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 March 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-36620

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 May 11, 2021, there were 14,306,614 shares of the Registrant's common stock outstanding.

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, 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 short operating history and the Anelixis acquisition, which may make it difficult to evaluate the success of our business to date and to assess our future viability;
- the impact of the COVID-19 pandemic on our operations, including our ability to execute clinical trials or access capital markets;
- expectations regarding the timing for the commencement and completion of product development or clinical trials for the Company's product candidates;
- the timing, costs, conduct and outcome of preclinical studies and clinical trials;
- meeting future clinical and regulatory milestones, such as New Drug Application ("NDA") submissions;
- the risk that clinical trials of the Company's product candidates may not be successful in establishing safety and tolerability or efficacy;
- the Company's plans and timing with respect to seeking regulatory approvals and uncertainties regarding the regulatory process;
- the anticipated treatment of data by the U.S. Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA") or other regulatory authorities of the Company's product candidates;
- the rate and degree of market acceptance and clinical utility of the Company's product candidates;
- the Company's commercialization, marketing, and manufacturing capabilities and strategy;
- the Company's intellectual property position and strategy;
- the Company's ability to identify additional product candidates with significant commercial potential;
- the availability of funds and resources to pursue the Company's research and development projects, including preclinical studies and clinical trials of its product candidates, and manufacturing activities;
- the Company's estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the Company's ability to continue as a going concern;
- developments relating to the Company's competitors and industry;
- the impact of government laws and regulations; and
- the duration over which the Company's cash balances will fund its operations.

Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the ability to develop commercially viable product formulations on a timely basis, or at all; the sufficiency of the Company's cash resources; the ability to obtain necessary regulatory and ethics approvals to commence additional clinical trials; whether data from early clinical trials will be indicative of the data that will be obtained from future clinical trials; whether the results of clinical trials will warrant submission for regulatory approval of any investigational product; whether any such submission will receive approval from the FDA or equivalent foreign regulatory agencies and, if the Company is able to obtain such approval for an investigational product, whether it will be successfully distributed and marketed; and the duration of the COVID-19 pandemic, including economic and other impacts of the pandemic and actions taken in response to it by governments, businesses, and individuals. 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 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.

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 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.
- 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.
- 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.

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

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

Risks Related to Our Dependence on Third Parties

- The 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 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.

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.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.
- 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.
- If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.
- We may be subject to trade secret claims from former employers of Company personnel.

Risks Related to Our Common Stock

- Our stock price could be volatile as holders of our preferred stock become able to convert their shares to common stock and sell these shares in the open market.
- 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.
- We do not expect to pay any cash dividends in the foreseeable future.

ELEDON PHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2021

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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)

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 108,579	$ 114,195
Prepaid expenses and other current assets	1,662	1,435
Total current assets	110,241	115,630
Operating lease asset, net	92	138
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	315	383
Total assets	$ 191,682	$ 197,185
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,514	$ 1,366
Current operating lease liability	97	144
Accrued severance	5	12
Accrued expenses and other liabilities	2,590	961
Total current liabilities	4,206	2,483
Deferred tax liabilities	3,605	4,106
Total liabilities	7,811	6,589
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Series X1 non-voting convertible preferred stock, $0.001 par value, 515,000 shares authorized; 108,070 shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Series X preferred stock, $0.001 par value, 10,000 shares authorized; 6,204 and no shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 14,306,614 and 15,160,397 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	14	15
Additional paid-in capital	272,749	270,974
Accumulated deficit	(88,892)	(80,393)
Total stockholders' equity	183,871	190,596
Total liabilities and stockholders' equity	$ 191,682	$ 197,185

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 March 31,	
	2021	**2020**
Operating expenses		
Research and development	$ 5,653	$ 1,648
General and administrative	3,352	1,730
Total operating expenses	9,005	3,378
Loss from operations	(9,005)	(3,378)
Other income, net	5	30
Warrant inducement expense	—	(4,829)
Loss before income tax benefit	(9,000)	(8,177)
Income tax benefit	501	—
Net loss and comprehensive loss	$ (8,499)	$ (8,177)
Net loss per share, basic and diluted	$ (0.57)	$ (8.52)
Weighted-average common shares outstanding, basic and diluted	14,831,049	959,285

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 X1 Preferred Stock		Series X Preferred Stock		Common Stock				
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
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	—	—	—	—	—	—	1,774	—	1,774
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(8,499)	(8,499)
Balance as of March 31, 2021	108,070	$ —	6,204	$ —	14,306,614	$ 14	$ 272,749	$ (88,892)	$ 183,871
Balance as of December 31, 2019	—	$ —	—	$ —	720,408	$ 1	$ 67,046	$ (57,582)	$ 9,465
Issuance of common stock in connection with exercise of warrants, net of issuance costs	—	—	—	—	383,234	—	5,191	—	5,191
Cancellation of common stock in connection with exchange for preferred stock	—	—	3,796	—	(210,889)	—	—	—	—
Warrant inducement expense	—	—	—	—	—	—	4,829	—	4,829
Stock-based compensation	—	—	—	—	—	—	437	—	437
Net loss and other comprehensive loss	—	—	—	—	—	—	—	(8,177)	(8,177)
Balance as of March 31, 2020	—	$ —	3,796	$ —	892,753	$ 1	$ 77,503	$ (65,759)	$ 11,745

See accompanying notes to unaudited condensed consolidated financial statements.

