a study in IgAN in Australia, Malaysia, New Zealand, Philippines, Spain, Sri Lanka and the United Kingdom, and plans to expand the study in up to 5 additional countries. The global study is a 96-week open-label, dose ranging trial, and will include up to 42 subjects in high dose and a low dose cohorts. The primary endpoint is change in urinary protein:creatinine ratio (UPCR) at week twenty-four. Secondary endpoints include change in estimated Glomerular Filtration Rate (eGFR) at week 96 as well as safety and tolerability. The first subject was dosed in May 2022.

Market Trends and Uncertainties

We may face future business disruption and related risks resulting from the ongoing outbreak of COVID-19 or from another pandemic, epidemic or infectious disease outbreak, or from broader macroeconomic trends, any of which could have a significant impact on our business or delay the development of our product candidates or completion of our current and proposed clinical trials. Although the impacts of COVID-19 have not been material to-date, we have experienced delays in certain clinical studies and resulting delays in data collection and have also experienced inefficiencies in planning and executing trials due to our limited ability to conduct meetings with key third parties and we could experience further delays and inefficiencies in the future. We will continue to monitor the impact of COVID-19 on our operations, including enrollment and execution of our clinical trials.

In addition, 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. We have utilized a range of financing methods to fund our operations in the past; however, current conditions in the financial and credit markets may limit the availability of funding or increase the cost of funding. If we are unable to obtain necessary debt or equity financing in a timely manner or on favorable terms, if at all, then our ability to continue clinical development of our product candidates or fund additional clinical studies will be adversely impacted.

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 months ended June 30, 2022, as compared to those disclosed in the Annual Report on Form 10-K for the year ended December 31, 2021, filed by the Company with the SEC on March 24, 2022.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended June 30, 2022 and 2021

The following table provides comparative unaudited results of operations for the three months ended June 30, 2022 and 2021 (in thousands):

	For the Three Months Ended June 30,		
	2022	2021	$ Variance
Operating expenses:			
Research and development	$ 5,743	$ 4,242	$ 1,501
General and administrative	3,540	3,729	(189)
Total operating expenses	9,283	7,971	1,312
Loss from operations	(9,283)	(7,971)	(1,312)
Other income/(expense), net	36	(1)	37
Loss before income tax benefit	(9,247)	(7,972)	(1,275)
Income tax benefit	—	588	(588)
Net loss	$ (9,247)	$ (7,384)	$ (1,863)

Research and Development Expenses

Research and development expenses increased $1.5 million, to $5.7 million for the three months ended June 30, 2022, as compared to $4.2 million for the three months ended June 30, 2021. The increase was primarily due to an increase in clinical development costs of $0.6 million, primarily with external CROs, as we advance our tegoprubart program, an increase in consulting expenses of $0.8 million as well as increases in personnel costs of $0.2 million, due to increased headcount and stock-based compensation costs of $0.1 million. The increase was partially offset by a decrease of $0.2 million in external costs related to the production of clinical trial materials.

General and Administrative Expenses

General and administrative expenses decreased $0.2 million to $3.5 million for the three months ended June 30, 2022, as compared to $3.7 million for the three months ended June 30, 2021. The decrease was primarily related to decline in personnel related costs of $0.5 million, due to lower headcount, and general operating costs of $0.1 million. The decrease was partially offset by an increase in professional services of $0.3 million and stock-based compensation costs of $0.1 million.

Other Income (Expense), Net

The increase in other income (expense), net was primarily due to an increase in interest income and a decrease in realized losses on foreign currency translation for the three months ended June 30, 2022.

Income Tax Benefit

The Company recognized an income tax benefit of $0.6 million for the three months ended June 30, 2021 due to the change in deferred tax liabilities for acquired in-process research and development ("IPR&D") related to the Anelixis acquisition.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table provides comparative unaudited results of operations for the six months ended June 30, 2022 and 2021 (in thousands):

	For the Six Months Ended June 30,		
	2022	2021	$ Variance
Operating expenses:			
Research and development	$ 12,378	$ 9,895	$ 2,483
General and administrative	6,764	7,081	(317)
Total operating expenses	19,142	16,976	2,166
Loss from operations	(19,142)	(16,976)	(2,166)
Other income, net	31	4	27
Loss before income tax benefit	(19,111)	(16,972)	(2,139)
Income tax benefit	—	1,089	(1,089)
Net loss	$ (19,111)	$ (15,883)	$ (3,228)

Research and Development Expenses

Research and development expenses increased $2.5 million, to $12.4 million for the six months ended June 30, 2022, as compared to $9.9 million for the six months ended June 30, 2021. The increase was primarily due to an increase in clinical development costs of $1.7 million, primarily with external CROs, as we advance our tegoprubart program, an increase in consulting services of $0.9 million as well as increases in personnel costs of $0.4 million, due to increased headcount, and stock-based compensation costs of $0.3 million. The increase was partially offset by a decrease of $0.8 million in external costs related to the production of clinical trial materials.

General and Administrative Expenses

General and administrative expenses decreased $0.3 million to $6.8 million for the six months ended June 30, 2022, as compared to $7.1 million for the six months ended June 30, 2021. The decrease was primarily related to declines in personnel costs of $0.6 million, due to lower headcount, and general operating costs of $0.1 million. The decrease was partially offset by an increase in stock-based compensation costs of $0.4 million.

Other Income (Expense), Net

The increase in other income, net, was primarily due to an increase in interest income and a decrease in realized losses on foreign currency translation for the six months ended June 30, 2022.

Income Tax Benefit

The Company recognized an income tax benefit of $1.1 million for the six months ended June 30, 2021 due to the change in deferred tax liabilities for acquired IPR&D related to the Anelixis acquisition.

LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

As of June 30, 2022, we had cash and cash equivalents of $70.5 million, consisting of readily available cash in bank accounts. While we believe our cash and cash equivalents are not subject to excessive risk, we maintain significant amounts of cash at one or more financial institutions that are in excess of federally insured limits. 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.

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.

We believe our cash balance at June 30, 2022, will be sufficient to meet our projected operating requirements for at least the next 12 months from the date of this filing. 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. 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 announced in May 2022. 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 ALS clinical 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, 2022, there have been no material changes in our 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, including the COVID-19 pandemic, the ongoing conflict in Ukraine;
- the impact of global macroeconomic trends and uncertainties, which have 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;
- the number and scope of indications we decide to pursue for tegoprubart development;
- the cost, timing and outcome of regulatory review of any 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.

Current 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, and may result in a prolonged suspension of our ALS clinical development or cause us to delay the scope of or suspend one or more of our other clinical trials, 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may 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.

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 $75.0 million in shares of its common stock, from time to time, pursuant to an open market sale agreement with Jeffries 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, 2022, due to the SEC's "baby shelf rules," the Company was permitted to sell up to $14.5 million of shares of common stock pursuant to the ATM Program. 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, 2022, no shares of common stock have been sold under the ATM program.

Cash Flows

The following table provides a summary of our net cash flow activity (in thousands):

	For the Six Months Ended June 30,	
	2022	**2021**
Net cash used in operating activities	$ (14,373)	$ (12,612)
Net cash used in financing activities	—	(450)
Net change in cash and cash equivalents	$ (14,373)	$ (13,062)

Comparison of the Six Months Ended June 30, 2022 and 2021

Net cash used in operating activities for the six months ended June 30, 2022 consisted primarily of our net loss of $19.1 million, partially offset by non-cash items consisting 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.

Net cash used in operating activities for the six months ended June 30, 2021 consisted primarily of our net loss of $15.9 million, partially offset by non-cash items consisting primarily of stock-based compensation and amortization of operating lease assets totaling $3.9 million, as well as deferred income taxes of $1.1 million. Additionally, cash used in operating activities for the six months ended June 30, 2021 reflected a net increase in cash from changes in operating assets and liabilities of $0.5 million, primarily due to an increase in our prepaid expenses and other current assets of $0.1 million, an increase in our accounts payable and other accrued expenses of $0.6 million, and a decrease in operating lease liability of $0.1 million.

There was no cash provided by or used in the Company's investing activities for the six months ended June 30, 2022 and 2021.

Net cash used in financing activities for the six months ended June 30, 2021 was comprised of $0.5 million of offering costs accrued as of December 31, 2020 in connection with the sale of shares of common stock.

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.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2022, 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 levels, as of June 30, 2022.

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, 2022 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

Information pertaining to legal proceedings is provided under the heading "Legal Proceedings" in Note 5, Commitments and Contingencies, to the condensed consolidated financial statements and is incorporated by reference herein.

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 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 our future business, prospects, financial position and operating results could be significantly different than those in historical periods or 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 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.

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 quarter ended June 30, 2022 is $9.2 million. As of June 30, 2022, the Company had cash and cash equivalents of $70.5 million, working capital of $69.5 million and an accumulated deficit of $134.0 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 sales of equity. We 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;
- 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.

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 our efforts and financial resources in product development, including funding our formulation and device development, manufacturing, nonclinical studies, and clinical trials. A significant portion of our financial resources were devoted to the development of products for patients with disorders of the ear, nose, and throat, particularly our surfactant-based product for the treatment of Otitis Media; however, in June 2020 topline results from our phase 2a clinical trial of OP0201 nasal aerosol in infants and children with acute otitis media did not meet the primary efficacy endpoints in the trial and our board of directors (the "Board") initiated a review of strategic alternatives that resulted in the acquisition of Anelixis, a privately held clinical stage biotechnology company with a single product candidate in clinical development (tegoprubart) and a second candidate in pre-clinical development (AT-2001). 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 dependent on our ability to successfully complete the development of and obtain regulatory 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;
- 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, clinical 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 ongoing COVID-19 pandemic and actions taken in response to it have resulted and may continue to result in disruptions to 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 ongoing COVID-19 pandemic, which has also caused significant disruption in the operations of third parties upon whom we rely.

Our clinical trials have also been affected by, and may continue to be affected by, the COVID-19 pandemic. Clinical site initiation and patient enrollment have been, and may continue to be, delayed due to the prioritization of hospital resources toward the COVID-19 pandemic. Some patients have not been able to, and others may not be able to, comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, any inability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

Our business may experience additional disruptions as a result of the COVID-19 pandemic or from another pandemic, epidemic or infectious disease outbreak 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 of 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;
- 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 or forced furloughs at our contract manufacturing organizations;
- delays in initiation of future clinical trials, including delays in receiving authorization from local regulatory authorities to initiate such clinical trials; and
- delays 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.

The further spread of COVID-19 and its effects, including actions to limit the spread of the illness, or other pandemics, epidemics or infectious disease outbreaks could impact our ability to carry out our business and may materially adversely impact global economic conditions. Any of the foregoing factors, or other effects of the COVID-19 pandemic or another pandemic, epidemic or infectious disease outbreak, 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 Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further 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, and may result in a prolonged suspension of our ALS clinical development or cause us to delay the scope of or suspend one or more of our other clinical trials, 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.

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 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.

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. 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 that 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 be 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 CROs and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators 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 trials 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 reasons, 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. For 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.

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 other 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.

We may not be able to conduct clinical trials in some jurisdictions outside of the United States.

We expect to open clinical trial sites in regions outside the United States during 2022, including the European Union and the United Kingdom, and we may conduct future clinical trials in markets outside the United States. 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 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. Although the length and impact of any military action and expansion of the conflict into other countries are highly unpredictable, if the conflict spreads or has effects on 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, 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.

Although we have raised significant capital, we will require additional funding to be able to complete the development of our lead drug candidate and identify and develop new product candidates. If we are unable to raise capital when needed, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

We expect our expenses to increase in parallel with our ongoing activities, particularly as we incur expenses relating to the exploration of strategic options intended to maximize stockholder value, seek to identify new clinical candidates and potentially seek to partner, out-license or otherwise monetize our drug candidates. If we are unable to raise capital when needed or on attractive terms, we may 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 development, 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, for 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, additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise sufficient capital to fund our planned operations, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or liquidate and cease operations altogether.

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 acquisition of Anelixis and the resulting integration of the company 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

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 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;
- 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.

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.

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, 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, 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.

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 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 as 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;
- 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 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, including Novartis, Boehringer Ingelheim, Astellas, AbbVie, Sanofi, UCB, Horizon Therapeutics (post acquisition of Viela Bio), 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 LN, FSGS 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®, 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, Cytokinetics, and Amylyx Pharmaceuticals 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 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.

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 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, including as a result of operational disruptions related to the ongoing COVID-19 pandemic, 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. In addition, the operations of these third parties have been and may continue to be significantly disrupted by the ongoing 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;
- 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 for 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 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 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 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.

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:

- our ability to obtain regulatory approvals for our product candidates or other product candidates, and delays or failures to obtain such approvals;
- 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; and
- period-to-period fluctuations in our financial results.

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 accounting principles generally accepted in the United States ("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.

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 "poison 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.

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.

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).
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).
10.1#	Amended and Restated License Agreement by and between ALS Therapy Development Foundation, Inc. and Anelixis Therapeutics, Inc., dated February 18, 2020
10.2	First Amendment to Restated License Agreement between ALS Therapy Development Foundation, Inc. and Anelixis Therapeutics, Inc. dated September 5, 2020
10.3#	License Agreement between Lonza Sales AG and Anelixis Therapeutics, LLC, dated September 11, 2018
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
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.

As permitted by Regulation S-K, Item 601(b)(10)(iv) of the Securities Exchange Act of 1934, as amended, certain portions of this exhibit have been redacted from the publicly filed document.

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 11, 2022 By: /s/ David-Alexandre C. Gros, M.D.

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

Date: August 11, 2022 By: /s/ Paul Little

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

Certain identified information has been redacted from this exhibit because it is both (i) not material and (ii) a type that the registrant treats as private or confidential. Information that has been omitted has been identified in this document with a placeholder identified by the mark "[***]."

AMENDED AND RESTATED LICENSE AGREEMENT

by and between

ALS THERAPY DEVELOPMENT FOUNDATION, INC.

and

ANELIXIS THERAPEUTICS, INC.

dated FEBRUARY 18,

2020

CONFIDENTIAL

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AMENDED AND RESTATED LICENSE AGREEMENT

This Amended and Restated License Agreement, dated as of February 18, 2020, (this "Agreement") amends and restates the May 20, 2015 License Agreement, as amended by a First Amendment dated December 5, 2017 and effective as of June 1, 2017, a Second Amendment dated and effective as of December 17, 2018, and a Third Amendment dated September 17, 2019 (collectively, the "Original License Agreement"), each by and between ALS Therapy Development Foundation, Inc., d/b/a ALS Therapy Development Institute, Inc., a Massachusetts non-profit corporation ("ALSTDI") and Anelixis Therapeutics, Inc., f/k/a Anelixis Pharmaceuticals, Inc., a Delaware corporation ("Company") (each referred to as a "Party", and together the "Parties"). This Agreement is a restatement of, and replaces in its entirety, the Original License Agreement and all prior amendments. In the event of any conflict between this Agreement and the Original License Agreement or the prior amendments, the terms contained in this Agreement will prevail.

