

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

Form 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

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

(949) 238-8090
(Registrant's telephone number, including area code)

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

Title of Class	Trading Symbol(s)	Name of Exchange on Which Registered
Common Stock, \$0.001 par value	ELDN	Nasdaq Capital Market

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

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/>	Smaller reporting company <input type="checkbox"/>
	Emerging growth company <input type="checkbox"/>

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

Indicate by check mark whether the registrant has filed a report on and attestation of the effectiveness of its internal control over financial reporting under Section 404(b) of Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by registered public accounting firm that prepared or issued its audit report

As of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates was \$7,293,179, based on the last reported sale price of such stock on the Nasdaq Global Market as of such date.

As of March 23, 2021, the registrant had 14,306,614 shares of Common Stock, \$0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2021 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year end December 31, 2020, are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

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In this Annual Report on Form 10-K, Annual Report, unless the context requires otherwise, “Eledon”, the “Company”, “we”, “our”, and “us” means Eledon Pharmaceuticals, Inc. (formerly Novus Therapeutics, Inc.) and all wholly owned subsidiaries.

Forward-Looking Statements

This Annual Report on Form 10-K 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 Annual Report on Form 10-K about the Company’s future expectations, plans and prospects, including statements about its strategy, future operations, development of its product candidates, the review of strategic alternatives and the outcome of such review and other statements containing words such as “believes,” “anticipates,” “plans,” “expects,” “estimates,” “intends,” “predicts,” “projects,” “targets,” “could,” “may,” and similar expressions, constitute forward-looking statements, although not all forward-looking statements include such identifying words. Forward-looking statements include, but are not limited to statements regarding:

- our 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 I, Item 1A. *Risk Factors* in this Annual Report on Form 10-K.

Any forward-looking statements contained in this Annual Report on Form 10-K 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 Annual 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 Annual Report on Form 10-K*. 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.

PART I

Item 1. Business.

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”). Our lead product candidate, AT-1501, is a humanized monoclonal antibody (mAb), designed to target CD40 Ligand (“CD40L”), also called CD154, a molecule expressed on the surface of human immune system T cells. 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.

In September 2020, we acquired Anelixis Therapeutics, Inc. (“Anelixis”), the company that owned or controlled the intellectual property related to AT-1501. AT-1501 is a humanized IgG1 anti-CD40L antibody lacking Fc effector function. It is designed to inhibit signaling via CD40L, a costimulatory type II membrane receptor expressed on activated T cells and CD40, a receptor expressed on Antigen Presenting Cells (“APC’s”). Interactions between B cells expressing CD40, and activated CD4+ “helper” T cells expressing CD40L, play a critical role in promoting germinal center formation, clonal expansion, antibody production, and the secretion of pro-inflammatory cytokines that amplify immune response. The role of CD40 in B cells has been extensively characterized and shown to have an important role in the generation of primary and secondary humoral immune responses to T cell dependent antigens. Anti-CD40L antibodies also inhibit both CD40 as well as CD11 costimulatory receptors on antigen presenting cells, thus inhibiting the pro-inflammatory polarization of CD4+ and CD8+ lymphocytes. Finally, blocking CD40L also polarizes CD4+ lymphocytes to FoxP3 positive Tregs, a specialized subpopulation of T cells that act to suppress immune response and create a more tolerogenic environment. Importantly, blocking the CD40-CD40L pathway has not been shown to cause systemic lymphopenia.

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 thrombotic 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 (Figure 2).