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

	For the Three Months Ended March 31,	
	2021	**2020**
Operating activities		
Net loss	$ (8,499)	$ (8,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	—	2
Amortization of operating lease asset	46	44
Warrant inducement expense	—	4,829
Stock-based compensation	1,774	437
Deferred tax liabilities	(501)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(159)	159
Accounts payable and accrued expenses	2,220	552
Operating lease liability	(47)	(43)
Net cash used in operating activities	(5,166)	(2,197)
Financing activities		
Proceeds from exercise of warrants, net	—	5,191
Offering costs in connection with PIPE transaction	(450)	—
Net cash (used in) provided by financing activities	(450)	5,191
Net change in cash and cash equivalents	(5,616)	2,994
Cash and cash equivalents at beginning of period	114,195	8,791
Cash and cash equivalents at end of period	$ 108,579	$ 11,785
Supplemental disclosure of non-cash investing and financing activities		
Common stock exchanged for warrants	$ 1	$ —

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 discovering or acquiring, and then 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"). We believe that this approach has the potential to allow us to: develop more precise therapies with a resulting potential for both increased efficacy and safety; identify patients and indications more likely to respond to our treatment approaches; and pursue multiple indications for product candidates. The company's lead compound in development is AT-1501, an anti-CD40L antibody with high affinity for CD40 ligand (CD40L, also called CD154), a well-validated biological target with broad therapeutic potential. AT-1501 is a humanized IgG1 antibody engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The central role of CD40/CD40L signaling in generating pro-inflammatory responses makes it an attractive candidate for therapeutic intervention in autoimmune disease, induction and maintenance of transplant tolerance, and neuroinflammation. Blocking the activation of the CD40L pathway prevents acute and long-term allograft transplant rejection in multiple animal species and ameliorates disease progression and pathology in preclinical models of autoimmunity and 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.

On September 14, 2020, we 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 (see Note 7). Following the acquisition of Anelixis, we changed our name to Eledon Pharmaceuticals, Inc. The Company has continued to maintain its corporate headquarters in Irvine, 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, 2020 included in the Annual Report on Form 10-K filed by the Company with the SEC on March 31, 2021. The results of operations and comprehensive loss for the three months ended March 31, 2021 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 $8.5 million for the three months ended March 31, 2021. As of March 31, 2021, the Company had cash and cash equivalents of $108.6 million, working capital of $106.0 million and an accumulated deficit of $88.9 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 months ended March 31, 2021, 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 condensed 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 unaudited condensed consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to stock-based transactions, accruals for liabilities, fair value of assets acquired and liabilities assumed in a business combination, impairment of long lived assets, including goodwill, and other matters that affect the condensed 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 condensed 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. 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 March 31, 2021 and December 31, 2020.

Concentration of Credit Risk and Other Risks and Uncertainties

As of March 31, 2021 and December 31, 2020, 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 the Company's 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 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, 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 through March 31, 2021.

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 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 months ended March 31, 2021 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 March 31,	
	2021	2020
	(In thousands, except share and per share data)	
Net loss used in the calculation of basic and diluted loss per share	$ (8,499)	$ (8,177)
Net loss per share, basic and diluted	$ (0.57)	$ (8.52)
Weighted-average number of common shares, basic and diluted	14,831,049	959,285

The computation of diluted earnings per share excludes stock options, warrants, and restricted stock units that are anti-dilutive. As of March 31, 2021 and 2020, common share equivalents of 4,659,416 shares and 528,659 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 options granted to employees, which is an average of the options ordinary vesting period and the contractual term. For stock options granted to the board of directors, 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 of directors may be exercised upon termination. The expected dividend assumption was based on the Company's history and expectation of dividend payouts. The Company has not paid and does not expect to pay dividends at any time in the foreseeable future. The Company recognizes forfeitures on an actual basis and as such did not estimate forfeitures to calculate stock-based compensation.

Restricted Stock Units ("RSU") and Performance-Based Restricted Stock Units ("PRSU") are measured and recognized based on the quoted market price of our common stock on the date of grant.

In March 2020, the Board of Directors approved an increase of 28,816 shares issuable under the 2014 Plan and 7,204 shares issuable under the ESPP.

On December 18, 2020, the Company held 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 available for issuance under the 2020 Plan will initially be 4,860,000 shares of Common Stock, which represents 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 of Directors currently intends that the initial shares under the 2020 Plan will be sufficient to fund the Company's equity compensation needs for approximately 3 years.

The 2014 Plan was closed to new grants following the approval of the 2020 plan, and therefore, there were no longer any shares reserved for issuance under the 2014 Plan as of December 31, 2020. The number of shares reserved for issuance under the 2020 Plan and ESPP was 4,135,044 and 24,077 shares, respectively, as of March 31, 2021.

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):

	March 31, 2021	December 31, 2020
Prepaid insurance	$ 892	$ 1,157
Prepaid clinical	481	89
Prepaid other	66	41
Insurance receivable	197	110
Other current assets	26	38
Total prepaid expenses and other current assets	$ 1,662	$ 1,435

Note 4. Accrued Expenses and Other Liabilities

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

	March 31, 2021	December 31, 2020
Accrued compensation and related expenses	$ 836	$ 31
Accrued clinical	1,415	258
Accrued professional services	159	9
Accrued vacation	128	67
Accrued costs associated with PIPE financing	—	450
Accrued other	52	146
Total accrued expenses and other liabilities	$ 2,590	$ 961

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 $63,000 and $47,000 for the three months ended March 31, 2021 and 2020, respectively.

The Company has an operating lease for 5,197 square feet of office space in Irvine, California, that expires on September 30, 2021, as amended. Additionally, the Company has operating leases for four serviced office spaces in Burlington, Massachusetts that expire on June 30, 2021. The Burlington, Massachusetts office leases are considered short-term leases and are not recorded on the condensed consolidated balance sheet.

The Company determines if a contract contains a lease at inception. Our office leases have a remaining term ranging from three months to six months and do not include options to extend the leases for additional periods.