R E C I T A L S

WHEREAS, ALSTDI is the owner of certain Licensed Patent Rights (as later defined herein);

WHEREAS, ALSTDI and Company have entered into a Research Services Agreement related to a certain Contract # W81XWH-17-1-0057 issued by the U.S. Army Medical Research Acquisition Activity, U.S. Department of Defense under which certain Inventions (as defined in the Research Services Agreement) are being assigned to ALSTDI.

WHEREAS, ALSTDI desires to have the Licensed Patent Rights developed and commercialized to benefit the public and is willing to grant a license thereunder;

WHEREAS, Company has represented to ALSTDI, to induce ALSTDI to enter into this Agreement, that Company shall commit itself to a diligent program of exploiting the Licensed Patent Rights so that public utilization shall result therefrom; and

WHEREAS, Company desires to obtain an amended license under the Licensed Patent Rights upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, ALSTDI and Company hereby agree as follows:

1. DEFINITIONS.

1.1 "Affiliate" means, as to a Person, any other Person that controls, is controlled by, or is under common control with, such Person, but only for so long as such control exists. For the purposes of this definition, the term "control" means: (i) beneficial ownership of at least fifty percent (50%) of the voting securities of a corporation or other business organization with voting securities, (ii) a fifty percent (50%) or greater interest in the net assets or profits of a partnership or other business organization without voting securities, (iii) having the right to direct, appoint or remove a majority of members of the board of directors (or equivalent), or (iv) having the power

to control the general management of the corporation or other business organization.

1.2 "Change of Control" means, with respect to Company, (a) a merger or consolidation of Company with a third party which results in the voting securities of Company outstanding immediately prior thereto ceasing to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger or consolidation, (b) a transaction or series of related transactions in which a third party, together with its Affiliates, becomes the owner of fifty percent (50%) or more of the combined voting power of Company's outstanding securities, or (c) the sale or other transfer to a third party of all or substantially all of Company's assets or all or substantially all of the Company's business to which this Agreement relates.

1.3 "Clinical Trial" means a Phase I Clinical Trial, Phase HA Clinical Trial, Phase IIB Clinical Trial or Phase III Clinical Trial.

1.4 "Commercially Reasonable Efforts" means, as to the efforts to be expended by a Party with respect to any objective, the efforts and resources that are consistent with the exercise of customary scientific and business practices that a company within the pharmaceutical or biopharmaceutical industry similarly situated to such Party (including in size and resources) relating to the research, development or commercialization of a similar product with comparable market potential and at a similar stage in its lifecycle, taking into account all relevant factors, including relative safety and efficacy, product profile, stage in product lifecycle, the regulatory environment, payors' policies and regulations, competitiveness of the marketplace and the market potential of such products, the nature and extent of market exclusivity, including patent coverage and regulatory data protection, and price and reimbursement status.

1.5 "Control" means, as to any Know-How, patent right or other intellectual property right, the possession (whether by ownership or license, other than by a license granted pursuant to this Agreement) by a Party or its Affiliates of the ability to grant to the other Party access, ownership, a license or a sublicense as required herein to such Know-How, patent right, or other intellectual property without (i) violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such party or its Affiliates would first be required hereunder to grant the other party such access, ownership, license or sublicense or (ii) violating any law or regulation. "Controlled", "Controls" and "Controlling" have their correlative meanings.

1.6 "Executive Officers" shall have the meaning set forth in Section 12.3(a) of this Agreement.

1.7 "Field" means any and all uses or indications in humans (for clarity, including preventative and diagnostic uses).

1.8 "First Commercial Sale" means the first sale, transfer, disposition, performance or practice of a Licensed Product, for value, following receipt of Regulatory Approval and any applicable pricing and reimbursement approvals for such product.

1.9 "IND" means an investigational new drug application filed with the United States Food and Drug Administration prior to beginning clinical trials in humans in the United States or

any comparable application filed with regulatory authorities in or for a country or group of countries other than the United States.

1.10 "Know-How" means all technical, scientific and other know-how, information, technology, methods, processes and practices, and all Provided Materials, whether or not confidential, proprietary, or patentable.

1.11 "Licensed IP" means the Licensed Patent Rights and the Licensed Know-How.

1.12 "Licensed Know-How" means (i) the Know-How owned and Controlled by ALSTDI as of the date of this Agreement that is necessary for the research, development or commercialization of Licensed Products, including the Know-How set forth in Exhibit 1.15(i) and
(ii) the Know-How set forth in Exhibit 1.15(ii) that is owned and Controlled by ALSTDI and necessary for the research, development or commercialization of Licensed Products, excluding in each case (i) and (ii) any patents, patent applications or other patent rights (or foreign equivalents thereof) that describe, claim or cover such Know-How.

1.13 "Licensed Patent Rights" means the patents and patent applications that are listed on the attached Appendix A and any and all divisionals, continuations, continuations-in-part (only to the extent of claims that are entitled to the priority date of and directed specifically to the subject matter claimed in the applications listed on the attached Appendix A, substitutes, counterparts and foreign equivalents thereof filed in any country, and any patents issuing thereon (but in the case of patents issuing on continuations-in-part applications, only to the claims thereof that are entitled to the priority date of and directed specifically to the subject matter claimed in the applications listed on the attached Appendix A and any reissues, reexaminations or extensions thereof.

1.14 "Licensed Product" means any product the manufacture, use or sale of which would infringe or be covered by one or more Valid Claims in Licensed Patent Rights.

1.15 "Maintenance Fee" has the meaning set forth in Section 4.1(c).

1.16 "Milestone Events" means, collectively, the milestone events indicated in Sections 4.1(a) and 4.1(b).

1.17 "Milestone Payments" means, collectively, the milestone payments indicated in Sections 4.1(a) and 4.1(b).

1.18 "Net Sales" means:

(a) The gross amount invoiced by Company, its Affiliates and Sublicensees (for the purposes of this Section 1.18, "Seller") for Licensed Products less the following:

(i) Customary trade, quantity, wholesaler, distributor, prompt payment, or cash discounts or rebates to the extent actually allowed and taken, including those granted on account of price adjustments;

(ii) Amounts repaid, rebated or credited by reason of claim, trade, retroactive

price reduction, rejection or return, and upon uncollectable amounts;

(iii) rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), international organizations or federal, state/provincial, local, and other governments, their agencies and purchasers and reimbursers, or to trade customers;

(iv) credits for allowances given or made for wastage replacement for the Licensed Products;

(v) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) that Seller allocates to sales of Licensed Products in accordance with such Seller's standard policies and procedures consistently applied across its products, as applicable;

(vi) To the extent separately stated on purchase orders, invoices, or other documents of sale, any taxes or other governmental charges levied on the Licensed Product;

(vii) Outbound transportation costs, including carriage and freight, and costs of insurance in transit to the extent actually incurred.

(b) In the case of a sale or other transfer of a Licensed Product within Seller, or between or among Company, a Sublicensee or an Affiliate of Company or a Sublicensee, or between or among such Affiliates, for further sale or other transfer by such transferee, Net Sales shall be based on the gross amount billed, invoiced or received for the first sale or other transfer of such Licensed Product to an entity other than Company, a Sublicensee or an Affiliate of Company or a Sublicensee.

(c) No deductions will be made for commissions paid to individuals whether they are with independent sales agencies or regularly employed by Seller, and on its payroll, or for cost of collections.

(d) Any sale or supply of a Licensed Product for the purposes of testing, or trials (including performance of Clinical Trials) or use prior to the grant of Regulatory Approval in the country of use, shall not result in any Net Sales. In addition, indigent patient, compassionate use and similar programs to provide Licensed Product at no cost, shall not result in any Net Sales.

(e) If a Licensed Product is transferred at a discounted price (other than such customary deductions provided in the definition of Net Sales) that is substantially lower than the customary price charged for such product, or for non-cash consideration (whether or not at a discount), Net Sales will be calculated based on the average non-discounted amount charged for the Licensed Product in an arms-length transaction to an independent Third Party during the same Reporting Period in the same country or, in the absence of such sales, on the fair market value of the Licensed Product at the time of the transaction assuming an arm's length transaction made in the ordinary course of business.

(f) Net Sales shall be deemed to occur on the date invoicing for a Licensed Product.

1.19 "Patent Challenge" means any action or proceeding, including any interference, patent opposition, *inter partes* review, post-grant review or re-examination proceeding, challenging or denying the validity, patentability or enforceability of, or opposing any extension of or the grant of a supplementary protection certificate with respect to any Patent Right within the Licensed Patent Rights, which, in the case of such an action brought or assisted by Company or its Affiliate, is directed to subject matter within the scope of the licenses granted to Company hereunder or, in the case of such an action brought or assisted by a Sublicensee, is directed to subject matter within the scope of the Sublicense granted to such Sublicensee. For purposes of this Agreement, Patent Challenges brought by Company, its Affiliate or Sublicensee (each, the "Patent Challenger"), or with respect to which any of them provides assistance, (a) shall not include any of the foregoing actions brought in defense of an infringement claim brought against the Patent Challenger by, or on behalf of, or under the authority of ALSTDI, and (b) shall not include any action or proceeding that is withdrawn within thirty (30) days of a written request by ALSTDI to do so.

1.20 "Person" means an individual and all other forms of legally recognized entity, including, without limitation, a partnership, corporation, limited liability company, association, joint stock company, trust, joint venture, unincorporated organization or governmental entity or any department, agency or political subdivision thereof.

1.21 "Phase I Clinical Trial" means, as to a specific Licensed Product, a study in humans of such product designed to satisfy the requirements of 21 C.F.R. § 312.21(a), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase I Clinical Trial shall be deemed initiated upon the first dosing of the first research subject.

1.22 "Phase IIA Clinical Trial" means as to a specific Licensed Product, a study in humans of such product, designed to study the safety, dosage and initial efficacy in a limited patient population, and designed to support the continued testing of such product in one or more further Phase HA Clinical Trials or Phase IIB Clinical Trials. A Phase HA Clinical Trial shall be deemed initiated upon the first dosing of the first research subject.

1.23 "Phase IIB Clinical Trial" means as to a specific Licensed Product, a study in humans of such product, designed to generate sufficient data to commence (if successful) a Phase III Clinical Trial, as further defined in 21 C.F.R. § 312.21(b), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase IIB Clinical Trial shall be deemed initiated upon the first dosing of the first research subject.

1.24 "Phase III Clinical Trial" means, as to a specific Licensed Product, a study in humans designed to satisfy the requirements of 21 C.F.R. § 312.21(c), as amended from time to time, or the corresponding regulation in jurisdictions other than the United States. A Phase III Clinical Trial shall be deemed initiated upon the first dosing of the first research subject.

1.25 "Prosecution" means the preparation, filing, prosecution, issuance and maintenance of the Licensed Patent Rights, including continuations, continuations-in-part, divisionals, extensions, reexaminations, *inter partes* review, reissues, supplemental examination, appeals,

interferences, derivation proceedings, oppositions, all other proceedings before the United States Patent and Trademark Office (including the Patent Trial and Appeal Board) and foreign patent

offices, and any judicial or other appeals of the foregoing. Cognates of the word "Prosecution" have their correlative meanings.

1.26 "Provided Materials" means the materials set forth in Exhibit 1.29.

1.27 "Regulatory Approval" means, with respect to any jurisdiction, those approvals or authorizations of a regulatory authority that are necessary for the commercial marketing and sale of a pharmaceutical product in such jurisdiction.

1.28 "Reporting Period" means a period beginning on the first day of each calendar quarter and ending on the last day of such calendar quarter. For purposes of this definition, the term "calendar quarter" means: a period of three (3) consecutive months corresponding to the calendar quarters commencing on the first day of January, April, July or October, or any partial period thereof immediately following the Effective Date or immediately prior to the termination or expiration of this Agreement.

1.29 "Royalty Term" has the meaning set forth in Section 4.1(f).

1.30 "Sublicense" means an agreement in which Company (i) grants or otherwise transfers to any Sublicensee any of the rights licensed to Company hereunder, (ii) agrees not to assert such rights or to sue, prevent or seek a legal remedy for the performance or practice of same, or (iii) is under an obligation to grant, assign or otherwise transfer any such rights or non-assertion, or to forebear from granting or otherwise transferring such rights to any other entity. Agreements expressly considered Sublicenses include licenses, option agreements, "lock up" agreements, rights of first refusal agreements or similar agreements. However, (a) an assignment pursuant to Section 14.3, (b) an agreement consummating a Change of Control of Company, or (c) an agreement to manufacture, make, have manufactured, or have made, use or sell Licensed Products on behalf of Company or its Affiliates shall not be considered a Sublicense.

1.31 "Sublicensee" means any Third Party or Company Affiliate to which Company has granted a Sublicense.

1.32 "Term" means the term of this Agreement, which shall commence on the Effective Date and shall remain in effect until the expiration of the Royalty Term in all countries in the Territory with respect to all Licensed Products, unless earlier terminated in accordance with the provisions of this Agreement.

1.33 "Territory" means worldwide.

1.34 "Third Party" means any Person other than (i) a Party or (ii) an Affiliate of a Party.

1.35 "Valid Claim" means any (i) issued claim of any Licensed Patent Right that has not been permanently revoked, nor held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction that is unappealable or unappealed in the time

allowed for appeal, and which has not been cancelled, withdrawn or abandoned or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; or (ii) pending claim of any Licensed Patent Right, which claim has not been pending for more than five years from the date of this Agreement.

1.36 "Withholding Taxes" means any and all income or other taxes, withholdings or other deductions required by applicable law to be withheld or deducted from any of the payments made by or on behalf of Company hereunder.

2. GRANT OF RIGHTS.

2.1 License Grants.

(a) Exclusive Patent License. Subject to the terms of this Agreement, ALSTDI hereby grants to Company (including its Affiliates) an exclusive license under ALSTDI' s interest in the Licensed IP solely to make, have made, use, sell, offer for sale, import, perform and practice Licensed Products in the Field in the Territory during the Term.

2.2 Retained Rights.

(a) Research and Educational Use. ALSTDI retains the right on behalf of itself and all non-profit, non-commercial or governmental entities to make, use, perform and practice the subject matter described, claimed or included in the Licensed IP for research, teaching and educational purposes, including within the Field.

(b) Federal Government. Notwithstanding anything herein to the contrary, any rights granted under this Agreement are subject to the rights and requirements of the United States government as set forth in 35 U.S.C. §§ 200-212 and the regulations promulgated thereunder, as amended, or any successor statutes or regulations. Company acknowledges that the U.S. federal government retains a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention claimed in any Licensed Patent Rights as set forth in 35 U.S.C. §§ 200-212 and the regulations promulgated thereunder, as amended, or any successor statutes or regulations.