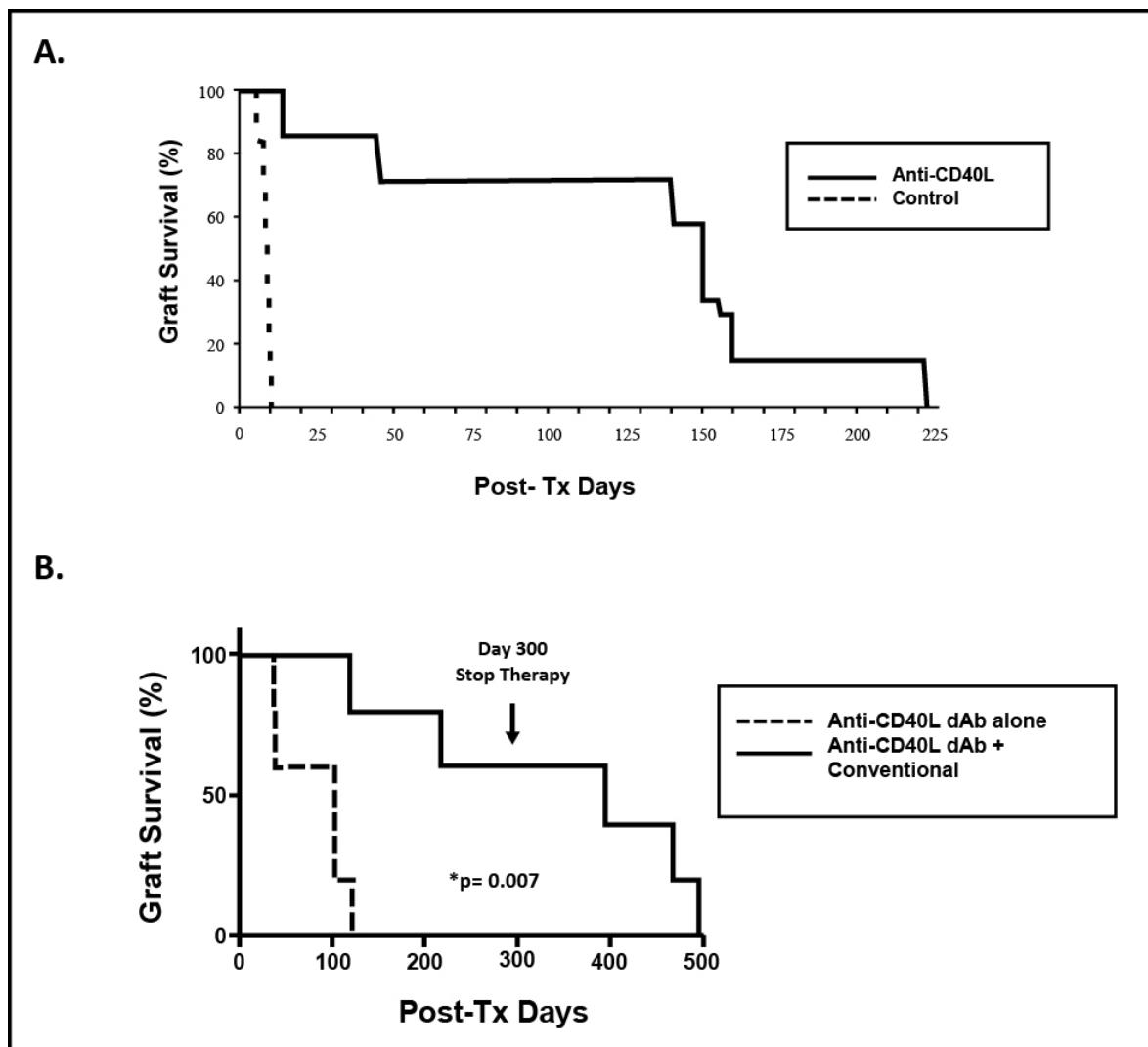


Figure 2: Historical Anti-CD40L Antibody 5c8 Prevents Acute and Long Term Kidney Transplant Rejection in Nonhuman Primates. (A) Kaplan Meier Graph: ABI793, an anti-CD40L antibody or an IgG isotype control antibody was given intravenously to seven monkeys on postoperative days (PODs) 0, 1, 4, 11, 18, 28, 56, and 84 at a dose of 20 mg/kg (Kanmaz, 2004). (B) The combination of anti-CD154 dAb with basiliximab, mycophenolate mofetil, and steroids significantly improved rejection-free allograft survival (Kim, 2017).

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 BT1D 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 (Figure 3).