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

Our Irvine lease contains 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 agreement does 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:

	Three Months Ended March 31, 2021
Operating lease cost[(a)]	$ 49

(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):

	Three Months Ended March 31, 2021
Supplemental Cash Flows Information	
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	$ 49
Remaining lease term	
Operating lease	0.5
Discount rate	
Operating lease	3.25%

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

Years ending

2021 (remainder of)	$ 97
Total minimum lease payments	97
Less imputed interest	—
Present value of lease liabilities	97
Less current portion	(97)
	$ —

Grants and Licenses

ALS Therapy Development Foundation, Inc. License Agreement

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

The first and second milestones of the Agreement are the dosing of the first subjects in a first toxicity study in non-human primates and the dosing of the first patient in a Phase I Clinical Trial, respectively. Both of these milestones were achieved as of December 31, 2018 and 2017. The fee due for the achievement of these milestones was $1,000,000 each. During 2018 and 2017, Anelixis issued $1,000,000 worth of its common stock in lieu of making a cash payment. There were no milestones achieved during the three months ended March 31, 2021 and the year ended December 31, 2020.

The Agreement was amended and restated in February 2020, and a first amendment to the restated license agreement was executed in September 2020. As amended in September 2020, the remaining milestone payments for a first 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 ALSTDI an amended annual license maintenance fee of $100,000 beginning on the earlier of January 1, 2022, the Company's first sublicense, or change in control, as defined in the Agreement.

Furthermore, the Company shall pay ALSTDI 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 million in aggregate net sales, the Company shall pay ALS TDI a one-time milestone payment of $15,000,000. Upon the first calendar year of reaching $1 billion in aggregate net sales, the Company is obligated to pay ALSTDI a one-time milestone payment of $30,000,000.

Israeli Innovation Authority Grant

From 2012 through 2015, the Company received grants in the amount of approximately $537,000 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 March 31, 2021; therefore, no liability was recorded for the repayment in the accompanying condensed consolidated financial statements.

Otodyne License Agreement

In November 2015, the Company entered into an exclusive license agreement with Scientific Development and Research, Inc. and Otodyne, Inc. (collectively, the "Licensors") granting the Company exclusive worldwide rights to develop and commercialize OP0201, a potential first-in-class treatment option for patients at risk for or with otitis media (middle ear inflammation with or without infection), which is often caused by Eustachian tube dysfunction ("ETD"). Under the terms of the agreement, the Company is obligated to use commercially reasonable efforts to seek approval for and commercialize at least one product for otitis media in the U.S. and key European markets (France, Germany, Italy, Spain, and the United Kingdom). The Company is responsible for prosecuting, maintaining, and enforcing all related intellectual property and will be the sole owner of improvements.

In December 2015, the Licensors completed transfer of all technology, including the active Investigational New Drug application for OP0201 to the Company. The Company is obligated to pay up to $42.1 million in development and regulatory milestones if OP0201 is approved for three indications in the United States, two in Europe, and two in Japan. The Company is also obligated to pay up to $36.0 million in sales-based milestones, beginning with sales exceeding $1.0 billion in a calendar year. The Company is also obligated to pay a tiered royalty for a period up to eight years, on a country-by-country basis. The royalty ranges from a low-single to mid-single digit percentage of net sales. The Company made a $300,000 milestone payment in March 2019 related to the first patient enrolled in a phase 2 study. There were no other milestones achieved during the three months ended March 31, 2021.

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

On September 22, 2014, Tokai, the legal predecessor of the Company, completed the initial public offering of its common stock (the "IPO"). On July 25, 2017, a purported stockholder of Tokai filed a lawsuit in the U.S. District Court for the District of Massachusetts, entitled *Peter B. Angelos v. Tokai Pharmaceuticals, Inc., et al.*, No. 1:17-cv-11365-MLW. The lawsuit was filed against Tokai, Jodie P. Morrison, Lee H. Kalowski, Seth L. Harrison, Timothy J. Barberich, David A. Kessler, Joseph A. Yanchik, III, and the underwriters of the IPO. The lawsuit alleges that Tokai made false and misleading statements and omissions about its clinical trials for galeterone, in violation of the Securities Act of 1933 and the Securities Exchange Act of 1934. The lawsuit seeks, among other things, unspecified compensatory damages, interest, costs, and attorneys' fees.

On September 7, 2018, plaintiff filed an amended complaint. Defendants moved to dismiss the amended complaint on October 15, 2018. Plaintiff opposed defendants' motion on November 19, 2018, defendants filed a reply in support of their motion on December 17, 2018, and plaintiff filed a sur-reply in support of his opposition on January 8, 2019. On February 18, 2020, the court held a hearing on defendants' motion to dismiss. The court also ordered the parties to confer and notify it by March 10, 2020, if they reached an agreement to settle the case. On March 10, 2020, pursuant to the court's order, the parties advised the court they did not agree on a settlement. On July 15, 2020, plaintiff filed a Notice of Supplemental Authority, and on July 21, 2020, defendants filed a response. On October 9, 2020, the court entered an order granting defendants' motion to dismiss and dismissing the action in its entirety. Judgment was entered on October 14, 2020. On November 12, 2020, plaintiff filed a notice of appeal. On February 17, 2021, the parties submitted a stipulated motion to dismiss the appeal, following a settlement payment to plaintiff by the Company's insurance carrier of an immaterial amount. On February 18, 2021, the United States Court of Appeals for the First Circuit granted the motion, entered judgment dismissing the appeal, and issued the mandate.

Indemnification

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 March 31, 2021.

Note 6. Stockholders' Equity

Equity Distribution Agreement

On July 23, 2018, the Company filed a prospectus and prospectus supplement (the "2018 Prospectus") under which the Company may offer and sell, from time to time, pursuant to an equity distribution agreement with Piper Jaffray & Co., up to $9.8 million in shares of its common stock. During the year ended December 31, 2020 and three months ended March 31, 2021, no shares were sold under the 2018 Prospectus.

Common Stock Warrants

As of March 31, 2021, a total of 846,939 warrants were exercisable into common stock. The shares of common stock underlying the warrants are registered for offer and sale under the Securities Act of 1933, as amended (the "Securities Act"), pursuant to the Company's effective registration statements on Form S-1.