2.3 Sublicense. Company is entitled to sublicense the rights granted under Section 2.1; provided, however, that Company shall only sublicense the rights for use in the development or commercialization of Licensed Products. Any Sublicense shall be in writing and shall be consistent with all of the terms and conditions of this Agreement. Company shall incorporate terms and conditions into any Sublicense agreement sufficient to enable Company to comply with this Agreement, including without limitation provisions to provide that in the event Sublicensee brings a Patent Challenge against ALSTDI or assists another party in bringing a Patent Challenge against ALSTDI (except as required under a court order or subpoena) then Company or ALSTDI may terminate the Sublicense. Company will specifically state that ALSTDI is an intended third party beneficiary of such Sublicense, including for the purpose of enforcing the terms required to be included in such Sublicense by this Agreement. Company shall specifically require Sublicensee to indemnify, hold harmless and defend ALSTDI and carry insurance under the same terms set forth in Article 8 below. Company agrees to be fully responsible for the performance of its Sublicensees hereunder, including acts and omissions of same. Sublicensees shall not have the right to grant

further Sublicenses. Company shall furnish ALSTDI with a fully executed copy of any Sublicense agreement promptly after execution without redaction, provided that the terms and conditions of each Sublicense shall be deemed Confidential Information. Upon termination of this

Agreement for any reason, any Sublicensee not then in default may seek a license from ALSTDI. ALSTDI agrees to negotiate such licenses in good faith under reasonable terms and conditions.

2.4 U.S. Manufacturing. Company agrees that any Licensed Products used or sold in the United States that are subject to 35 U.S.C. §§ 201-212 and the regulations promulgated thereunder, as amended, or any successor statutes or regulations will, to the extent required by law, be manufactured substantially in the United States.

2.5 No Additional Rights. Nothing in this Agreement shall be construed to confer any rights upon Company by implication, estoppel, or otherwise as to any technology or patent rights of ALSTDI or any other entity other than the Licensed IP regardless of whether such technology or patent rights shall be dominant or subordinate to any Licensed IP.

2.6 Provided Materials. To the extent Provided Materials are provided by ALSTDI to Company under this Agreement, Company shall use such Provided Materials only in accordance with and for purposes of exercising the rights granted to it under this Agreement and in compliance with applicable law. Legal title to such Provided Materials shall remain with ALSTDI. Company acknowledges that any Provided Materials provided hereunder are experimental and their properties are not completely known. Company shall destroy or, if requested by ALSTDI in its sole discretion, return any unused quantities of Provided Materials. The Provided Materials shall not be used by Company in research or testing involving human subjects.

3. COMPANY DILIGENCE OBLIGATIONS.

3.1 Diligence Requirements. Company shall use Commercially Reasonable Efforts, or shall cause its Sublicensees to use Commercially Reasonable Efforts, to develop Licensed Products and to introduce Licensed Products into the commercial market; and thereafter, Company or its Sublicensees shall use Commercially Reasonable Efforts to market Licensed Products and make Licensed Products reasonably available to the public.

In addition to the foregoing general diligence obligation, Company shall, or shall cause its Sublicensee to, use Commercially Reasonable Efforts to meet its obligations pursuant to a written development plan, as mutually agreed by the parties.

4. ROYALTIES AND PAYMENT TERMS.

4.1 Consideration for Grant of Rights.

(a) Milestone Payments. Company shall notify ALSTDI within ten (10) days of the first achievement of any of the following milestones for the Licensed Product by Company or any of its Sublicensees. At the time of such notification, Company shall pay to ALSTDI the following

one-time Milestone Payments for the first occurrence of each milestone event for the first Licensed

Product:

Milestone Event	Payment
Dosing of first subject in first toxicity study in non-human primates	$1,000,000
Dosing of first patient in a Phase I Clinical Trial	$1,000,000
Dosing of first patient in Phase IIB Clinical Trial	$ 200,000
Dosing of first patient in a Phase III Clinical Trial	$ 300,000
First completion of a Phase III Clinical Trial with a positive clinical endpoint	$ 500,000
First Regulatory Approval in the US	$1,000,000
First Regulatory Approval in the European Union	$1,000,000
First Regulatory Approval in Asia	$1,000,000
First Commercial Sale in the Territory	$1,000,000

The parties acknowledge that the issuance to ALSTDI of 555,555 shares of the Company's non-voting common stock pursuant to that certain Non-Voting Common Stock Purchase Agreement dated on or about June 1, 2017 fully satisfies the Company's obligation to make that certain Milestone Payment for the dosing of the first subject in the first toxicity study in non- human primates pursuant to Section 4.1(a) of the Agreement.

Each Milestone Event may be achieved only once and each Milestone Payment shall be due only once following upon the first achievement of the corresponding Milestone Event. For the avoidance of doubt, in no event shall Company be obligated to pay to ALSTDI Milestone Payments exceeding $7,000,000.

The first five Milestone Events above (the "Clinical Trial Milestones") are intended to be successive; if any of the Clinical Trial Milestones is reached without achieving a preceding Clinical Trial Milestone, then the amount which would have been payable on achievement of the preceding Clinical Trial Milestone shall be payable upon achievement of the next successive Clinical Trial Milestone. For purposes of the above Milestone Events, the "completion" of a pre- clinical or clinical study means the date of the last examination or intervention of the last research subject for the purpose of data collection for the primary endpoint in that trial.

In the event that the Company develops a second Licensed Product for disease indications different than the first Licensed Product, Company shall notify ALSTDI within ten (10) days of the first achievement of any of the following milestones for the second Licensed Product by Company or any of its Sublicensees. At the time of such notification, Company shall pay to

ALSTDI the following one-time Milestone Payments for the first occurrence of each milestone

event for the second Licensed Product for a disease indication different than the first Licensed Product:

First completion of a Phase III Clinical Trial with a positive clinical endpoint	$	500,000
First Regulatory Approval in the US	$	500,000
First Regulatory Approval in the European Union	$	500,000
First Regulatory Approval in Asia	$	500,000
First Commercial Sale in the Territory	$	500,000

Notwithstanding the foregoing, ALSTDI may, in its sole discretion, defer receipt or acceptance of any Milestone Payment to any later date that it selects.

(b) Sales Milestone Payments. Company shall pay to ALSTDI within sixty (60) days of the end of the calendar year in which is achieved the first occurrence of the following sales Milestone Events the Milestone Payments set forth below:

Milestone Event	Payment
$500 million in aggregate Net Sales of Licensed Products in one calendar year, across all indications and uses	$15,000,000
$1 billion in aggregate Net Sales of Licensed Products in one calendar year, across all indications and uses	$30,000,000

Notwithstanding the foregoing, ALSTDI may, in its sole discretion, defer receipt or acceptance of any Milestone Payment to any later date that it selects.

(c) Annual License Maintenance Fee. Beginning upon the earlier of (i) January 1, 2022; or (ii) a Change of Control event, Company shall pay to ALSTDI a non-refundable annual license maintenance fee ("Maintenance Fee") of one hundred thousand dollars ($100,000) per calendar year. Each Maintenance Fee shall be due and payable on January 1st of the calendar year to which such fee applies and, for each calendar year after the year in which the First Commercial Sale is achieved, shall be creditable against any royalties due and payable under Section 4.1(e) below with respect to Licensed Products sold in the same calendar year that such Maintenance Fee was due.

(d) Change of Control. In the event of a Change of Control, Company shall notify ALSTDI in writing within thirty (30) days of such event.

(e) Royalties. Royalties shall be payable for each Reporting Period and shall be due to ALSTDI within sixty (60) days of the end of each Reporting Period. During the Royalty Term, Company shall pay to ALSTDI four percent (4%) royalties on aggregate Net Sales of Licensed Products under this Agreement (including all indications and uses of such Licensed Products) in

the Territory in a calendar year.

(f) Royalty Term. The royalties set forth in Section 4.1(e) shall be payable, on a Licensed Product-by-Licensed Product and country-by-country basis, until the expiration or termination of the last to expire Valid Claim of a patent covering the making, having made, use, sale, offering for sale or importation of such Licensed Product in such country of sale ("Royalty Term").

(g) Consequences of a Patent Challenge. In the event that: (i) Company or any of its Affiliates brings a Patent Challenge against ALSTDI, or (ii) Company or any of its Affiliates assists another party in bringing a Patent Challenge against ALSTDI (except as required under a court order or subpoena), or (iii) a Sublicensee or any of its Affiliates brings a Patent Challenge or assists another in bringing a Patent Challenge against ALSTDI and Company does not terminate such Sublicensee's Sublicense within thirty (30) days of delivery of notice by ALSTDI and (iv) ALSTDI does not choose to exercise its rights to terminate this Agreement pursuant to Section 11.4, then the Milestone Payments due under Sections 4.1(a) and 4.1(b), and the royalties due under Section 4.1(e), shall be doubled for the remainder of the Term of this Agreement. Company shall continue to make all royalties, milestone payments, maintenance fees and other payments due hereunder during the Patent Challenge and in the event that the Patent Challenge is successful, Company will have no right to recoup any royalties or payments paid during the period of challenge. In the event that a Patent Challenge is unsuccessful, or as otherwise required under this Agreement, Company shall reimburse ALSTDI for all reasonable legal fees and expenses incurred in its defense against the Patent Challenge. If any of the provisions of this Section 4.1(g) is held invalid or unenforceable for any reason, such invalidity or unenforceability shall not affect any of the other provisions of this Section 4.1(g) or other provisions of this Agreement.

(h) No Multiple Royalties. If the manufacture, use, performance or sale of any Licensed Product is covered by more than one of the Licensed Patents, multiple royalties shall not be due as a result of being so covered.

4.2 Payments.

(a) Method of Payment. All payments under this Agreement should be made payable to ALSTDI and sent to the address identified in Section 14.1. Each payment should reference this Agreement and identify the obligation under this Agreement that the payment satisfies.

(b) Payments in U.S. Dollars. All payments due under this Agreement shall be drawn on a United States bank and shall be payable in United States dollars. Conversion of foreign currency to U.S. dollars shall be made at the conversion rate existing in the United States (as reported in the *Wall Street Journal*, or if the *Wall Street Journal* no longer quotes such rates, as report in another source mutually agreed by the parties) on the last working day of the calendar quarter of the applicable Reporting Period.

(c) Taxes. All payments under this Agreement will be made without any deduction or withholding for or on account of any tax, except as expressly permitted in this Agreement. If any Withholding Taxes are imposed on a payment by any applicable law, Company will pay such Withholding Taxes to the proper taxing authority and, if available, evidence of such payment will

be secured and sent to ALSTDI within one (1) month of such payment.

(d) Late Payments. Any payments by Company that are not paid on or before the date such payments are due under this Agreement shall bear interest, to the extent permitted by law, at two percentage points above the Prime Rate of interest as reported in the *Wall Street Journal* (or if the *Wall Street Journal* no longer quotes such rate, as reported in another source mutually agreed by the parties) on the date payment is due, compounded and accrued daily, but not to exceed the maximum permitted by law. Any such overdue payment when made shall be accompanied by all interest so accrued.

5. REPORTS AND RECORDS.

5.1 Diligence Reports. Within sixty (60) days after the end of each calendar year, Company shall report in writing to ALSTDI on progress made toward the objectives set forth in Section 3.1 during such preceding twelve (12) month period, including progress on research and development, status of applications for Regulatory Approvals, manufacturing, sublicensing and the number, scope, and territory of sublicenses entered into, and marketing. The report shall also contain a discussion of intended efforts, development progress, and sales projections for the year in which the report is submitted.

5.2 Frequency of Reports. Company shall report to ALSTDI the date of the first Net Sale of a Licensed Product within sixty (60) days of occurrence in each country. After the first Net Sale of any Licensed Product, Company shall deliver reports to ALSTDI within sixty (60) days of the end of each Reporting Period containing information concerning the immediately preceding Reporting Period, as further described in Section 5.3.

5.3 Content of Reports and Payments. Each report delivered by Company to ALSTDI shall contain at least the following information for the immediately preceding Reporting Period:

(a) the quantity of Licensed Products sold or otherwise transferred in each country, including an itemized listing of the Licensed Product type;

(b) the gross prices charged by Company and Sublicensees for each Licensed Product in each country;

(c) calculation of Net Sales for the applicable Reporting Period in each country;

(d) total royalty payable on Net Sales in U.S. dollars, together with the exchange rates used for conversion; and

(e) description and product codes, or other Company identifier, for each Licensed Product sold.

If no amounts are due to ALSTDI for any Reporting Period, the report shall so state.

5.4 Records. Company shall maintain, and shall cause its Sublicensees to maintain, complete and accurate records relating to the rights and obligations under this Agreement and any amounts payable to ALSTDI in relation to this Agreement, which records shall contain sufficient

information to permit ALSTDI to confirm the accuracy of any reports delivered to ALSTDI and compliance in other respects with this Agreement. The relevant party shall retain such records for at least three (3) years following the end of the calendar year to which they pertain, during which time an independent certified public accounting firm, selected by ALSTDI, shall have the right, not more than once in each calendar year, at ALSTDI's expense and pursuant to the terms and conditions of a customary confidentiality and non-disclosure agreement, to audit and inspect such records during normal business hours to verify any reports and payments made under this Agreement. Company shall also cause each Sublicensee to provide ALSTDI with a comparable right of audit. In the event that any audit performed under this Section 5.4 reveals an underpayment
(i) where such underpayment is in excess of five percent (5%) for any twelve (12) month period, Company shall bear the full cost of such audit, and (ii) Company shall remit any amounts due to ALSTDI within thirty (30) days of receiving notice thereof from ALSTDI. In the event that any audit performed under this Section 5.4 reveals an overpayment, ALSTDI shall deliver written notice to Company within thirty (30) days of acquiring knowledge of such overpayments, and shall remit any amounts due to Company as a result of such overpayment along with delivery of such notice.

6. PATENT PROSECUTION.

6.1 Responsibility. ALSTDI shall have primary right to Prosecute the Licensed Patent Rights. ALSTDI shall keep Company reasonably informed as to the Prosecution of any Licensed Patent Rights, including the status thereof, and provide to Company copies of all substantive correspondence to or from, or other filings with, any patent office related thereto in order to have the opportunity to review and comment upon any such correspondence or other filings. ALSTDI will reasonably consider any reasonable comments that are provided by Company in a timely manner. ALSTDI may, in its discretion, abandon, or otherwise elect to forego its rights in, any Licensed Patent Rights. ALSTDI shall notify Company in writing prior to any deadline if it intends to abandon any Licensed Patent Rights, whereupon such abandoned patent shall no longer be a Licensed Patent Right for the calculation of payments pursuant to Article 4, and Company shall have the opportunity to continue prosecuting and to maintain any such Licensed Patent Right in the name of ALSTDI, at Company's expense.