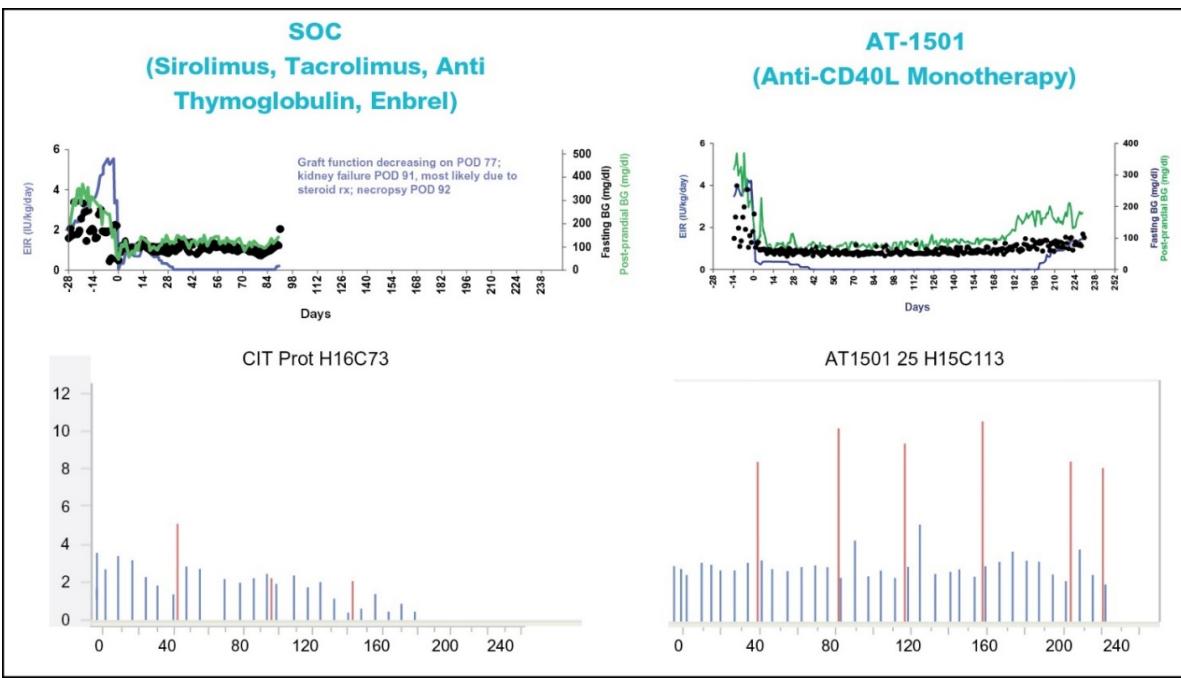


Figure 3: Fasting, Postprandial Blood Glucose and C-Peptide Levels Over Time. **Top Graphs:** Daily fasting glucose levels (black circles); post prandial glucose levels (green line) and exogenous insulin (blue line) versus time (days). **Bottom Graphs:** C peptide levels fasting blue bars) and post prandial (red bars) versus time (days). **Left Panel Standard of Care (SOC):** Thymoglobulin at 5 mg/kg on post-operative day (POD) -2, -1, 0, 1, 2, Enbrel at 0.8 mg/kg on POD 0 and at 0.4 mg/kg on POD 3, 7, 10. Sirolimus, starting on POD -2 at 0.02 mg/kg; target trough levels 8-12 ng/ml and Tacrolimus, starting on POD 1 at 0.025 mg/kg target trough levels 4-6 ng/ml. **Right Panels AT-1501 Monotherapy:** AT-1501 at 23-26 mg/kg in the first 3 months post-transplant on POD -1, 0, 3, 10, 18, 23, 28 and then every 14 days until end of study.

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 (Figure 3).