The following table shows the warrant activity:

	Rollforward of Warrant Activity				
	Registered direct warrants, placement agent	Private placement warrants	Private placement warrants, placement agent	Warrants exchanged for common stock	Total
Balance as of December 31, 2020	9,581	319,064	9,177	—	337,822
Issued	—	—	—	509,117	509,117
Exercised	—	—	—	—	—
Cancelled/Expired	—	—	—	—	—
Balance as of March 31, 2021	9,581	319,064	9,177	509,117	846,939

Preferred Stock Warrants

As of March 31, 2021, 55,853.875 warrants were exercisable into Series X1 Preferred Stock. Each share of Series X1 Preferred Stock is convertible into approximately 55.5556 shares of common stock. The shares of Series X1 Preferred Stock underlying the assumed and replaced warrants in connection with the Anelixis acquisition are expected to be converted into shares of Eledon common stock in the second fiscal quarter of 2021.

The following table shows the warrant activity:

	Rollforward of Warrant Activity	
	Warrants assumed and replaced in acquisition	Total
Balance as of December 31, 2020	55,583.875	55,583.875
Assumed and replaced	—	—
Exercised	—	—
Cancelled/Expired	—	—
Balance as of March 31, 2021	55,583.875	55,583.875

Exchange Agreements

On December 31, 2020, the Company entered into an exchange agreement (the "Series X 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") and Cormorant Global Healthcare Master Fund, LP (together with the BVF Exchanging Stockholders, the "Series X Exchanging Stockholders"), pursuant to which the Series X Exchanging Stockholders exchanged (the "Series X Exchange") 344,666 shares of the Company's common stock for 6,203.98 shares of Series X Convertible Preferred Stock.

In addition, on December 31, 2020 the Company entered into an exchange agreement (the "Warrant Exchange Agreement," and together with the Series X Exchange Agreement, the "Exchange Agreements") with the BVF Exchanging Stockholders, pursuant to which the BVF Exchanging Stockholders exchanged (the "Warrant Exchange," and together with the Series X Exchange, "the Exchanges") 509,117 shares of the Common Stock for one or more pre-funded warrants to purchase an aggregate of 509,117 shares of the Common Stock at a nominal exercise price (the "Warrants").

The Company recorded the shares of Series X Convertible Preferred Stock and Warrants issuable as preferred stock and warrant subscriptions at December 31, 2020 since the physical settlement of the Exchanges was made on January 5, 2021, whereby the transfer agent recorded the exchange of common stock for the issuance of preferred stock and warrants.

Following the Exchanges, the Company had 14,306,614 shares of Common Stock outstanding and 6,203.98 shares of Series X Preferred Stock outstanding, which are convertible into 344,663 shares of Common Stock (after rounding for fractional shares).

As of March 31, 2021, a total of 509,117 warrants were available for exercise. The shares of common stock underlying the registered direct placement agent warrants are registered for offer and sale under the Securities Act, pursuant to the Company's effective registration statements on Form S-1.

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 March 31,	
	2021	2020
Research and development	$ 685	$ 154
General and administrative	1,089	283
Total stock-based compensation	$ 1,774	$ 437

Note 7. Business Acquisition

On September 14, 2020, the Company acquired Anelixis pursuant to that certain Agreement and Plan of Merger, dated September 14, 2020 (the "Merger Agreement"), by and among Eledon, Nautilus Merger Sub 1, Inc., a Delaware corporation and wholly owned subsidiary of Eledon ("First Merger Sub"), Nautilus Merger Sub 2, LLC, a Delaware limited liability company and wholly owned subsidiary of Eledon ("Second Merger Sub"), and Anelixis. Pursuant to the Merger Agreement, First Merger Sub merged with and into Anelixis, pursuant to which Anelixis was the surviving entity and became a wholly owned subsidiary of Eledon (the "First Merger"). Immediately following the First Merger, Anelixis merged with and into Second Merger Sub, pursuant to which Second Merger Sub was the surviving entity (the "Second Merger," together with the First Merger, the "Merger"). The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes. Following the acquisition of Anelixis, the Company has continued to maintain its corporate headquarters in Southern California and maintain research and development facilities in the Boston area.

Under the terms of the Merger Agreement, at the closing of the Merger, Eledon issued to the stockholders of Anelixis 175,488 shares of the common stock of Eledon, par value $0.001 per share and 140,026 shares of newly designated Series X1 Preferred Stock. Subject to stockholder approval, each share of Series X1 Preferred Stock is convertible into approximately 55.5556 shares of common stock. The preferences, rights and limitations applicable to the Series X1 Preferred Stock are set forth in the Certificate of Designation, as filed with the SEC.

In addition to the common stock and preferred stock issued, certain outstanding warrants issued and equity awards granted by Anelixis were not settled upon completion of the merger, and instead were assumed and then replaced with Eledon warrants and equity awards. The amounts for the assumed and replaced warrants and equity awards attributed to pre-merger services are included in other consideration amounts transferred and added to goodwill.

The Company determined that FASB Accounting Standards Codification Topic 805 ("ASC 805"), *Business Combinations*, is the authoritative guidance in accounting for this transaction and for determining whether Anelixis was a

dormant, non-operating entity that would not meet the definition of a business under ASC 805. If Anelixis was not an operating entity, the acquisition would instead be considered a capital transaction and equivalent to the issuance of shares by Eledon for the net monetary assets of Anelixis accompanied by a recapitalization. Conversely, if Anelixis was determined to be a business, the acquisition method of accounting would apply and the difference between the acquisition date fair value of the total consideration transferred and the aggregate values assigned to the assets acquired and liabilities assumed would be recorded as goodwill.