6.2 Common Interest. All non-public information exchanged between the parties or between ALSTDI's outside patent counsel and Company regarding Prosecution of the Licensed Patent Rights, and all shared information regarding analyses or opinions of Third Party intellectual property, will be deemed Confidential Information. In addition, the parties acknowledge and agree that, with regard to such Prosecution of the Licensed Patent Rights, the interests of the parties as licensor and licensee are to obtain the strongest patent protection possible, and as such, are aligned and are legal in nature. The parties agree and acknowledge that they have not waived, and nothing in this Agreement constitutes a waiver of, any legal privilege concerning the Licensed Patent Rights or the Confidential Information, including privilege under the common interest doctrine and similar or related doctrines.

6.3 Payment of Expenses. Company shall be responsible for paying all fees and costs, including attorneys' fees, relating to the Prosecution of the Licensed Patent Rights whether such amounts were incurred before or after the Effective Date.

7. INFRINGEMENT.

7.1 Notification of Infringement. Each party agrees to provide written notice to the other party within ten (10) days after becoming aware of any infringement of the Licensed Patent Rights.

7.2 Company Right to Prosecute Infringement. So long as Company remains the exclusive licensee of the Licensed Patent Rights in the Field in the Territory, Company, to the extent permitted by law, shall have the right, under its own control and at its sole expense, to prosecute any Third Party infringement of the Licensed Patent Rights in the Field in the Territory, subject to Section 7.5. If required by law to establish standing for the institution or maintenance of such infringement action by Company, ALSTDI shall permit any action under this Section 7.2 to be brought in its name, including being joined as a party-plaintiff, provided that (i) ALSTDI shall not be the first named plaintiff in any such action, (ii) Company shall hold ALSTDI harmless from, and indemnify ALSTDI against, any out of pocket costs, expenses, or liability that ALSTDI incurs in connection with the prosecution, adjudication, defense, management or settlement of any such action, and any resulting appeals, remands or other related proceedings, and (iii) Company shall reimburse any such out of pocket costs, expenses or liabilities within thirty (30) days of receiving an invoice therefor.

Prior to commencing any such action, Company shall consult with ALSTDI and shall consider the views of ALSTDI regarding the advisability of the proposed action and its effect on the public interest. ALSTDI may participate in any such action with counsel of its choosing at its own expense.

7.3 ALSTDI Right to Prosecute Infringement. In the event that Company does not stop the infringement, or fails to have initiated an infringement action, within a reasonable time, but no longer than ninety (90) days, after Company first becomes aware of the basis for such action, ALSTDI shall have the right, at its sole discretion, to prosecute such infringement under its sole control and at its sole expense, and any recovery obtained shall belong to ALSTDI.

7.4 Declaratory Judgment Actions. In the event that a Patent Challenge is brought against ALSTDI or Company by a Third Party, ALSTDI, at its option, shall have the right within twenty (20) days after commencement of such action to take over the sole defense of the action at its own expense. If ALSTDI does not exercise this right, Company may take over the sole defense of the action with respect to Licensed Patent Rights at Company's sole expense. Company will immediately notify ALSTDI in the event that a Patent Challenge is brought against Company.

7.5 Recovery. Any recovery obtained in an action brought by Company under Sections 7.2 or 7.4 shall be distributed as follows: (a) each party shall be reimbursed for any expenses incurred in the action, (b) as to ordinary damages, Company shall receive an amount equal to its lost profits or a reasonable royalty on the infringing sales, or whichever measure of damages the court shall have applied, and Company shall pay to ALSTDI based upon such amount a reasonable

approximation of the royalties and other amounts that Company would have paid to ALSTDI if Company had sold the infringing products, processes and services rather than the infringer, and
(c) as to special or punitive damages, the parties shall share equally in any award.

7.6 Cooperation. Each party agrees to cooperate in any action under this Article 7 which

is controlled by the other party, provided that the controlling party reimburses the cooperating party promptly for any costs and expenses incurred by the cooperating party in connection with providing such assistance. Neither Party shall unilaterally enter into any settlement or compromise of any action or proceeding under this Article 7 that would in any manner be reasonably expected to alter, diminish, or be in derogation in any material respect of the other Party's rights under this Agreement without the prior written consent of such other Party, which shall not be unreasonably conditioned, withheld, or delayed

8. INDEMNIFICATION AND INSURANCE.

8.1 Indemnification.

(a) Indemnity. Company shall indemnify, defend, and hold harmless ALSTDI, its Affiliates, and their respective directors, trustees, officers, employees, staff, agents and investigators, and their respective successors, heirs and assigns (the "ALSTDI Indemnitees"), against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses) (collectively, "Losses") incurred by or imposed upon any of the ALSTDI Indemnitees in connection with any Third Party claims, suits, investigations, actions, demands or judgments ("Third Party Claims") arising out of or related to the exercise of any rights granted to Company under this Agreement, any breach of this Agreement by Company or its Affiliates or Sublicensees, or Company's performance under this Agreement. Company's obligations to indemnify, defend and hold harmless the ALSTDI Indemnitees shall not apply to the extent that such Third Party Claims result from any Loss (i) directly caused from a material breach of this Agreement by ALSTDI or (ii) arising out of or relating to the ALSTDI Indemnitees' fraud, willful misconduct or gross negligence.

(b) Procedures. The ALSTDI Indemnitees agree to provide Company with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement; provided that, an ALSTDI Indemnitee's failure to do so shall not affect the rights of such ALSTDI Indemnitee unless, and then only to the extent that, such delay or failure is prejudicial to or otherwise adversely affects Company. Company agrees, at its own expense, to provide attorneys reasonably acceptable to ALSTDI to defend against any such claim whether or not rightfully brought. The ALSTDI Indemnitees shall cooperate with Company in such defense and shall permit Company to conduct and control such defense and the disposition of such claim, suit, or action (including all decisions relative to litigation, appeal, and settlement); provided, however, that any ALSTDI Indemnitee shall have the right to retain its own counsel, at the expense of Company, if representation of such ALSTDI Indemnitee by the counsel retained by Company would be inappropriate because of actual or potential differences in the interests of such ALSTDI Indemnitee and any other party represented by such counsel. Company agrees to keep ALSTDI informed of the progress in the defense and disposition of such claim and to consult with ALSTDI with regard to any proposed settlement.

(c) Settlement. Notwithstanding anything to the contrary in this Agreement, Company shall not enter into any settlement, consent judgment, or other voluntary final disposition of any claim that has an adverse effect on the rights of any ALSTDI Indemnitee(s) hereunder or on the Licensed IP, or admits any wrongdoing or fault by any ALSTDI Indemnitee(s), or imposes on any ALSTDI Indemnitee(s) any payment or other liability, without the prior written consent of

ALSTDI.

Company shall require any Sublicensee(s) to indemnify, hold harmless and defend the ALSTDI Indemnitees under the same terms set forth in this Section 8.1.

8.2 Insurance.

(a) At such time as any product, process or service relating to, or developed pursuant to, this Agreement is being used in a Clinical Trial or is commercially distributed or sold by Company or by a Sublicensee of Company, Company shall, at its sole cost and expense, procure and maintain policies of commercial general liability insurance in amounts not less than
$2,000,000 per incident and $5,000,000 annual aggregate and naming ALSTDI Indemnitees as additional insureds. Such commercial general liability insurance must provide (a) product liability coverage and (b) broad form contractual liability coverage for Company's indemnification under Section 8.1 of this Agreement. The minimum amounts of insurance coverage required under these provisions may not be construed to create a limit of Company's liability with respect to its indemnification obligation under Section 8.1 of this Agreement. Company shall provide ALSTDI with written evidence of such insurance upon request..

(b) Company shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being used in a Clinical Trial or is being commercially distributed or sold by Company or by a Sublicensee and (ii) a reasonable period after the period referred to in (c)(i) above which in no event shall be less than three (3) years.

Company shall require any Sublicensee(s) to maintain insurance in favor of ALSTDI Indemnitees under the same terms set forth in Section 8.2 above.

9. NO REPRESENTATIONS OR WARRANTIES.

9.1 ALSTDI MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE LICENSED PATENT RIGHTS OR LICENSED KNOW-HOW AND HEREBY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS OF ALSTDI OR THIRD PARTIES, VALIDITY, ENFORCEABILITY AND SCOPE OF LICENSED PATENT RIGHTS, VALIDITY OF LICENSED PATENT RIGHTS CLAIMS, WHETHER ISSUED OR PENDING, AND THE ABSENCE OF LATENT OR OTHER DEFECTS, WHETHER OR NOT DISCOVERABLE.

9.2 IN NO EVENT SHALL EITHER PARTY, OR ITS DIRECTORS, TRUSTEES, OFFICERS, EMPLOYEES, STAFF, AGENTS OR INVESTIGATORS, BE LIABLE FOR

INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND, INCLUDING ECONOMIC DAMAGES OR INJURY TO PROPERTY AND LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING;

PROVIDED THAT NOTHING IN THIS SECTION 9.2 SHALL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS UNDER SECTION 8.1.

10. GENERAL COMPLIANCE WITH LAWS

10.1 Compliance with Laws. Company and its Sublicensees shall use Commercially Reasonable Efforts to comply with all applicable local, state, federal and international laws and regulations relating to the development, manufacture, use, performance, practice, and sale of Licensed Products.

10.2 Export Control. Company and its Sublicensees shall comply with all United States laws and regulations controlling the export of certain commodities and technical data, including all Export Administration Regulations of the United States Department of Commerce. Among other things, these laws and regulations prohibit or require a license for the export of certain types of commodities and technical data to specified countries. Company hereby gives written assurance that it will comply with, and will cause its Sublicensees to comply with, all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or its Sublicensees, and that it will indemnify, defend, and hold ALSTDI harmless (in accordance with Section 8.1) for the consequences of any such violation.

10.3 Non-Use of Name. Company and its Sublicensees shall not use the name of ALS Therapy Development Institute, Inc., or any variation, adaptation, or abbreviation thereof, or the name of any of ALSTDI's trustees, directors, officers, faculty, students, staff, employees, agents, or investigators, or any trademark or service rank owned by ALSTDI, or any terms of this Agreement, in any promotional material or other public announcement or disclosure without the prior written consent of ALSTDI which consent ALSTDI may withhold in its sole discretion. The foregoing notwithstanding, without the consent of ALSTDI, Company may use such names, trademarks or service marks to make factual statements during the Term of this Agreement that Company has a license from ALSTDI under one or more of the patents or patent applications comprising the Licensed Patent Rights, and it may use such names or provide any terms of this Agreement to the extent required by law or to the extent already disclosed as permitted herein.

10.4 Marking of Licensed Products. To the extent consistent with prevailing business practices, or as required by applicable law, Company shall mark, and shall cause its Sublicensees to mark, all Licensed Products that are manufactured or sold under this Agreement with the number of each issued patent under the Licensed Patent Rights that applies to such Licensed Product.

11. TERMINATION.

11.1 Term. This Agreement will remain in effect until the expiration of the Term unless earlier terminated as provided hereunder.

11.2 Voluntary Termination by Company. Company shall have the right to terminate this Agreement in its entirety, for any reason: (i) upon at least ninety (90) days prior written notice to ALSTDI, such notice to state the date at least ninety (90) days in the future upon which termination is to be effective, and (ii) upon payment of all amounts due to ALSTDI through such termination effective date.

11.3 Termination for Default.

(a) Nonpayment. In the event Company fails to pay any amounts due and payable to ALSTDI hereunder, and fails to make such payments within thirty (30) days after receiving written notice of such failure, ALSTDI may terminate this Agreement immediately upon written notice to Company; provided, however, that if a portion of the invoice is in dispute, the undisputed portion of the invoice shall be paid and this Agreement shall remain in full force and effect subject to Section 12.4; and the disputed portion shall be resolved in accordance with Article 12 hereof.

(b) Material Breach. In the event either party commits a material breach of its obligations under this Agreement, except for breach as described in Section 11.3(a), and fails to cure that breach within sixty (60) days after receiving written notice thereof, the non-breaching party may terminate this Agreement immediately after the aforesaid sixty (60) day period by written notice to the other party.

11.4 Termination as a Consequence of Patent Challenge by Company. If Company or any of its Affiliates, or Sublicensees or any of Sublicensee's Affiliates, brings a Patent Challenge against ALSTDI, or assists others in bringing a Patent Challenge against ALSTDI (except as required under a court order or subpoena), then ALSTDI may immediately terminate this Agreement.

11.5 Effect of Termination.

(a) Survival. The following provisions shall survive the expiration or termination of this Agreement along with any other provision which by their context are intended to survive for a period of five (5) years following such expiration or termination: Articles 1, 8, 9, 11, 12, 13 and 14, and Section 5.4, and, in the case of a termination by Company pursuant to Section 11.3(b), Article 2.

(b) Pre-termination Obligations. In no event shall termination of this Agreement release Company or its Sublicensees from obligations accrued prior to the effective date of termination of this Agreement, including the obligation to pay all amounts that become due on or before the effective date of termination.

(c) Termination of Licenses. Upon termination of this Agreement by Company pursuant to Section 11.2 or by ALSTDI pursuant to Sections 11.3 and 11.4, all rights and licenses granted to Company under the terms of this Agreement will terminate entirely. Upon any such termination, Company shall cease to make, have made, use, sell, offer for sale, import, perform and practice Licensed Products described in Section 1.14.

(d) Deliverables. Within sixty (60) days of the effective date of termination, (a) each Party shall deliver to the other Party or destroy (at the other Party's election): all materials relating to or containing Confidential Information (as defined in Article 13), and (b) Company shall deliver to ALSTDI final reports under Article 5 and all payments incurred up to the effective date of

termination; provided, however, that each Party may keep one copy of such Confidential Information in its legal files solely for the purpose of enabling it to comply with the provisions of

this Agreement, and shall not be required to remove such Confidential Information from its back- up or archive electronic records, including its electronic laboratory notebook and laboratory information management systems.

(e) Documentation, right of reference, and license. In the event of termination of this Agreement other than by Company under Section 11.3(b):

(i) At ALSTDI's request, Company shall deliver to ALSTDI, and ALSTDI and its licensees shall be free to use, (a) all records required by regulatory authorities to be maintained with respect to Licensed Products, all regulatory filings, approvals, reports, records, correspondence and other regulatory materials (including any related to reimbursement or pricing approvals), and all documents, data and other information related to clinical trials and other studies of Licensed Products, and (b) any documentation and technical information that is necessary or useful for the manufacture of Licensed Products.

(ii) Company shall permit ALSTDI and its licensees to utilize, reference, cross reference, incorporate in applications and filings, and otherwise have the benefit of all Regulatory Approvals of, or clinical trials or other studies conducted on, and all filings made with regulatory agencies with respect to, the Licensed Products.