Figure 4: Blocking CD40L Improves Survival and Pathophysiology Associated with Autoimmune Nephritis

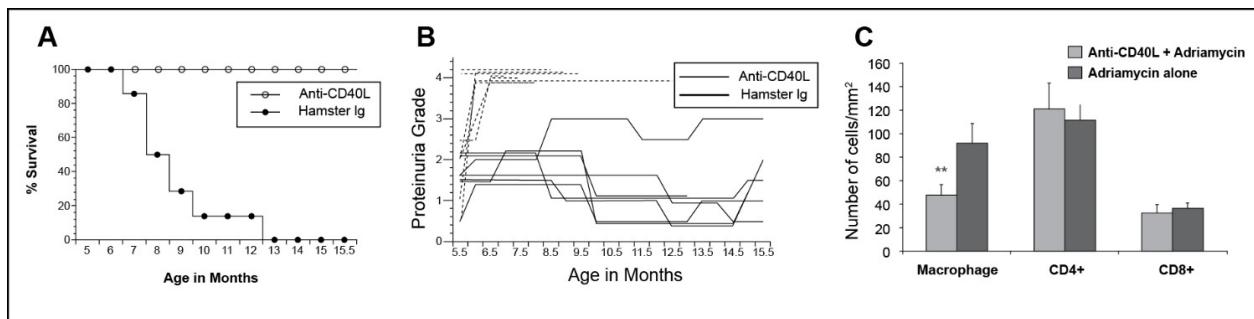


Figure 4: Effect of anti-CD40L in the SNF1 rodent model of Lupus. (A) The survival curves of anti-CD40L treated and HIg controls differ significantly ($p < 0.001$ by Wilcoxon test). Control mice receiving HIgG control die rapidly with the onset of severe nephritis, and all but one are dead by age 12 mo while all anti-CD40L treated mice are alive when the study is terminated at age 15.5 months (Kalled, 1998). (B) Urine was monitored weekly for proteinuria. Proteinuria was scored as follows: 0.5+ (15 to 30 mg/dl); 1+ (30 mg/dl); 2+ (100 mg/dl); 3+ (300 mg/dl) and 4+ (>20000 mg/dl). The proportion of mice with $\geq 3+$ proteinuria differed significantly between anti-CD40L treated and HIg controls at all timepoints ($p < 0.001$ by χ^2 test). Controls that did not have $\geq 3+$ proteinuria at the start of treatment became 4+ soon after, as opposed to anti-CD40L treated mice where the proteinuria levels of six of seven mice declined and only one mouse developed 3+ proteinuria (Kalled, 1998). (C) MR1 treatment was associated with a significant reduction in the number of infiltrating macrophages. The number of infiltrating CD4+ and CD8+ cells was not statistically different from the Adriamycin alone group. Bars represent mean values + standard deviation. ** $P < 0.01$ vs. Adriamycin alone group (Kairatis, 2003).