The Company evaluated the terms of the Merger Agreement and the transaction under the applicable accounting guidance and determined that Anelixis satisfied the definition of a business under ASC 805 and as further clarified by ASU 2017-01. Based on this analysis, the Company accounted for the acquisition of Anelixis as a business combination under the acquisition method of accounting as it had determined that Anelixis' assets acquired in the transaction included an input and a substantive process that together significantly contributed to the ability to create outputs. Additionally, the Company was determined to be both the legal and accounting acquirer as it had issued equity interests to acquire all of Anelixis' equity interests. Goodwill generated from the acquisition was primarily attributable to the expected synergies from combining operations and expanding market potential, together with certain intangible assets that do not qualify for separate recognition. None of the approximately $48.6 million in goodwill is expected to be deductible for tax purposes.

Concurrently and in connection with the execution of the Merger Agreement, the Company entered into the Purchase Agreement with certain institutional and accredited investors. Pursuant to the Stock Purchase Agreement, the Company agreed to sell an aggregate of approximately 199,112 shares of Series X1 Preferred Stock for an aggregate purchase price of approximately $99.1 million in the Financing (collectively, the "Financing"). Eledon had commitments for an additional $9.0 million in equity financing that was contingent upon the satisfaction of certain incremental closing conditions, including stockholders' approval of the issuance of the Company's common stock upon the conversion of the Company's Series X1 Preferred Stock and the effective registration of its common stock. The merger was a pre-requisite in order for the Financing to transpire; without the merger, those certain institutional and accredited investors would not have purchased the Company's Series X1 convertible preferred stock.

On December 18, 2020, the Company held the Special Meeting, whereby the Company's stockholders approved the issuance of the Company's common stock, upon conversion of the Company's Series X1 Preferred Stock, par value $0.001 per share, issued in September 2020. As a result, approximately 231,068 shares of Series X1 Preferred Stock were converted into 12,837,056 shares of the Company's common stock. As of March 31, 2021 and December 31, 2020, approximately 108,070 shares of Series X1 Preferred Stock remain outstanding.

On December 23, 2020, the Company sold 1,004,111 shares of its common stock for gross proceeds of $9.0 million that was contingent upon the satisfaction of certain incremental closing conditions, as described above.

Acquisition Consideration

The following table summarizes the fair value of purchase price consideration to acquire Anelixis (in thousands):

Description	Amount	
Fair value of purchase consideration:		
Common shares issued (1)	$	1,194
Preferred shares issued (2)		69,723
Options assumed (3)		2,950
Warrants assumed (3)		12,944
Total purchase consideration	$	86,811

(1) The fair value of common shares issued in the merger is based on 175,488 shares issued on the September 14, 2020 acquisition date at the closing price of the Company's common stock of $6.80 per share.

(2) The fair value of preferred shares issued in the merger is based on the amount per share of Series X1 preferred stock in the September 2020 Purchase Agreement.

(3) The fair value of the options and warrants assumed and replaced in the merger is based on applying the Black-Scholes valuation method using appropriate inputs of volatility rates ranging from 82% to 83%, expected terms of 5.0 to 5.9 years and risk-free rates of 0.27% to 0.45%.

Purchase Price Allocation

The following is an allocation of purchase price as of the September 14, 2020 acquisition closing date based upon an estimate of the fair value of the assets acquired and the liabilities assumed by the Company in the acquisition (in thousands):

Description	Amount
Cash and cash equivalents	$ 11,035
Prepaid expenses and other current assets	26
Other non-current assets	11
Accounts payable	(580)
Accrued expenses and other liabilities	(205)
Deferred tax liability	(4,510)
Net identifiable assets acquired	5,777
Goodwill	48,648
Identifiable intangible assets	32,386
Net assets acquired	$ 86,811

Acquisition costs of approximately $2.9 million were included in general and administrative expenses in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2020.

Deferred Income Taxes

The net deferred tax liability was based upon the difference between the estimated book basis and tax basis of net assets acquired and an estimate for the final pre-acquisition net operating losses of Anelixis.

Identifiable Intangible Assets

Through its acquisition of Anelixis, the Company acquired intangible assets that consisted of in-process research and development ("IPR&D") with an estimated fair value of $32.4 million, related to its clinical development program of AT-1501. The estimated fair value of the IPR&D was determined by management based on external valuation specialists' analysis of replacement costs to recreate AT-1501 in its current clinical stage. The replacement cost method contemplates the cost to recreate the utility of AT-1501 but in a form that is not a replica of AT-1501. In this method, the replacement cost is determined and reduced for depreciation of the asset. In this context, depreciation has three components: (i) physical deterioration, (ii) functional obsolescence, and (iii) economic obsolescence.

Goodwill

Under the acquisition method of accounting, goodwill of approximately $48.6 million would be generated after accounting for Anelixis' assets acquired, liabilities assumed, and intangible assets identified and valued.

Pro Forma Information (Unaudited)

The following unaudited pro forma combined financial information is presented to illustrate the estimated effects of the Merger based on the historical financial statements and accounting records of Eledon and Anelixis after giving effect to the Merger and the Merger-related pro forma adjustments.

	Three Months Ended March 31,	
	2021	2020
Net loss and other comprehensive loss	$ (8,499)	$ (10,297)

The unaudited pro forma combined statements of operations for the three months ended March 31, 2021 and 2020 combine the historical statements of operations of Eledon and Anelixis, giving effect to the Merger as if it had occurred on January 1, 2020, the first day of the fiscal year ended December 31, 2020.

The unaudited pro forma combined financial information has been presented for informational purposes only. The unaudited pro forma combined financial information does not purport to represent the actual results of operations that Eledon and Anelixis would have achieved had the companies been combined during the periods presented in the unaudited pro forma combined financial statements and is not intended to project the future results of operations that the combined company may achieve after the Merger. The unaudited pro forma combined financial information does not reflect any potential cost savings that may be realized as a result of the Merger and also does not reflect any restructuring or integration-related costs to achieve those potential cost savings.

Additionally, the unaudited pro forma combined financial information does not reflect any merger-related expenses, which totaled approximately $30,000 during the period ended March 31, 2020. There were no merger related expenses during the period ended March 31, 2021.