12. DISPUTE RESOLUTION

12.1 Mandatory Procedures. The parties agree that any dispute arising out of or relating to this Agreement shall be resolved by means of the procedures set forth in this Article, and that such procedures constitute legally binding obligations that are an essential provision of this Agreement. If either party fails to observe the procedures of this Article, as may be modified by their written agreement, the other party may bring an action for specific performance of these procedures in any court of competent jurisdiction.

12.2 Equitable Remedies. Notwithstanding the procedures specified in this Article for the resolution of disputes arising out of or relating to this Agreement, either party may seek a preliminary injunction or other provisional equitable relief if, in its reasonable judgment, such action is necessary to avoid irreparable harm to itself or to preserve its rights under this Agreement.

12.3 Dispute Resolution Procedures.

(a) Escalation. The Parties agree that, in the event of any dispute arising out of or relating to this Agreement, either Party by written notice to the other Party may have such issue referred for resolution to the Chief Executive Officer of each Party (collectively, the "Executive Officers"). The Executive Officers shall meet promptly to discuss the matter submitted and to determine a resolution.

(b) Pursuit of other Remedies. If the Executive Officers are unable to resolve the dispute within thirty (30) days after it is referred to them, then the Parties may pursue all other rights and

remedies available to them under this Agreement, including the right to terminate the Agreement, and the matter may be brought by a Party as a suit in a court of competent jurisdiction in accordance with Section 14.2 hereof.

12.4 Performance to Continue. Each party shall continue to perform its undisputed obligations under this Agreement pending final resolution of any dispute arising out of or relating to this Agreement; provided, however, that a party may suspend performance of its undisputed obligations during any period in which the other party fails or refuses to perform its undisputed obligations. Nothing in this Article is intended to relieve Company from its obligation to make undisputed payments pursuant to Articles 4 and 6 of this Agreement.

12.5 Statute of Limitations. The parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) shall be tolled while the procedures set forth in Section 12.3(a) are pending. The parties shall cooperate in taking any actions necessary to achieve this result.

13. CONFIDENTIALITY.

13.1 Notice. Information, whether in oral or written form, that is provided to either Party in connection with this Agreement, including but not limited to royalty reports, strategies regarding prosecution of the Licensed Patent Rights, and Know-How that is not in the public domain at the time of disclosure, is deemed to be "Confidential Information." Each Party agrees, during the Term of this Agreement, and for five (5) years thereafter, to employ all reasonable efforts to maintain Confidential Information secret and confidential, such efforts to be no less than the degree of care employed by such Party to preserve and safeguard its own confidential information. Confidential Information shall not be disclosed or revealed to anyone except employees or agents of or consultants to each Party who have a need to know Confidential Information for purposes of performing their obligations under this Agreement and who have entered into a nondisclosure agreement under which such employees, agents or consultants are required to maintain the confidentiality and non-use of Confidential Information, or are otherwise bound by an obligation of confidentiality and non-use. In addition, the Parties agree to keep the terms of this Agreement confidential, applying the confidentiality provisions of this Article 13. These obligations of confidentiality shall not apply to information which:

(a) Can be demonstrated to have been in the public domain prior to the date of disclosure;

(b) later becomes part of the public domain through no act or omission of the receiving party, its employees, agents, successors or assigns;

(c) was lawfully disclosed to the receiving party by a Third Party having the right to disclose it;

(d) was already known by the receiving party at the time of disclosure as demonstrated by documentary evidence; or

(e) was independently developed by the receiving party as demonstrated by

documentary evidence.

13.2 Authorized Disclosures. Notwithstanding the obligations set forth in Section 13.1, the receiving party may disclose Confidential Information of the disclosing party to the extent such disclosure is reasonably necessary in the following instances:

(a) filing or prosecuting of patents as permitted by this Agreement;

(b) enforcing the receiving party's rights under this Agreement or performing the receiving party's obligations under this Agreement;

(c) in regulatory documentation for Licensed Products that such Party has the right to file under this Agreement;

(d) prosecuting or defending litigation as permitted by this Agreement;

(e) to the Company's actual or potential Sublicensees, commercial partners, independent contractors, who, in each case, have a need to know such Confidential Information in order for the Company to exercise its rights or fulfill its obligations under this Agreement, provided that, in each case, any such person agrees to be bound by terms of confidentiality and non-use (or, in the case of the receiving party's attorneys and independent accountants, such person is obligated by applicable professional or ethical obligations) at least as restrictive as those set forth in this Agreement;

(f) to the Company's actual or potential investors, investment bankers, lenders, other financing sources or acquirors (and attorneys and independent accountants thereof) in connection with potential investment, acquisition, collaboration, merger, public offering, due diligence or similar investigations by such Third Parties or in confidential financing documents, provided that, in each case, any such Third Party agrees to be bound by terms of confidentiality and non-use (or, in the case of the receiving party's attorneys and independent accountants, such Third Party is obligated by applicable professional or ethical obligations) that are no less stringent than those contained in this Agreement (except to the extent that a shorter confidentiality period is customary in the industry); or

(g) such disclosure is required by court order, judicial or administrative process or law or regulation, provided that in such event the receiving party shall promptly inform the disclosing party of such required disclosure and provide the disclosing party an opportunity to challenge or limit the disclosure obligations. Confidential Information that is disclosed as required by court order, judicial or administrative process or law or regulation shall remain otherwise subject to the confidentiality and non-use provisions of this Agreement, and the receiving party shall take all steps reasonably necessary, including seeking of confidential treatment or a protective order, to ensure the continued confidential treatment of such Confidential Information

14. MISCELLANEOUS.

14.1 Notice. Any notices required or permitted under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall be sent by hand, recognized national

overnight courier, or registered or certified mail, postage prepaid, return receipt requested, to the following addresses of the parties:

If to ALSTDI:	ALSTDI [***]
If to Company:	Anelixis Therapeutics, Inc. [***]

All notices under this Agreement shall be deemed effective upon receipt. A party may change its contact information immediately upon written notice to the other party in the manner provided in this Section 14.1.

14.2 Governing Law. This Agreement and all disputes arising out of or related to this Agreement, or the performance, enforcement, breach or termination hereof, and any remedies relating thereto, shall be construed, governed, interpreted and applied in accordance with the laws of the Commonwealth of Massachusetts, without regard to its conflict of laws principles, except that questions affecting the construction and effect of any patent shall be determined by the law of the country in which the patent shall have been granted. Any dispute arising from this Agreement, shall be subject to the exclusive jurisdiction of the federal and state courts having jurisdiction over the Commonwealth of Massachusetts, and each party consents and agrees to the personal jurisdiction of any such court with subject matter jurisdiction in any action arising from such dispute. Company waives any claim that such court lacks jurisdiction over Company or its Sublicensees or constitutes an inconvenient or improper forum.

14.3 Assignment. Company may assign this Agreement to a successor in connection with a merger or consolidation, or to the purchaser of all or substantially all the assets of Company, so long as such successor or purchaser shall agree in writing to be bound by the terms and conditions hereof prior to such assignment. Company shall notify ALSTDI in writing of any such assignment. Any attempted assignment in contravention of this Section 14.3 shall be null and void.

14.4 Amendment and Waiver. No amendment, modification, or waiver of the terms of this Agreement shall be binding on either party unless reduced to writing and signed by an authorized representative of the party to be bound. The failure of either party at any time or times to require performance of any provision hereof shall in no manner affect its rights at a later time to enforce the same. No waiver by either party of any condition or term shall be deemed as a further or continuing waiver of such condition or term or of any other condition or term.

14.5 Independent Contractors. It is understood and agreed that the relationship between the parties is that of independent contractors and that nothing in this Agreement shall be construed

as authorization for either party to act as agent for the other. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the parties or any of their agents or employees for any purpose, including tax purposes, or to create any other legal arrangement that would impose liability upon one party for the act or failure to act of the other party. Neither party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other party, or to bind the other party in any respect whatsoever.

14.6 Severability. In the event that any provision of this Agreement shall be held invalid or unenforceable for any reason, such invalidity or unenforceability shall not affect any other provision of this Agreement, and the parties shall negotiate in good faith to modify this Agreement to preserve (to the extent possible) their original intent.

14.7 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and permitted assigns.

14.8 Force Majeure. Neither Party shall be held liable to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in performing any obligation under this Agreement to the extent such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party, potentially including embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, fire, floods, or other acts of God, or acts, omissions or delays in acting by any governmental authority or unavailability of materials related to the manufacture of Compounds or Licensed Products. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practical and shall promptly undertake and continue diligently all reasonable efforts necessary to cure such force majeure circumstances or to perform its obligations in spite of the ongoing circumstances.

14.9 Interpretation. All headings are for convenience only and shall not affect the meaning of any provision of this Agreement. The parties acknowledge that each party has read and negotiated the language used in this Agreement. Because all parties participated in negotiating and drafting this Agreement, no rule of construction shall apply to this Agreement which construes ambiguous language in favor of or against any party by reason of that party's role in drafting this Agreement. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include," "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person's successors and permitted assigns, (f) the words "herein," "hereof" and "hereunder," and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to section, attachments, appendices, exhibits or the like

will be construed to refer to sections, attachments, appendices, exhibits or the like of this

Agreement, and references to this Agreement include all attachments, appendices, exhibits or the like attached hereto, (h) references to any law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof and (i) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

14.10 Language. The language of this Agreement shall be the American usage of the English language and the parties hereby waive, and agree that this Agreement shall be valid and enforceable notwithstanding, any requirement that it be written in or translated into any language other than English. If, for any reason, this Agreement is translated into a language other than English, the English language version shall be controlling for all purposes.

14.11 Entire Agreement. This Agreement (including any attachments, appendices, exhibits or the like) constitutes the entire agreement between the parties with respect to its subject matter and supersedes all prior agreements or understandings between the parties relating to its subject matter.

14.12 Counterparts. This Agreement may be executed in counterparts, including by facsimile or by electronic scan copies, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.

[Signatures Follow]

IN WITNESS WHEREOF, the parties have caused this Amended and Restated License Agreement to be executed by their duly authorized representatives as of the date first written above.

ALS THERAPY DEVELOPMENT FOUNDATION INC.

By: /s/ Paul Sallaberry

Name: Paul A. Sallaberry

Title: Authorized Director

ANELIXIS THERAPEUTICS, INC.

By: /s/ Steven Perrin

Name: Steven Perrin

Title: President

[Signature Page to LicenseAgreement}

APPENDIX A LICENSED

PATENT RIGHTS

Methods for the treatment of Neurodegenerative Disease					
Country	Application No.	Filing date	Publication or Patent Number	Publication or Issue Date	Status
[***]	[***]	[***]	[***]	[***]	[***]
PCT	PCT/US2009/066715	12/4/2009	W02010/065819	6/10/2012	Nationalized
US	13/858667	8/18/2011	8,435,514	5/7/2013	Issued
US (Divisional)	13/858,667	4/8/2013	9,044,459	6/2/2015	Issued
[***]	[***]	[***]	[***]	[***]	[***]
Japan	2011-539720	12/4/2009	JP201211014	5/17/2012	Abandoned
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

Anti-CD40L Antibodies And Method For Treating					
[***]	[***]	[***]	[***]	[***]	[***]
PCT	PCT/US2016/016165	2/2/2016	WO/2016/126702	11/8/2016	Nationalized
[***]	[***]	[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]	[***]	[***]

Therapeutic Anti-CD40 Ligand Antibodies					
[***]	[***]	[***]	[***]	[***]	[***]
PCT	PCT/US2018/034172	5/23/18	WO2018/217918	11/29/2018	Nationalized

Any patents, patent applications or other patent rights (or foreign equivalents thereof) owned and Controlled by ALSTDI that arise or result directly from the conduct of the activities set forth in Exhibit 1.15(ii), in each case to the extent necessary for the research, development or commercialization of Licensed Products.

Exhibit 1.15(i)

Licensed Know-How includes the following Know-How to the extent it is actually provided by ALSTDI to Company:

- [***]
- [***]

Exhibit 1.15(ii)

Licensed Know-How includes Know-How to the extent it arises or results directly from:

- [***]

Exhibit 1.29

Provided Materials means the following materials, to the extent they are actually provided by ALSTDI to Company:

- [***]

FIRST AMENDMENT TO RESTATED LICENSE AGREEMENT
Between
ALS THERAPY DEVELOPMENT FOUNDATION, INC.
And
ANELIXIS THERAPEUTICS, INC.

This First Amendment ("Amendment #1") dated as of September 5, 2020 by and between ALS Therapy Development Foundation, Inc., d/b/a ALS Therapy Development Institute, Inc., a Massachusetts non-profit corporation ("ALSTDI") and Anelixis Therapeutics, Inc., f/k/a Anelixis Pharmaceuticals, Inc., a Delaware corporation ("Company") (each referred to as a "Party", and together the "Parties") hereby amends the Amended and Restated License Agreement between ALSTDI and the Company dated February 18, 2020, (the "Agreement"). Capitalized terms not otherwise defined in this Amendment #1 will have the same meanings as ascribed to such terms in the Agreement. In the event of any conflict between this Amendment #1 and the Agreement or the prior amendments, the terms contained in this Amendment #1 will prevail.

R E C I T A L S

WHEREAS, ALSTDI and the Company are parties to the Agreement, under which ALSTDI has licensed certain rights in patents and know-how to the Company; and

WHEREAS, the Company also has financial obligations to ALSTDI in an amount of $904,805.45 pursuant to a separate service agreement (the "Master Services Agreement" dated May 20, 2015) for services through December 31, 2019 and the Company wishes to resolve these obligations in part by revision of certain financial terms in the Agreement as hereinafter set forth.

NOW, THEREFORE, ALSTDI and Company hereby agree as follows:

1. The Company shall pay ALSTDI two hundred and fifty thousand dollars ($250,000) contemporaneously with the execution of the Agreement.

2. Article 4.1(a) of the Agreement is amended to read as follows.

(a)Milestone Payments. Company shall notify ALSTDI within one hundred and twenty (120) days of the first achievement of any of the following milestones for the Licensed Product by Company or any of its Sublicensees. At the time of such notification, Company shall pay to ALSTDI the following one-time Milestone Payments for the first occurrence of each milestone event for the first Licensed Product:

Milestone Event	Payment
Dosing of first subject in first toxicity study in non- human primates	$1,000,000
Dosing of first patient in a Phase I Clinical Trial	$1,000,000
Dosing of first patient in Phase IIB Clinical Trial	$ 200,000
Dosing of first patient in a Phase III Clinical Trial	$ 800,000
First completion of a Phase III Clinical Trial with a positive clinical endpoint	$1,000,000
First Regulatory Approval in the US	$1,000,000
First Regulatory Approval in the European Union	$1,000,000
First Regulatory Approval in Asia	$1,000,000
First Commercial Sale in the Territory	$1,000,000

The parties acknowledge that the issuance to ALSTDI of 555,555 shares of the Company's non-voting common stock pursuant to that certain Non-Voting Common Stock Purchase Agreement dated on or about June 1, 2017 fully satisfies the Company's obligation to make that certain Milestone Payment for the dosing of the first subject in the first toxicity study in non-human primates pursuant to Section **Error! Reference source not found.** of the Agreement.