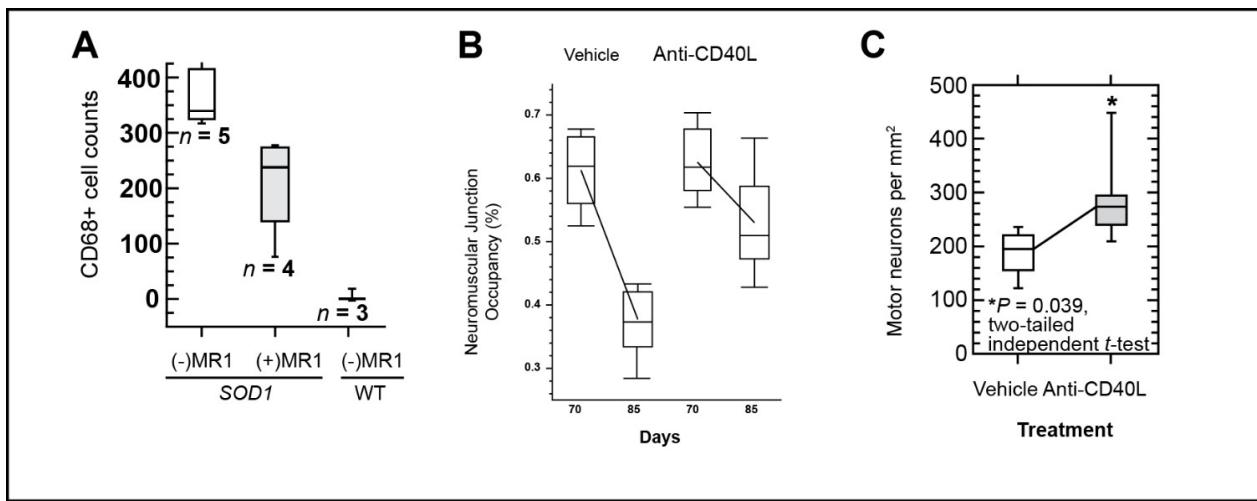
Amyotrophic Lateral Sclerosis

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 (Figure 5).

Figure 5: Blocking CD40L Improves Survival and Pathophysiology Associated with ALS



Anti-CD40L (MR1) treatment decreases CD68+ macrophages, improves neuromuscular junction occupancy and improves motor neuron survival. (A) Quantification of reduction of CD68+ macrophages by anti-CD40L treatment at day 100. (White bar, control IgG); gray bar (anti-CD40L-treatment); black bar (untreated age-matched non-transgenic mice) (B) Quantification of neuromuscular occupancy in SOD1 mice prior to overt symptoms (day 70) versus after symptom onset (day 85) treated with an IgG control antibody (veh) or anti-CD40L antibody. (C) Quantitative comparison of lumbar spinal cord motor neuron counts per mm² in IgG vehicle control (White bar) versus anti-CD40L treated mice (grey bar) at day 100 (Lincecum, 2010).

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.

The competitive conditions faced by the Company are described in greater detail in Part I, Item 1A. *Risk Factors* in this Annual Report on Form 10-K under the caption “We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.”

Intellectual Property

Eledon's success depends in part on its ability to obtain and maintain proprietary protection for its product candidates, novel discoveries, product technologies and other know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing Eledon's proprietary rights. Eledon seeks to protect its product candidates by, among other methods, filing U.S. and foreign patent applications related to its proprietary technology, inventions and improvements that are important to the development and implementation of its business. Eledon also relies on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain Eledon's proprietary protection for Eledon's product candidates.

Eledon's intellectual property portfolio includes issued patents and patent applications directed toward isolated antibodies and methods of treatment using the isolated antibodies that block the interaction of CD40L and CD40 to treat CD-40L related diseases or disorders. Eledon has exclusive rights to three patent families. Two of the three families are directed to AT-1501 and related antibodies. The first family is directed to methods for treating amyotrophic lateral sclerosis with antibodies and includes two United States patents and 14 foreign patents (Japan, Hong Kong, Belgium, China, Germany, Denmark, Spain, Finland, France, Great Britain, Ireland, Italy, the Netherlands, and Sweden). The second family is directed to AT-1501 (JB5 in the patents/applications in this family). AT-1501 is the current clinical candidate, with 14 pending applications, and issued/allowed patents including two issued United States patents, one allowed United States patent application, and a Russian patent. The third family is directed to AT-1501 with 15 pending applications, including one United States patent application. In the first family, the patents will expire in December 2029, absent any term adjustments or extensions. In the second family, any issued patent will expire in February 2036, absent any term adjustments or extensions. In the third family, any issued patent will expire in May 2038, absent any term adjustments or extensions.

Eledon's intellectual property portfolio also includes issued patents and patent applications directed towards products derived from Eledon's surfactant platform and foam platform with claims to drug substance, pharmaceutical preparations as well as to methods of treatment. For OP0201, Eledon owns or has exclusive rights to one U.S. patent application, one international application, and seven foreign patent applications. If allowed, the last to expire patent application will expire in December 2039, absent any adjustments or extensions. For OP0101 and OP0102, Eledon owns or has exclusive rights to two families of patents, one with three United States and seven foreign patents (Canada, France, Germany, Israel, Italy, Spain, and the United Kingdom), and a second with two United States and five foreign patents (France, Germany, Italy, Spain and the United Kingdom). In the first family the last to expire issued patent in the United States will expire in September 2027, including patent term adjustment. In the second family the last to expire issued patent in the United States will expire in December 2033.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

Eledon also protects its proprietary information by requiring its employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. In addition, Eledon also requires confidentiality or service agreements from third parties that receive confidential information or materials.