Anelixis has not recognized any revenue since its acquisition by the Company.

8. Subsequent Events

The Company has evaluated events subsequent to March 31, 2021 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.

On May 3, 2021, the Company amended its operating lease in Irvine, California, which was set to expire on September 31, 2021. The Company extended the term of the lease through December 31, 2022, effective October 1, 2021.

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, 2020 included in the Annual Report on Form 10-K filed by the Company with the Securities and Exchange Commission (the "SEC") on March 31, 2021, as amended. 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. 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 living with an autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis ("ALS"). The company's lead compound in development is AT-1501, an anti-CD40L antibody with high affinity for CD40 ligand (CD40L, also called CD154), a well-validated biological target with broad therapeutic potential. AT-1501 is a humanized IgG1 antibody engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. AT-1501 is a humanized IgG1 antibody engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is widely 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 B cells, macrophages, and dendritic cells. By blocking CD40L and not the CD40 receptor, AT-1501 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 also play a therapeutic role for autoimmune diseases and in the transplant setting.

In September 2020, we acquired Anelixis Therapeutics, Inc. ("Anelixis"), the company that owned or controlled the intellectual property related to AT-1501.

Our business strategy is to optimize the clinical and commercial value of AT-1501, and become a global biopharmaceutical company with a focused autoimmune franchise.

AT-1501 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 AT-1501 to CD40L. In non-human primate studies, dosing of AT-1501 up to 200 mg/kg per week for 26 weeks, demonstrated no adverse events regarding coagulation, platelet activation or thromboembolism.

We have completed a single ascending dose Phase 1 study of AT-1501 in healthy volunteers and people with ALS. In this study, the doses of AT-1501 studied were well tolerated in healthy subjects and adults with ALS, and demonstrated a safety profile comparable to placebo. AT-1501 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.

We plan to develop AT-1501 in up to four indications: prevention of kidney allograft rejection, prevention of islet cell allograft rejection, autoimmune nephritis, and ALS. We selected our indications based on preclinical and clinical data that was generated with either our molecule or historical anti-CD40L molecules. In October 2020, we initiated a Phase 2a clinical trial of AT-1501 in ALS. In November 2020, we received clearance from Health Canada to proceed with the initiation of a Phase 2 clinical trial of AT-1501 in islet cell transplantation for the treatment of type 1 diabetes.

Prior to our acquisition of Anelixis, we had been focused on developing medicines for patients with disorders of the ear, nose, and throat ("ENT"). In June 2020, we announced that our lead program did not achieve statistical significance for the primary efficacy endpoints in the treatment of acute otitis media. As a result of this failure to achieve the primary study endpoint, we suspended the clinical development of our legacy ENT assets while we assessed potential development strategies. Following the June 2020 announcement, we significantly curtailed development expenses as we sought to identify strategic alternatives that would maximize stockholder value. As a result of these activities, we acquired Anelixis and raised additional capital in September 2020, as described above.

Kidney transplantation: prevention of allograft rejection

Kidney transplantation is the most common type of solid organ transplantation in the United States with an estimated 200,000 Americans living with a transplanted kidney. In 2019, an estimated 23,000 kidneys were transplanted, of which 10-15% were re-transplants in persons that had already received at least one other kidney. Yet, 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 inhibitor ("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, an increase in opportunistic infections, increased malignancies, and an increase in type 1 diabetes due to pancreatic Beta cell toxicity. These liabilities may result in a requirement for reduced exposures to CNIs over long periods of time and a resulting decrease in the ability to prevent long-term rejection.

AT-1501 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.

Several historical studies have described the effects of anti-CD40L antibodies in nonhuman primate models of kidney transplant and shown that even short courses of anti CD40L therapy can prevent both acute rejection and long-term rejection in nonhuman primates with durable efficacy.

Islet cell transplantation ("ICT"): 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 is gaining attention as 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, and the procedure has been evolving from an experimental treatment to a clinical treatment option. In November 2020, we received clearance from Health Canada to proceed with the initiation of a Phase 2 clinical trial of AT-1501 in islet cell transplantation for the treatment of type 1 diabetes.

A number of issues are believed to continue to hamper the overall success of ICT 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 donors in order for BTID patients to have optimal response to blood glucose levels and possibly achieve insulin independence. AT-1501 seeks to address the challenges associated with current ICT immunosuppressive regimens using CNI-based therapies, by replacing the CNIs with AT-1501. CD40L blockade may abolish many effector mechanisms of inflammation, prevent and intervene in the progression of autoimmunity, and instill transplant tolerance.

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. AT-1501 has shown pre-clinical, proof-of-concept efficacy in a non-human primate model of type 1 diabetes, where animals undergoing ICT maintained glucose control and sustained levels of C-peptide with chronic AT-1501 treatment for up to a year. Compared to combination immunosuppressive therapy including CNIs, AT-1501 monotherapy was more effective in preventing long term islet cell rejection, associated with better graft function, and showed an improved safety profile.

Autoimmune Nephritis

Autoimmune Nephritis refers to a group of autoimmune disorders associated with inflammation and eventual destruction of the kidney. These disorders include Lupus Nephritis ("LN"), focal segmental glomerulosclerosis ("FSGS") and IgA Nephropathy ("IgAN"). Systemic lupus erythematosus, ("SLE"), is one of the largest autoimmune populations globally and up to an estimated 40 percent of people with SLE develop LN, which may lead to kidney dysfunction, dialysis and end stage renal disease. LN is an orphan disease with an estimated prevalence of between 65,000 and 120,000 persons in the United States. FSGS is also an orphan disease with an estimated prevalence of 40,000 people in the US and variable progression to end stage renal failure. FSGS results from renal podocyte injury associated with immune complex formation in the glomeruli. IgAN, also called Berger's disease, is a type of glomerulonephritis that occurs when galactose-deficient IgA immune complexes build up in the kidneys, causing inflammation that ultimately damages kidney tissues. With an estimated prevalence of approximately 140,000 persons in the United States, IgAN is one of the most common, orphan, kidney diseases. There are currently no European Medicines Agency ("EMA") or U.S. Food and Drug Administration ("FDA") approved treatments for IgAN or FSGS, and only two approved for LN, although immunosuppressants such as systemic steroids and CNIs are prescribed off-label.