Each Milestone Event may be achieved only once and each Milestone Payment shall be due only once following upon the first achievement of the corresponding Milestone Event. For the avoidance of doubt, in no event shall Company be obligated to pay to ALSTDI Milestone Payments exceeding $7,000,000.

The first five Milestone Events above (the "Clinical Trial Milestones") are intended to be successive; if any of the Clinical Trial Milestones is reached without achieving a preceding Clinical Trial Milestone, then the amount which would have been payable on achievement of the preceding Clinical Trial Milestone shall be payable upon achievement of the next successive Clinical Trial Milestone. For purposes of the above Milestone Events, the "completion" of a pre-clinical or clinical study means the date of the last examination or intervention of the last research subject for the purpose of data collection for the primary endpoint in that trial.

In the event that the Company develops a second Licensed Product for disease indications different than the first Licensed Product, Company shall notify ALSTDI within ten (10) days of the first achievement of any of the following milestones for the second Licensed Product by Company or any of its Sublicensees. At the time of such notification,

Company shall pay to ALSTDI the following one-time Milestone Payments for the first

occurrence of each milestone event for the second Licensed Product for a disease indication different than the first Licensed Product:

First completion of a Phase III Clinical Trial with a positive clinical endpoint	$ 500,000
First Regulatory Approval in the US	$ 500,000
First Regulatory Approval in the European Union	$ 500,000
First Regulatory Approval in Asia	$ 500,000
First Commercial Sale in the Territory	$ 500,000

Notwithstanding the foregoing, ALSTDI may, in its sole discretion, defer receipt or acceptance of any Milestone Payment to any later date that it selects.

3. The payment by the Company of $250,000 and the above amendment to Article 4.1 (a) of the Agreement shall be deemed by the Parties to constitute full and complete payment of the aforementioned $904,805.45 owed by the Company to ALSTDI for services through December 31, 2019 pursuant to the Master Services Agreement.

4. This Amendment #1, when fully executed and delivered together with the aforementioned $250,000 payment by the Company to ALSTDI, will be incorporated into the Agreement and the Agreement and this Amendment #1 will be deemed one and the same contract. Other than as specifically provided in revised Article 4.1(a), the terms and conditions of the Agreement are not modified by this Amendment # 1 and will remain in full force and effect.

5. This Amendment #1 constitutes the entire agreement between the parties with respect to the subject matter of Amendment #1 and supersedes all prior agreements or understandings between the parties relating to its subject matter, and may not be changed except by a further written agreement executed by the Parties.

6. In the event of any conflict between the Agreement and this Amendment #1, the terms contained in this Amendment #1 will prevail.

7. This Amendment #1 may be executed in counterparts, including by facsimile or by electronic scan copies, each of which counterparts, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.

[SIGNATURES FOLLOW]

IN WITNESS WHEREOF, the parties have caused this Amendment# 1 to the Amended and Restated License Agreement between ALSTDI and the Company dated February 18, 2020 to be executed by their duly authorized representatives as of the date first written above.

ALS THERAPY DEVELOPMENT FOUNDATION, INC.

By: /s/ Alexander L. Cappello

Name: Alexander L. Cappello

Title: Authorized Director

ANELIXIS THERAPEUTICS, INC.

By: /s/ Steven Perrin

Name: Steven Perrin

Title: President

Lonza

CONFIDENTIAL

Exhibit 10.3

Certain identified information has been redacted from this exhibit because it is both (i) not material and (ii) a type that the registrant treats as private or confidential. Information that has been omitted has been identified in this document with a placeholder identified by the mark "[***]."

LICENCE AGREEMENT

between

LONZA SALES AG

and

ANELIXIS THERAPEUTICS LLC

Exhibit 10.3

INDEX

Exhibit 10.3

THIS AGREEMENT is made the BETWEEN the 11th day of September 2018

BETWEEN

LONZA SALES AG incorporated and registered in Switzerland whose registered office is at Muenchensteinerstrasse 38, CH-4002, Basel, Switzerland (hereinafter referred to as "Lonza"), and

ANELIXIS THERAPEUTICS LLC, of 300 Technology Square, 4th floor, Cambridge, MA, 02139, USA (hereinafter referred to as "Licensee")

The Licensee and Lonza shall hereinafter jointly be referred to as the **"Parties"** and individually as the **"Party".**

WHEREAS

A Lonza is the proprietor of the System and the CDACF Version 8.8 System and has the right to grant certain Intellectual Property Rights in relation thereto (all as hereinafter defined), and

B. The Licensee wishes to take a licence under Intellectual Property Rights of which Lonza is the proprietor to commercially exploit the Product (as hereinafter defined) in the form hereunder.

NOW THEREFORE the Parties hereby agree as follows:

1. **Definitions and Interpretation**

1.1 In this Agreement the following words and phrases shall have the following meanings:

1.1.1 **"Affiliate"** means any company, corporation, limited liability company, partnership or other entity which directly or indirectly controls, is controlled by or is under common control, directly or indirectly, with the relevant Party to this Agreement. "Control" means the ownership of more than fifty percent (50%) of the issued share capital of the party in question or the legal power to direct or cause the direction of the general management and policies of the party in question. Such entity shall be deemed an Affiliate only so long as it satisfies the foregoing definition.

1.1.2 **"CDACF Version 8.8 Base Powders"** means the powders set out in Appendix 2.

1.1.3 **"CDACF Version 8.8 Feeds"** means the concentrated nutrient solutions used in order to maintain the growth and productivity of mammalian cells, as more fully set out in Appendix 3

1.1.4 **"CDACF Version 8.8 Media"** means the solutions of nutrients used in mammalian cell culture, as more fully set out in Appendix 3.

1.1.5 **"CDACF Version 8.8 Know-How"** means any Know-How specifically relating to the CDACF Version 8.8 Base Powders, CDACF Version 8.8 Feeds, CDACF Version 8.8 Media or the CDACF Version 8.8 Supplements used either in combination or individually, as set out in Appendix 4.

1.1.6 **"CDACF Version 8.8 System"** means the CDACF Version 8.8 Base Powders, CDACF Version 8.8 Feeds, CDACF Version 8.8 Media, CDACF Version 8.8 Know-How and the CDACF Version 8.8 Supplements used either in combination or individually.

1.1.7 **"CDACF Version 8.8 Supplements"** means the supplement solutions, as more fully set out in Appendix 3.

1.1.8 **"Cell Lines"** means those cell lines referred to in Clause 2.1.1.

1.1.9 **"Competing Contract Manufacturer"** shall mean any Third Party who, together with its affiliates, undertakes or performs more than fifty percent (50%) of their business as a third party manufacturer of monoclonal antibodies and/or therapeutic proteins or any product of a similar nature to which this Agreement relates.

1.1.10 **"Confidential Information"** means any Know-How and confidential information disclosed by one Party to the other in connection with this Agreement including for the avoidance of doubt the terms of this Agreement itself. In the case of Lonza, Confidential Information shall mean all information relating to the System and/or CDACF Version 8.8 System and any other materials, specifications or information which is provided and/or disclosed by Lonza, its Affiliates and their respective officers, employees, agents and advisors to the Licensee and its officers, employees, agents and advisors, whether directly or indirectly, including, without limitation, all agreements, research databases, trade secrets, Intellectual Property Rights, business and/ or commercial and/ or financial data (including data pertaining to Lonza's suppliers, agents, distributors and customers), specifications, technical designs, documents and drawings which are related to the System, the CDACF Version 8.8 System and/or Lonza's business.

1.1.11 **"Effective Date"** means the date first above written.

1.1.12 **"Initiation"** means, with respect to any clinical trial, the first date that a human subject is dosed in such clinical trial.

1.1.13 **"Intellectual Property Rights"** means all rights, title and interests, vested and/or arising out of any industrial or intellectual property, whether protected at common law or under statute, which includes (without limitation) any rights and interests in copyrights, designs, trademarks, service marks, trade-names, technology, business names, logos, commercial symbols, processes, developments, licenses, trade secrets, goodwill, drawings, computer software, formulae, technical information, research data, procedures, designs, Confidential Information and any other knowledge of any nature whatsoever throughout the world whether in existence today or which will come into existence in the future, and including all applications for patents, copyrights, trademarks, trade names, rights to apply and any amendments/modifications or renewals thereto; and all other intellectual property rights.

1.1.14 **"Know-How"** means any technical and other information, whether patented or unpatented, including, but without prejudice to the generality of the foregoing,

ideas, concepts, trade secrets, know-how, inventions, discoveries, data, formulae, specifications, processes, procedures for experiments and tests and other protocols, results of experimentation and testing, fermentation and purification techniques and assay protocols.

1.1.15 **"Net Sale"** means all revenues recorded by or on behalf of Licensee or its Sublicensees for Product sold in the Territory. The permitted deductions booked on an accrual basis by Licensee and its Sublicensees under their respective accounting standards to calculate the recorded net sales from gross sales are as follows:

(a) normal discounts actually granted, including without limitation, quantity, trade, cash and other discounts, rebates and charge-backs;

(b) amounts refunded or credits allowed for Product or other goods returned or not accepted by customers;

(c) packaging, transportation and prepaid insurance charges on shipments or deliveries to customers;

(d) taxes, tariffs, customs duties, surcharges and other governmental charges actually incurred and paid by Licensee or its sublicensee hereunder in connection with the sale, exportation, importation or delivery of Product or other goods to customers.

Subject to the qualification stated below, upon any sale or other disposal of Product by or on behalf of Licensee or its Sublicensee hereunder other than a bona fide arm's length transaction exclusively for money at market value or upon any use of the Product for purposes which do not result in a disposal of such Product in consideration of sales revenue customary in the country of use, such sale, other disposal or use shall be deemed to constitute a sale at the then current maximum selling price in the country in which such sale, other disposal or use occurs.

Notwithstanding anything contained in this Agreement to the contrary, the supply of Product free of charge as commercial samples, or for use in preclinical studies, clinical trials or similar or related research studies, shall not be included in this provision.

If the Product is sold as a combined product that consists of Product together with another therapeutically active ingredient or product for the same indication (a **"Combination"),** the Net Sales will be calculated by multiplying the Net Sales of the Combination (as defined using the Net Sales definition above) by the fraction, A/(A+B) where A is the weighted (by sales volume) average sale price of the Product in the relevant country, and B is the weighted average sale price (by sales volume) in that country of the product(s) containing the other component(s) in finished form. Regarding prices comprised in the weighted average price when sold separately referred to above, if these are available for different dosages from the dosages of Product and other components that are included in the Combination, then the Parties shall mutually agree on the appropriate proportional adjustment to such prices in calculating the royalty bearing Net Sales of the Combination. If the weighted average sale price cannot be determined for the Product or other component(s), the calculation of Net Sales for a Combination will be mutually agreed upon by the Parties based

on the relative value contributed by each component, such agreement to be negotiated in good faith without unreasonable delay.

1.1.16 **"Patent Rights (Lonza)"** means the patents and applications, short particulars of which are set out in Appendix 1A hereto, and all patents and applications thereof of any kind throughout the world whether national or regional including but without prejudice to the generality of the foregoing, author certificates, inventor certificates, improvement patents, utility certificates and models and certificates of addition, and including any divisions, renewals, continuations, continuations in part, reissues, patent disclosures, improvements and extensions of reissue thereof.

1.1.17 **"Patent Rights (Third Party)"** means the patents and applications, short particulars of which are set out in Appendix 1B hereto, and to the extent granted to Lonza by the owners of the Patent Rights (Third Party), all patents and applications thereof of any kind throughout the world whether national or regional including but without prejudice to the generality of the foregoing, author certificates, inventor certificates, improvement patents, utility certificates and models and certificates of addition, and including any divisions, renewals, continuations, continuations in part, reissues, patent disclosures, improvements and extensions of reissue thereof.

1.1.18 **"Product"** means AT-1501 of which Licensee is the proprietor and which is obtained by the expression of any one gene or of any combination of genes by use of the System, or any formulation containing the same.

1.1.19 **"Strategic Partner"** means a party with whom Licensee has entered into a contractual relationship, to identify a therapeutic target, collaborate in the performance of research and development and/or commercialization of a Product or a product of which the Strategic Partner is the Proprietor. In no event may any entity that is primarily a Competing Contract Manufacturer be deemed a Strategic Partner for the purposes of this Agreement.

1.1.20 **"Sublicensee"** means any Third Party to which Licensee grants a sublicence of the rights granted to Licensee pursuant to this Agreement.

1.1.21 **"System"** means Lonza's glutamine synthetase gene expression system known as GS Xceed™ consisting of the Cell Lines and the Vectors, and the System Know-How, whether used individually or in combination with each other. For the avoidance of doubt, any gene proprietary to Licensee inserted into the System for the purposes of producing Product does not form part of the System.

1.1.22 **"System Know-How"** means Know-How relating directly or indirectly to the System known to Lonza from time to time, of which Lonza is the proprietor.

1.1.23 **"Territory"** means world-wide.

1.1.24 **"Third Party"** means any individual or entity other than Lonza and Licensee

1.1.25 **"Valid Claim"** means a claim within the Patent Rights (Lonza) or the Patent Rights (Third Party) (including any re-issued and unexpired patents) which, but for the licence and other rights granted pursuant to Clauses 4.1 and 4.3 hereof, would be infringed by the manufacture, use, sale, offer for sale, exportation or

importation of Product by Licensee or its Sublicensees and which also (a) has not been cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, and (b) has not been revoked, held invalid or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, and (c) has not been rendered unenforceable through disclaimer or otherwise, and (d) has not been disclaimed or otherwise dedicated to the public by Lonza, and (e) is not lost through an interference proceeding and any appeals therefrom.

1.1.26 **"Vectors"** means those vectors referred to in Clause 2.1.1.

1.2 The headings of this Agreement are inserted only for convenience and shall not affect the construction hereof.

1.3 Where appropriate words denoting a singular number only shall include the plural and vice versa.

1.4 References to the recitals, clauses and appendix shall be deemed to be a reference to the recitals, clauses and appendix to this Agreement and shall form an integral part of this Agreement.

1.5 References to any statute or statutory provision include a reference to the statute or statutory provision as from time to time amended, extended or re-enacted.

1.6 Reference in this Agreement to Lonza shall, unless repugnant to the subject or context thereof, include its Affiliates, successors and assigns.