See *Note 5. Commitments and Contingencies* under the caption "Grants and Licenses" for further information about the Company's intellectual property.

Government Regulation

Government authorities in the United States, including federal, state, and local authorities, and in other countries, extensively regulate, among other things, the manufacturing, research and clinical development, marketing, labeling and packaging, storage, distribution, post-approval monitoring and reporting, advertising and promotion, and export and import of pharmaceutical and biological products, such as those we are developing. Pricing of such products is also subject to regulation in many countries. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations, and biologics under the FDCA and the Public Health Service Act (“PHSA”) and its implementing regulations. FDA approval is required before any new unapproved drug or biologic or dosage form, including a new use of a previously approved drug, can be marketed in the U.S. Drugs and biologics are also subject to other federal, state, and local statutes and regulations. If we fail to comply with applicable FDA or other requirements at any time during the product development process, clinical testing, approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA’s refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us.

The process required by the FDA before product candidates may be marketed in the United States generally involves the following:

- completion of extensive preclinical laboratory tests and preclinical animal studies, all performed in accordance with the Good Laboratory Practices (“GLP”) regulations;
- submission to the FDA of an IND which must become effective before human clinical trials may begin and must be updated annually;
- approval by an independent institutional review board (“IRB”) or ethics committee representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication;
- completion of manufacturing scale up and stability studies, all performed in accordance with the Good Manufacturing Practices “GMP” regulations;
- preparation of and submission to the FDA of a biologics license application (“BLA”) or a new drug application, or NDA, after completion of all pivotal clinical trials;
- potential review of the product application by an FDA advisory committee, where appropriate and if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA or NDA to file the application for review;
- satisfactory completion of a FDA pre-approval inspection of the manufacturing facilities where the proposed product is produced to assess compliance with current Good Manufacturing Practices (“cGMP”) regulations;
- potential FDA audit of the clinical trial sites that generated the data in support of the BLA or NDA; and
- FDA review and approval of a BLA or NDA prior to any commercial marketing or sale of the product.

The preclinical and clinical testing and approval process requires substantial time, effort, and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

An IND is a request for authorization from the FDA to administer an investigational new drug product to humans in clinical trials. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational new drug. An IND must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to the proposed clinical trials. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before clinical trials can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. The FDA may impose a clinical hold at any time during clinical trials and may impose a partial clinical hold that would limit trials, for example, to certain doses or for a certain length of time.

Clinical Trials

Clinical trials involve the administration of the investigational new drug to human subjects under the supervision of qualified investigators in accordance with Good Clinical Practices (“GCPs”) which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Additionally, approval must also be obtained from each clinical trial site’s IRB before the trials may be initiated, and the IRB must monitor the trial until completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The clinical investigation of a drug is generally divided into three phases. Although the phases are usually conducted sequentially, they may overlap or be combined.

- Phase 1. The drug is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational new drug in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- Phase 2. The drug is administered to a limited patient population to evaluate dosage tolerance and optimal dosage, identify possible adverse side effects and safety risks, and preliminarily evaluate efficacy.
- Phase 3. The drug is administered to an expanded patient population, generally at geographically dispersed clinical trial sites to generate enough data to evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational new drug product, and to provide an adequate basis for physician labeling.

In some cases, the FDA may condition approval of a BLA or NDA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after approval. In other cases, a sponsor may voluntarily conduct additional clinical trials after approval to gain more information about the drug. Such post-approval studies are typically referred to as Phase 4 clinical trials.

Sponsors must also report to the FDA, within certain timeframes, serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator’s brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product candidate. The FDA, the IRB, or the clinical trial sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial. We may also suspend or terminate a clinical trial based on evolving business objectives or competitive climate.

The clinical trial process can take three to ten years or more to complete, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Results from one trial are not necessarily predictive of results from later trials.