In historical preclinical animal models of lupus nephritis, anti-CD40L antibodies ameliorated disease progression, improved kidney function, reduced immune cell infiltrate into the kidney, and improved survival. Systemic biomarkers of SLE such as anti-dsDNA antibodies have also been reduced with anti-CD40L treatment in animal models. Similar data has been described in preclinical models of FSGS. FSGS models using historical anti-CD40L treatments have shown ameliorated kidney function as measured by a reduction in proteinuria and were associated with a decrease in immune cell infiltrate into the glomeruli.

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 approximately 2 to 5 years after diagnosis, with 50% of patients living ≥3 years from diagnosis and only 20% of patients living ≥5 years from diagnosis.

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. While the exact pathogenic mechanism of ALS is still not fully understood, there is strong evidence indicating that this neuroinflammation plays an important role in the disease's pathogenesis.

AT-1501 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 AT-1501 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 October 2020, we initiated a Phase 2a, open-label, multi-center study to evaluate the safety and tolerability of multiple doses of AT-1501 in adult subjects with ALS. Approximately 54 subjects with ALS are planned to be enrolled into the study in the United States and Canada at up to 13 ALS treatment sites. Ascending doses of AT-1501 will be administered as IV infusions to four sequentially enrolling cohorts. The first two cohorts will consist of nine participants, and the last two cohorts of 18 participants, who will each receive six bi-weekly infusions of AT-1501 over a 12-week study period. Blood samples for target engagement, and exploratory biomarkers for inflammation and neurodegeneration will be taken and analyzed. Participant-focused clinical outcomes will also be assessed.

COVID-19 Impact

The COVID-19 pandemic and resulting global disruptions have adversely affected our business and operations, including, but not limited to, the operations of third parties upon whom we rely. The effects of executive and similar government orders, shelter-in-place orders and our work-from-home policies may negatively impact our productivity and disrupt our business. Although the impacts of COVID-19 have not been material to-date, we have experienced delays in certain preclinical 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. In addition, in response to public health directives and orders, we have ceased all non-essential business travel and implemented optional work-from-home policies for all of our employees, resulting in limited business development and investor relations activities. The magnitude of such effects which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

The COVID-19 pandemic and resulting global disruptions have caused significant volatility in financial and credit markets. 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. Due to the rapidly evolving nature of the global situation, it is not possible to predict the extent to which these conditions could adversely affect our liquidity and capital resources in the future.

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 three months ended March 31, 2021, as compared to those disclosed in the Annual Report on Form 10-K for the year ended December 31, 2020 filed by the Company with the SEC on March 31, 2021.

RESULTS OF OPERATIONS

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table provides comparative unaudited results of operations for the three months ended March 31, 2021 and 2020 (in thousands):

	For the Three Months Ended March 31,		
	2021	2020	$ Variance
Operating expenses:			
Research and development	$ 5,653	$ 1,648	4,005
General and administrative	3,352	1,730	1,622
Total operating expenses	9,005	3,378	5,627
Loss from operations	(9,005)	(3,378)	(5,627)
Other income, net	5	30	(25)
Warrant inducement expense	—	(4,829)	4,829
Loss before income tax benefit	(9,000)	(8,177)	(823)
Income tax benefit	501	—	501
Net loss	$ (8,499)	$ (8,177)	(322)

Research and Development Expenses

The increase in research and development expenses of $4.0 million for the three month period was primarily due to increases in costs related to the production of clinical trial materials and clinical costs as we advance our AT-1501 program of $2.3 million and $251,000, respectively, an increase in consulting services of $533,000, as well as increases in personnel costs of $400,000, and stock-based compensation costs of $531,000 due to increased headcount.

General and Administrative Expenses

The increase in general and administrative expenses of $1.6 million for the three month period was primarily due to increases in professional fees of $729,000, general operating costs of $45,000, as well as personnel costs and stock-based compensation costs of $75,000 and $806,000, respectively. The increases were offset by decreases in travel-related costs of $25,000 and litigation costs of $8,000.

Other Income, Net

The change in other income, net was due to a decrease in interest income of $19,000 and an increase in realized losses on foreign currency translation of $6,000 for the three months ended March 31, 2021.

Warrant Inducement Expense

In January 2020, the Company recognized warrant inducement expense of $4.8 million as a result of the Warrant Exercise Transaction in addition to the fair value of the Private Placement Warrants issued.

Income Tax Benefit

The Company recognized an income tax benefit of $501,000 for the three months ended March 31, 2021 due to the current quarter change in deferred tax liabilities for acquired IPR&D related to the Anelixis acquisition.

LIQUIDITY AND CAPITAL RESOURCES

As of March 31, 2021, we had cash of $108.6 million, consisting of readily available cash in bank accounts. While we believe our cash is 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. Our primary use of cash is to fund operating expenses, which consist of research and development expenses and general and administrative expenses. Cash used to fund operating expenses is impacted by the timing of when we pay or prepay these expenses. We expect our expenses to increase in connection with our ongoing activities, particularly as we expand our clinical program with AT-1501, 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 product candidates 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. Adequate additional funding may not be available to us on acceptable terms on a timely basis, or at all. 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 cause us to delay the scope of or suspend one or more of our 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* for additional risks associated with our substantial capital requirements and the challenges we may face in raising capital.