2. Supply of the System, CDACF Version 8.8 System and System Know-How

2.1 Unless previously supplied by Lonza under a separate agreement, Lonza shall, if requested by Licensee in writing, for regulatory purposes only and as approved by Lonza in writing, arrange for the supply ex-works Lonza's premises, Slough, Berkshire (Incoterms 2010) to Licensee of the following:

2.1.1 Vectors
Approximately 20µg of vector pXC-17.4 Approximately 20µg of vector pXC-18.4
Approximately 20µg of vector pH31K5 containing anti-insulin monoclonal
antibody H31K5

2.1.2 Cell Lines
Two 1.5 ml vials of the CHOK1SV-GS-KO cell line

2.1.3 System Know-How
System Know-How contained as at the date hereinabove in (a) manuals of operating procedures for the System, (b) regulatory information in pdf format, and (c) Vector nucleotide sequences.

2.2 In the event that Licensee requires any additional quantities of the materials referred to in Clauses 2.1.1 and 2.1.2, and if Lonza at its sole discretion is willing to supply such

additional materials, such supply shall be subject to the payment of an additional fee by Licensee to Lonza in accordance with Lonza's prices at the time.

2.3 In relation to the CDACF Version 8.8 System, Lonza shall following signature of this Agreement (a) provide Licensee with details of how to purchase the CDACF Version 8.8 Base Powders and CDACF Version 8.8 Supplements to enable Licensee (and only Licensee) to make CDACF Version 8.8 Feeds and CDACF Version 8.8 Media and (b) supply Licensee with the CDACF Version 8.8 Know-How.

2.4 Licensee shall use the System only in the expression of Product by insertion of gene(s) coding for Product(s) into the System, and shall not use, cause the use of or permit to be used the System for any purpose not directly authorised by this Agreement.

2.5 The CDACF Version 8.8 System may only be used in conjunction with the System and may not be used in conjunction with any other gene expression system or for any other purpose whatsoever.

2.6 Any transportation of the System and/or CDACF Version 8.8 System by Lonza on behalf of Licensee shall be made at sole risk of the Licensee who shall be deemed to have full knowledge of the carrier's terms and conditions of carriage **("Carriage Terms").** The Licensee shall, as appropriate, observe, perform, and be subject to the Carriage Terms in relation to the transportation of the System and shall indemnify Lonza against all losses, expenses, demands, claims, actions, judgements, assessments, damages, liabilities, fines, penalties, costs and fees incurred by Lonza by reason of Licensee's failure to observe and perform the Carriage Terms.

3. Ownership of Property and Intellectual Property

3.1 It is hereby acknowledged and agreed that as between the Parties any and all property and Intellectual Property Rights in the System and System Know-How Is vested in Lonza. Similarly it is hereby acknowledged as between the Parties any and all Intellectual Property Rights in the Product and any gene proprietary to Licensee, or any of its licensors or sublicensees, inserted into the System for the purpose of producing Product, is vested in Licensee, or its applicable licensors and sublicensees.

3.2 The provisions of this Clause 3 shall survive termination of this Agreement.

4. Licences

4.1 Lonza hereby grants to Licensee on the Effective Date:

(a) a world-wide non-exclusive licence under the System Know-How, CDACF Version 8.8 Know-How, and the Patent Rights (Lonza) (with the right to sublicence, subject to Clause 4.3 below);

(b) a world-wide non-exclusive sublicence under the Patent Rights (Third Party) (with the right to sublicense, subject to Clause 4.3 below);

in each case (a) and (b) to use, develop, manufacture, market, sell, offer for sale, distribute, import and export Product in the Territory **("Commercial Activities").**

4.2 Save as expressly provided by Clause 2.4 above, the Licensee hereby undertakes not to make any modifications or adaptations to the System and the CDACF Version 8.8 System during the subsistence of this Agreement. For the avoidance of doubt, Licensee is not prevented from adding any materials to the System.

4.3 Subject to the provisions of this Clause 4.3, Licensee shall be entitled to grant a sublicence to the rights granted by Clause 4.1 to any one or more Third Parties for the purposes of any such Third Party producing Product for Licensee provided always:

4.3.1 Licensee shall ensure such sublicensee's use of the System the CDACF Version 8.8 System, Lonza's Intellectual Property Rights and the Product is undertaken solely for undertaking Commercial Activities, for or on behalf of Licensee; and

4.3.2 The Sublicensee shall not, by virtue of this Agreement, be granted any right or licence, either express or implied, under any patent or proprietary right vested in Lonza or otherwise, to use the System, the CDACF Version 8.8 System, Lonza's Intellectual Property Rights or the Product other than for undertaking Commercial Activities for or on behalf of Licensee and Licensee agrees to ensure that such Sublicensee shall not assign, transfer, further sublicense or otherwise make over the benefit or the burden of the rights granted to it pursuant to this Agreement; and

4.3.3 Any sublicence granted shall be granted expressly subject to the terms of this Agreement, and it shall be Licensee's responsibility to ensure the strict adherence by Sublicensee hereunder to the terms and conditions of this Agreement; and

4.3.4 Prior to the grant of any sublicence pursuant to this Clause 4 Licensee shall obtain the written consent of Lonza (such consent not to be unreasonably withheld, conditioned or delayed), to the grant of such sublicence. It is agreed between the Parties that Lonza shall be considered to be reasonably withholding its consent if it holds commercial concerns as to protection of its Intellectual Property Rights and confidentiality should Lonza's Intellectual Property Rights be licensed to the proposed Sublicensee; and

4.3.5 Licensee shall not sublicense the rights sublicensed to it under the Precision patents listed in Appendix 1B to Cellectis S.A. or any of its affiliates or its or their successors with affiliate meaning for the purposes of this Clause 4.3.5 any entity controlling, controlled by, or under common control with Cellectis S.A.

4.4 If, on a country-by-country basis, any granted patents that form part of the Patent Rights (Lonza) or Patent Rights (Third Party) (including any re-issued patents and unexpired patents), subsequently expire or no longer contain a Valid Claim such Patent Rights shall automatically fall outside the scope of this Agreement and the provisions of Clauses 4.1 to 4.3 shall only apply, with respect to granted patents, to those granted patents which contain a Valid Claim and form part of the Patents Rights (Lonza) or Patent Rights (Third Party) for as long as those granted patents remain in force.

4.5 Notwithstanding clause 4.4, on a country-by-country basis, where no Valid Claim remains in force, the provisions of Clauses 4.1 to 4.3 shall only apply for as long as the System Know-How and CDACF Version 8.8 Know-How (as appropriate) remain secret and substantial.

4.6 No licence is granted save as expressly provided herein and no licence in addition thereto shall be deemed to have arisen or be implied by way of estoppel or otherwise.

5. Payments

5.1 In consideration of the licence granted to Licensee pursuant to Clause 4.1 above, and in consideration for the right to sublicense the rights granted by Clause 4.1 pursuant to Clause 4.3, Licensee shall pay Lonza as follows, subject to the adjustment as set forth in Clause 5.2:

5.1.1 in respect of Product manufactured by Lonza, a royalty of zero point eight five percent (0.85%) of Net Sales;

5.1.2 where Licensee or Licensee's Strategic Partner manufactures Product (whether for clinical or commercial purposes):

5.1.2.1 a payment of Swiss Francs one hundred thousand (CHF 100,000) due annually during the course of this Agreement, and being first payable upon Initiation of phase II clinical trials for Product and thereafter on each anniversary of such date; and

5.1.2.2 a royalty of one percent (1%) of Net Sales of Product.

5.1.3 where any party other than Lonza, Licensee or Licensee's Strategic Partner manufactures Product (whether for clinical or commercial purposes:

5.1.3.1 a payment of Swiss Francs four hundred thousand (CHF 400,000) per sublicence due annually during the course of such sublicence (irrespective as to the years of manufacture), and being first payable on the commencement date of the relevant sublicence; and

5.1.3.2 a royalty of one point seven five percent (1.75%) of Net Sales of Product.

5.2 If, on a country-by-country basis, the manufacture and/or sale of the Product are not protected by a Valid Claim (either because no patent or application was ever filed for such territory or the patent or application is no longer of effect) then in respect of sales in such countries:

(a) the royalties referred to in 5.1.1, 5.1.2.2 and 5.1.3.2 shall be due only in respect of the System Know-How;

(b) the royalties referred to in 5.1.1 and 5.1.2.2 shall be at the rate of zero point four two five per cent (0.425%) and zero point five per cent (0.5%) respectively of the Net Sales;

(c) the royalties referred to in 5.1.3.2 shall be at the rate of zero point eight seven five per cent (0.875%) of the Net Sales.

5.3 For the avoidance of doubt the licence to use the CDACF Version 8.8 System is given in consideration of the obligations incumbent upon the Licensee under the terms of this Agreement but is otherwise royalty-free.

6. Royalty Procedures

6.1 Licensee shall, and shall ensure that its Sublicensees shall, keep true and accurate records and books of account containing all data necessary for the calculation of royalties payable to Lonza. Such records and books of account shall, upon reasonable notice having been given by Lonza (which in no event shall be less than thirty (30) days prior notice), be open at all reasonable times during regular business hours for inspection by independent auditors selected by Lonza and reasonably acceptable to Licensee. Such independent auditors shall agree to maintain the confidentiality of the information and materials disclosed during the audit. Any such audit shall be conducted in a manner that does not interfere unreasonably with the operations of Licensee's business. Lonza may perform an audit once each calendar year. Each audit shall begin upon the date specified by Lonza and shall be completed as soon as reasonably practicable. Lonza shall pay the costs of the independent auditors conducting such audit, unless the results of the audit reveal an underpayment of 5% or more by Licensee, in which case, Licensee shall pay the reasonable costs of the independent auditors. If an audit concludes that an overpayment or underpayment has occurred during the audited period, such payment shall be remitted by the Party responsible for such payment to the other Party within thirty (30) days after the date such auditor's written report identifying the overpayment or underpayment is delivered to the Party responsible for such payment.

6.2 Licensee shall prepare a statement in respect of each calendar quarter which shall show for the immediately preceding quarter details of the sales of Product on a country by country basis and the royalty due and payable to Lonza thereon.

Such statement shall be submitted to Lonza within thirty (30) days after the end of the calendar quarter to which it relates, together with a remittance for the royalties due to Lonza to which Lonza shall issue a receipted invoice in return.

6.3 All sums due under this Agreement:

6.3.1 shall be paid in Swiss Francs to Lonza.

6.3.2 are exclusive of any Value Added Tax or of any other applicable taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority, and shall be paid by Licensee (other than taxes on Lonza's income). The parties agree to co-operate in all respects reasonably necessary to take advantage of such double taxation treaties as may be available.

6.4 To the extent that Licensee reports Net Sales otherwise than in Swiss Francs then royalty payments due to Lonza shall be first calculated in the local currency in which Net Sales are reported and then shall be converted to a Swiss Franc value first published in the Financial Times on the first business day after the relevant quarterly reporting period.

6.5 Where Lonza does not receive payment of any sum by the due date, interest shall accrue thereafter on the sum due and owing to Lonza at the rate of four percent (4%) per annum over the base rate from time to time of National Westminster Bank plc,

interest to accrue on a day-to-day basis without prejudice to Lonza's right to receive payment on the due date.

7. Liability and Warranties

7.1 Subject to Clause 7.2, Lonza gives no representation or warranty that the Patent Rights (Lonza) or Patent Rights (Third Party) which are patent applications will be granted or if granted will be valid nor that the exercise of the rights granted to Licensee hereunder will not infringe other patent rights or intellectual property rights vested in Lonza or any Third Party.

7.2 Lonza warrants that the patents included in the Patent Rights (Lonza) are the only patents that must be licensed from Lonza and/or its Affiliates in order to operate the System.

7.3 The Licensee hereby acknowledges that in order to exploit the rights granted herein the Licensee may require licences under Lonza patent rights (other than those herein licensed) or under Third Party patent rights (including those vested in Affiliates of Lonza) that may be infringed by the use by the Licensee of the rights licensed herein and it is hereby agreed that it shall be the Licensee's responsibility to satisfy itself as to the need for such licences and if necessary to obtain such licences; provided that any such patent rights vested in Lonza or its Affiliates which are necessary for Licensee and its Sublicensees to operate the System as permitted by the terms of this Agreement shall be automatically included within the Intellectual Property Rights licensed to Licensee hereunder.

7.4 Each Party **("Indemnifying Party")** shall indemnify and hold harmless the other Party and its Affiliates, and their respective officers, employees and agents (each an **"Indemnified Party")** at all times in respect of any and all losses, damages, costs and expenses (collectively **"Losses")** suttered or incurred as a result of any contractual, tortious or other claims or proceedings by Third Parties (collectively **"Third Party Claims")** against Indemnified Party arising out of the Indemnifying Party's breach of this Agreement, including breach of representations and warranties, violation of applicable law, negligence or wilful misconduct; provided that with respect to any Third Party Claim for which each Party is entitled hereunder to seek indemnification from the other Party, each Party as the Indemnifying Party shall indemnify the other Party for its Losses only to the extent of the Indemnifying Party's relative responsibility for the facts underlying the Third Party Claim .

7.5 With respect to product liability claims or proceedings, the following shall apply: (a) except to the extent provided in (b) below, Licensee shall indemnify and hold harmless Lonza, its Affiliates and their respective officers, employees and agents at all times in respect of any and all losses, damages, costs and expenses suffered or incurred as a result of any tortious claims or proceedings of death or bodily injury relating to the Product, and (b) Lonza shall indemnify and hold harmless Licensee, its Affiliates and their respective officers, employees and agents at all times in respect of any and all losses, damages, costs and expenses suffered or incurred as a result of any tortious claims or proceedings of death or bodily injury relating to the Product to the extent such claims or proceedings result from defects in the Cell Lines and Vectors, or from Lonza's breach of this Agreement.

7.6 Any condition or warranty other than those relating to title which might otherwise be implied or incorporated within this Agreement by reason of statute or common law or otherwise is hereby expressly excluded.

7.7 EXCEPT FOR EITHER PARTY'S BREACH OF CLAUSE 8 HEREOF IN NO EVENT SHALL EITHER PARTY OR THEIR RESPECTIVE AFFILIATES BE LIABLE TO THE OTHER PARTY, THEIR AFFILIATES AND THEIR RESPECTIVE OFFICERS, EMPLOYEES AND AGENTS WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT WHETHER IN CONTRACT IN TORT IN NEGLIGENCE OR FOR BREACH OF STATUTORY DUTY OR OTHERWISE FOR LOSS OF PROFITS, SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES. Nothing in this Agreement shall exclude or limit the liability of either Party for fraud or for death or personal injury caused by its negligence or for any other liability that may not be limited or excluded as a matter of law.