We plan to continue to fund losses from operations and capital funding needs through cash on hand and future equity or debt financings, as well as potential additional collaborations or strategic partnerships with other companies. The sale of additional equity or convertible debt could result in additional dilution to our stockholders. The incurrence of indebtedness would result in debt service obligations and could result in operating and financing covenants that would restrict our operations.

Our primary uses of capital are, and we expect will continue to be, funding research efforts and the development of our product candidates, compensation and related expenses, hiring additional staff (including clinical, scientific, operational, financial, and management personnel) and costs associated with operating as a public company. We expect to incur substantial expenditures in the foreseeable future for the development and potential commercialization of our product candidates.

Cash Flows

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

	For the Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	$ (5,166)	$ (2,197)
Net cash (used in) provided by financing activities	(450)	5,191
Net change in cash and cash equivalents	$ (5,616)	$ 2,994

Comparison of the Three Months Ended March 31, 2021 and 2020

Net cash used in operating activities for the three months ended March 31, 2021 consisted primarily of our net loss of $8.5 million, partially offset by non-cash items consisting primarily of stock-based compensation and depreciation and amortization totaling $1.8 million, as well as net deferred income taxes of $501,000. Additionally, cash used in operating activities for the three months ended March 31, 2021 reflected a net increase in cash from changes in operating assets and

liabilities of $2.0 million, primarily due to an increase in our prepaid expenses and other assets of $159,000, an increase in our accounts payable and other accrued expenses of $2.2 million, and a decrease in operating lease liability of $47,000.

Net cash used in operating activities for the three months ended March 31, 2020 consisted primarily of our net loss of $8.2 million, partially offset by non-cash items consisting primarily of stock-based compensation and depreciation and amortization totaling $483,000, as well as warrant inducement expense of $4.8 million. Additionally, cash used in operating activities for the three months ended March 31, 2020 reflected a net increase in cash from changes in operating assets and liabilities of $668,000, primarily due to a decrease in our prepaid expenses and other current assets of $92,000, a decrease in other assets of $67,000 and an increase in our accounts payable and other accrued expenses of $552,000.

There was no cash provided by or used in the Company's investing activities for the three months ended March 31, 2021 and 2020.

Net cash used in financing activities for the three months ended March 31, 2021 was comprised of $450,000 of offering costs accrued as of December 31, 2020 in connection with the sale of shares of common stock.

Net cash provided by financing activities for the three months ended March 31, 2020 was comprised of $5.2 million in net proceeds from the exercise of warrants by stockholders to purchase approximately 6.9 million shares of common stock.

CONTRACTUAL OBLIGATIONS AND COMMITMENTS

Contractual Obligations

Per §229.303 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.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

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 March 31, 2021, 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 Securities Exchange Act of 1934, as amended (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 as of March 31, 2021 in alerting them in a timely manner to material information required to be disclosed in our periodic reports filed with the SEC.

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 March 31, 2021 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. 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 AT-1501 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 three months ended March 31, 2021 is $8.5 million. As of March 31, 2021, the Company had cash and cash equivalents of $108.6 million, working capital of $106.0 million and an accumulated deficit of $88.9 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.

Although we raised approximately $108.1 million in total gross offering proceeds from our September and December 2020 financings, 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 and, even if we do, 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 OM; 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 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 (AT-1501) 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 or 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:

- 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 AT-1501 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 may result in additional disruptions to our business operations, which could have a material adverse effect on our business.

Our business and its operations, including but not limited to ongoing or planned research and development activities, have been adversely affected by the ongoing COVID-19 pandemic, which has also caused significant disruption in the operations of third parties upon whom we rely. The COVID-19 pandemic and actions taken by governments, businesses, and individuals in response to it, including executive orders, shelter-in-place orders and work-from-home policies, have had effects that have and may continue to negatively impact productivity and disrupt our business. For example, we have experienced delays in certain preclinical 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. In addition, in response to public health directives and orders, we have ceased all non-essential business travel and implemented work-from-home policies for all of our employees, resulting in reduced productivity. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place, executive and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases, could also impact personnel at the third parties on whom we are highly dependent for clinical trials as well as formulation and device development in the United States and other countries, or the timing, availability or cost of materials we use or require to conduct our business.

If COVID-19 continues to spread in the United States, Canada and elsewhere, we may experience additional disruptions that could severely impact our business 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.

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 contract research organizations (“CROs”) and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or 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.

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.

AT-1501 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. 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 shareholder 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. 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 AT-1501 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 AT-1501 will face competition from other FDA-approved therapeutics for the treatment of LN, FSGS or IgAN, including LUPKYNIS™ and BENLYSTA®, and numerous other branded and generic medicines are already being used “off-label” to treat them.

We expect that AT-1501 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 $5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of $5.0 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 AT-1501 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 AT-1501 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 the board of directors 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 the board of directors. Among other things, these provisions:

- establish a classified board of directors 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 of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- 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 the board of directors 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 of directors; 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.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

Exhibit Index

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 X1 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†	Executive Employment Agreement, dated March 1, 2021, between Eledon Pharmaceuticals, Inc. and Jon Kuwahara (filed with the SEC as Exhibit 10.9 to the Company's Annual Report on Form 10-K filed March 31, 2021).
10.2†	Executive Employment Agreement, dated March 15, 2021, between Eledon Pharmaceuticals, Inc. and Paul Little (filed with the SEC as Exhibit 10.10 to the Company's Annual Report on Form 10-K filed March 31, 2021).
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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† Indicates a management contract or compensatory plan

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: May 13, 2021 By: /s/ David-Alexandre C. Gros, M.D.

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

Date: May 13, 2021 By: /s/ Paul Little

Paul Little
Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS

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

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

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: May 13, 2021

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: May 13, 2021

By: /s/ Paul Little
Paul Little
Chief Financial Officer
(Principal Financial 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 March 31, 2021 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: May 13, 2021

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 March 31, 2021 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: May 13, 2021

By: /s/ Paul Little
Paul Little
Chief Financial Officer
(Principal Financial Officer)