7.8 The terms of this Clause 7 shall survive expiration or termination of this Agreement for whatever reason.

8. Confidentiality

8.1 Licensee expressly acknowledges that Confidential Information disclosed by Lonza pursuant to this Agreement is supplied in circumstances imparting an obligation of confidence and Licensee shall keep such Confidential Information secure, secret and confidential and undertakes to respect Lonza's proprietary rights therein and to use the same for the sole purpose of this Agreement and not during the period of this Agreement or at any time for any reason whatsoever to disclose, cause or permit to be disclosed such Confidential Information to any Third Party other than its Sublicensee hereunder for use in accordance with the terms of this Agreement. Licensee shall procure that only its employees and employees of its Sublicensee hereunder shall have access to Confidential Information and then only on a need to know basis and that all such employees shall be informed of their secret and confidential nature and shall be subject to the same obligations as Licensee and its Sublicensee hereunder pursuant to this Clause 8.1.

8.2 Lonza expressly acknowledges and undertakes that any Confidential Information disclosed by the Licensee to Lonza pursuant to this Agreement is disclosed in circumstances imparting an obligation of confidence and Lonza shall keep such Licensee's Confidential Information secure, secret and confidential and undertakes to respect Licensee's proprietary rights therein and to use the same for the sole purpose of this Agreement and not during the period of this Agreement or at any time for any reason whatsoever disclose and/or cause and/or permit to be disclosed such Licensee's Confidential Information to any Third Party.

8.3 Each Party will restrict the disclosure of Confidential Information to such officers, employees, professional advisers, finance-providers, and consultants of itself and its Affiliates ("Representatives") who have been informed of the confidential nature of the Confidential Information and who have a need to know such Confidential Information for the purpose of this Agreement. Prior to disclosure to such persons, the Party in receipt of the Confidential Information shall bind its and its Affiliates' Representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The receiving Party shall notify the disclosing Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information.

8.4 The obligations of confidence referred to in this Clause 8 shall not extend to any information which the receiving Party demonstrates:

8.4.1 is or shall become generally available to the public otherwise than by reason of a breach by the recipient Party of such information of the provisions of this Clause 8;

8.4.2 is known to the recipient Party of such information and is at its free disposal prior to its receipt from the other;

8.4.3 is subsequently disclosed to the recipient Party without obligations of confidence by a Third Party owing no such obligation of confidentiality to the disclosing Party; or

8.4.4 can be demonstrated by competent written evidence as having been independently developed by the recipient of the information in question without access to or use or knowledge of the information of the disclosing Party.

8.5 Notwithstanding the foregoing it is acknowledged between the Parties that Lonza or Licensee may be required to disclose Confidential Information to a government agency for the purpose of any statutory, regulatory or similar legislative requirement applicable to the production of Product, or to a court of law or to meet the requirements of any Stock Exchange to which the Parties may be subject. In such circumstances the disclosing Party will inform the other Party prior to disclosure being made as to the nature of the required disclosure, shall only make the disclosure to the extent legally required and shall seek to impose obligations of secrecy wherever possible. Notwithstanding such disclosure such Confidential Information shall otherwise remain subject to this Clause 8.

8.6 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided hereunder by a Party may cause irreparable harm to the other Party **("Non-Breaching Party")** and that money damages may not provide a sufficient remedy to the Non-Breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then in addition to all other remedies available at law or in equity, the Non-Breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the Non-Breaching Party.

8.7 The obligations of both Parties under this Clause 8 shall survive the expiration or termination of this Agreement for whatever reason.

9. Intellectual Property Enforcement

9.1 Lonza hereby undertakes and agrees that at its own cost and expense it will:

9.1.1 prosecute or procure prosecution of such of the Patent Rights (Lonza) which are patent applications diligently so as to secure the best commercial advantage obtainable, as determined by Lonza in its commercially reasonable discretion, and will pursue, as determined by Lonza in its commercially reasonable discretion, all necessary actions against any Third Party that Lonza reasonably believes is infringing, misappropriating or violating any Lonza Intellectual Property Rights; and

9.1.2 pay or procure payment of all renewal fees in respect of the Patent Rights (Lonza) to ensure they are valid and subsisting for the full term thereof and in particular will procure such renewal of the registrations thereof as may be necessary from time to time so far as it is reasonable to do so with particular reference to commercial considerations.

9.2 Licensee shall promptly notify Lonza in writing of any infringement or improper or unlawful use of or of any challenge to the validity of the Patent Rights (Lonza) and/or Know-How. Lonza undertakes and agrees to take all such steps and proceedings and to do all other acts and things as may in Lonza's sole discretion be necessary to restrain any such infringement or improper or unlawful use or to defend such challenge to validity and Licensee shall permit Lonza to have the sole conduct of any such steps and proceedings including the right to settle them whether or not Licensee is a party to them. Licensee shall have the right at its own cost and for its own benefit to initiate, prosecute and control the enforcement of the Patent Rights (Lonza) against infringement by a Third Party in the Territory if all of the following conditions are fulfilled
(a) the product manufactured through the infringing activity is a competing product to the Product, (b) Lonza has not granted rights to Third Parties which prevent Lonza from granting such a right to enforce to Licensee, and (c) Lonza does not initiate proceedings within sixty (60) days of being requested to do so by Licensee.

10. Term and Termination

10.1 Unless terminated earlier in accordance with the provisions of this Clause 10 or Clause 14, this Agreement shall continue in force in each country of the world, until (i) expiry of the last Valid Claim or (ii) ten (10) years from the First Commercial Sale of the Product provided that the System Know-How and/or CDACF Version 8.8 Know-How is identified and remains secret and substantial, whichever is later.

10.2 Licensee may terminate this Agreement by giving sixty (60) days' notice in writing to Lonza.

10.3 Either Lonza or Licensee may terminate this Agreement forthwith by notice in writing to the other upon the occurrence of any of the following events:

10.3.1 if the other commits a breach of this Agreement which in the case of a breach capable of remedy shall not have been remedied within thirty (30) days of the receipt by the other of a notice identifying the breach and requiring its remedy

10.3.2 if the other is unable to pay its debts or enters into compulsory or voluntary liquidation (other than for the purpose of effecting a reconstruction or amalgamation in such manner that the company resulting from such reconstruction or amalgamation if a different legal entity shall agree to be bound by and assume the obligations of the relevant Party under this Agreement) or compounds with or convenes a meeting of its creditors or has a receiver or administrator appointed over all or any part of its assets or takes or suffers any similar action in consequence of a debt, or ceases for any reason to carry on business.

10.4 If at any time during this Agreement Licensee knowingly, directly or indirectly, opposes or assists any Third Party to oppose the grant of letters patent or any patent application within any of the Patent Rights (Lonza) or disputes or knowingly, directly or indirectly, assists any Third Party to dispute the validity of any patent within any of the Patent

Rights (Lonza) or any of the claims thereof Lonza shall be entitled at any time thereafter to terminate all or any of the licences granted hereunder forthwith by notice to Licensee.

10.5 If this Agreement expires or is terminated for any reason any and all licences granted hereunder shall terminate with effect from the date of termination and Licensee shall destroy all Vectors, Cell Lines and Product and all Confidential Information which is provided by Lonza (including all Know-How, all System Know-How and all CDACF Version 8.8 System Know-How) forthwith and shall certify such destruction immediately thereafter in writing to Lonza provided however that the Licensee and Sublicensees shall have the right to sell or otherwise dispose of all Product then on hand, subject to the payment of royalties and the other terms of this Agreement.

10.6 Termination for whatever reason or expiration of this Agreement shall not affect the accrued rights of the Parties arising in any way out of this Agreement as at the date of termination. The right to recover damages against the other and all provisions which are expressed to survive this Agreement shall remain in full force and effect.

11. Assignment

11.1 Save as expressly provided by Clause 4, neither Party shall be entitled to assign, transfer, charge or in any way make over the benefit and/or the burden of this Agreement without the prior written consent of the other which consent shall not be unreasonably withheld or delayed, save that Lonza shall be entitled without the prior written consent of the Licensee to assign, transfer, charge, sub-contract, deal with or in any other manner make over the benefit and/or burden of this Agreement (i) to an Affiliate or (ii) to any joint venture company of which Lonza is the beneficial owner of at least fifty percent (50%) of the issued share capital thereof or (iii) to any company with which Lonza may merge or (iv) to any company to which Lonza may transfer its assets and undertaking.

11.2 This Agreement shall be binding upon the successors and assigns of the parties and the name of a Party appearing herein shall be deemed to include the names of its successors and assigns provided always that nothing herein shall permit any assignment by either Party except as expressly provided herein.

12. Governing Law and Dispute Resolution

12.1 The validity, construction and performance of this Agreement shall be governed by English law to which the Parties submit.

12.2 Subject to Clause 12.3, the Courts of England and Wales shall have exclusive jurisdiction in relation to this Agreement provided that the Parties shall have the right to proceed to a suitable jurisdiction for the purpose of enforcing a judgment, award, or order (including without limitation seeking specific performance) and injunctive reliefs.

12.3 Any dispute arising between the Parties under this Agreement may upon the mutual agreement of the Parties be referred to and finally settled by arbitration under the Rules of Arbitration of the International Chamber of Commerce by a single arbitrator knowledgeable in biopharmaceutical research and development related matters and familiar with the biopharmaceutical industry, appointed in accordance with the said Rules. The place of arbitration shall be London, England and the arbitration shall be

conducted in the English language. The arbitrator's award shall be final and binding. The Parties covenant and agree that they will participate in the arbitration in good faith and that they will share equally the costs of the arbitration, except as otherwise provided herein. Any Party refusing to comply with an order of the arbitrator will be liable for costs and expenses, including attorney's fees, incurred by the other Party in enforcing an award.

13. Force Majeure

Neither Party shall be in breach of this Agreement if there is any total or partial failure of performance by it of its duties and obligations under this Agreement occasioned by any act of God (including without limitation, fire), act of government or state, war, civil commotion, insurrection, embargo, epidemic, terrorism or earthquake, prevention from or hindrance in obtaining any raw materials, energy or other supplies, labour disputes of whatever nature and any other reason beyond the control of either Party. If either Party is unable to perform its duties and obligations under this Agreement as a direct result of the effect of one of the reasons set out in this Clause 13 such Party shall give written notice to the other of such inability stating the reason in question. The operation of this Agreement shall be suspended during the period (and only during the period) in which the reason continues. Forthwith upon the reason ceasing to exist the Party relying upon it shall give written notice to the other of this fact. If the reason continues for a period of more than ninety (90) days and substantially affects the commercial basis of this Agreement the Party not claiming under this Clause 13 shall have the right to terminate this Agreement by giving written notice of such termination to the other Party.

14. Illegality

14.1 If any provision or term of this Agreement or any part thereof shall become or be declared illegal, invalid or unenforceable for any reason whatsoever including but without limitation by reason of the provisions of any legislation or other provisions having the force of law or by reason of any decision of any Court or other body or authority having jurisdiction over the parties hereto or this Agreement including the EC Commission or the European Court of Justice:

(i) such provision shall, so far as it is illegal, invalid or unenforceable, be given no effect by the Parties and shall be deemed not to be included in this Agreement;

(ii) the other provisions of this Agreement shall be binding on the Parties as if such provision was not included therein; and

(iii) the Parties agree to negotiate in good faith to amend such provision to the extent possible for incorporation herein in such reasonable manner as most closely achieves the intention of the Parties without rendering such provision invalid or unenforceable.

15. Miscellaneous

15.1 This Agreement embodies and sets forth the entire agreement and understanding of the parties and supersedes all prior oral and written agreements, representations, misrepresentations (where innocently or negligently made), understandings or

arrangements relating to the subject matter of this Agreement **("Understandings").** Neither Party shall be entitled to rely on any Understandings which are not expressly set forth in this Agreement.

15.2 This Agreement shall not be amended, modified, varied or supplemented except in writing signed by duly authorised representatives of the Parties.

15.3 No failure or delay on the part of either Party hereto to exercise any right or remedy under this Agreement shall be construed or operated as a waiver thereof nor shall any single or partial exercise of any right or remedy under this Agreement preclude the exercise of any other right or remedy or preclude the further exercise of such right or remedy as the case may be. The rights and remedies provided in this Agreement are cumulative and are not exclusive of any rights or remedies provided by law.

15.4 Except as required by law, the text of any press release or other communication to be published by or in the media whether of a scientific nature or otherwise and concerning this Agreement shall require the prior written approval of Lonza and Licensee.

15.5 Each of the Parties shall be responsible for its respective legal and other costs incurred in relation to the preparation of this Agreement.

15.6 The Parties do not intend that any term hereof should be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999, or by any other statute or common-law principle, by any person who is not a party to this Agreement.

16. Notice

16.1 Any notice or other document to be given under this Agreement shall be in writing and shall be deemed to have been duly given if left at or sent by registered post or by a reputable overnight courier to a Party or delivered ,n person to a Party at the address set out below for such Party or such other address as the Party may from time to time designate by written notice to the other(s):

Address of Lonza
Lonza Sales AG, Muenchensteinerstrasse 38 CH-4402, Basel, Switzerland

With a copy to: Lonza Biologics Plc
[***]
E-mail: [***]
Attn: [***]

Address of Licensee
ANELIXIS THERAPEUTICS LLC
300 Technology Square, 4th floor, Cambridge, MA 02139
Email: [***]
Attn: [***]

16.2 All such notices and documents shall be in the English language. Any such notice or other document shall be deemed to have been received by the addressee seven (7) working days following the date of dispatch of the notice or other document by post or, where the notice or other document is sent by hand, at the time of such delivery. To prove the giving of a notice or other document it shall be sufficient to show that it was dispatched.

Exhibit 10.3

AS WITNESS the hands of the duly authorised representatives of the parties hereto

Signed for and on behalf of

LONZA SALES AG

/s/ Bart A. M. van Aarnhem

Senior Legal Counsel

Signed for and on behalf of

LONZA SALES AG

/s/ Jacov Wirtz

Assoc. General Counsel

Signed for and on behalf of

ANELIXIS THERAPEUTICS LLC

/s/ Steve Perrin

CEO

Exhibit 10.3

APPENDIX 1A

[***]

Exhibit 10.3

APPENDIX 1B

[***]

Exhibit 10.3

APPENDIX 2

[***]

Exhibit 10.3

APPENDIX 3

[***]

Exhibit 10.3

APPENDIX 4

[***]

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.;

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 11, 2022

By: /s/ David-Alexandre C. Gros, M.D.
David-Alexandre C. Gros, M.D.
Chief Executive Officer
(Principal Executive Officer)

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):

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 11, 2022

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, 2022 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 11, 2022

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

David-Alexandre C. Gros, M.D.

Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

**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, 2022 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 11, 2022

By: /s/ Paul Little

Paul Little

Chief Financial Officer
(Principal Financial and Accounting Officer)