A drug being studied in clinical trials may be made available to individual patients in certain circumstances. Pursuant to the 21st Century Cures Act (“Cures Act”) which was signed into law in December 2016, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug (compassionate use). This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug. At this time, Eledon does not have a program for the compassionate use of an investigational product outside of a clinical trial as it is not applicable to our investigational products.

Submission of a BLA or NDA to the FDA

Assuming successful completion of all required testing (e.g. completion of pivotal clinical trials) in accordance with all applicable regulatory requirements, detailed investigational new drug product information is submitted to the FDA in the form of a BLA or NDA requesting approval to market the product for one or more indications. Under federal law, the submission of most BLAs and NDAs is subject to an application user fee and these fees are typically increased on an annual basis. Applications for orphan drug products are exempted from the BLA and NDA user fees and may be exempted from product and establishment user fees, unless the application includes an indication for other than a rare disease or condition. No application user fees were paid for AT-1501 or OP0201 in calendar 2020.

A BLA or NDA for a new molecular entity must include all relevant data available from pertinent preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from several alternative sources, including investigator-initiated trials that are not sponsored by Eledon. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational new drug product to the satisfaction of the FDA.

Once a BLA or NDA for a new molecular entity has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by the FDA's requests for additional information or clarification.

Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA or NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on a BLA or NDA

The FDA evaluates a BLA to determine whether the data demonstrate that the biologic is safe, pure, and potent, or effective, and an NDA to determine whether the drug is safe and effective. After the FDA evaluates the BLA or NDA and conducts inspections of manufacturing facilities where the product will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application is not ready for approval. A Complete Response Letter may require additional clinical data or an additional pivotal Phase 3 clinical trial(s), or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the BLA or NDA does not satisfy the criteria for approval and issue a denial. The FDA could also approve the BLA or NDA with a Risk Evaluation and Mitigation Strategy ("REMS") plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Post-Approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

Drug manufacturers are subject to periodic unannounced inspections by the FDA and state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

We rely, and expect to continue to rely, on third parties for the production of clinical quantities of our product candidates and expect to rely in the future on third parties for the production of commercial quantities. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production, distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA or NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, untitled or warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or NDAs or supplements to approved BLAs or NDAs, or suspension or revocation of licenses or withdrawal of approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

Orphan Designation and Exclusivity

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making the drug for this type of disease or condition will be recovered from sales in the United States.

Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. In addition, if a product is the first to receive FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in

limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. The Company received an orphan drug designation for AT-1501 for the treatment of ALS.

Pediatric Trials and Exclusivity

Under the Pediatric Research Equity Act of 2003 (“PREA”) as amended, BLAs and NDAs must contain data to assess the safety and effectiveness of an investigational new drug product for the claimed indications in all relevant pediatric populations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. A sponsor who is planning to submit a marketing application for a drug product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan (“PSP”) within sixty days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults or full or partial waivers if certain criteria are met. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials, and/or other clinical development programs. The requirements for pediatric data do not apply to any drug for an indication for which orphan designation has been granted. In the future we may seek pediatric approval for AT-1501 applications in connection with renal and islet cell transplants, which may require the submission of a PSP.

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the five-year and three-year non-patent and orphan exclusivity. This six-month exclusivity may be granted if a BLA or NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA’s request, the additional protection is granted. If reports of FDA-requested pediatric trials are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection covering the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot accept or approve another application relying on the BLA or NDA sponsor’s data.

Patent Term Restoration

Depending upon the timing, duration, and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA or NDA, plus the time between the submission date and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of the product’s approval. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of the patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA or NDA.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application (“ANDA”) to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference listed drug (“RLD”).

Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. At the same time, the FDA must also determine that the generic drug is “bioequivalent” to the innovator drug. Under the statute, a generic drug is bioequivalent to an RLD if “the rate and extent of absorption of the generic drug do not show a significant difference from the rate and extent of absorption of the listed drug...”

Upon approval of an ANDA, the FDA indicates that the generic product is “therapeutically equivalent” to the RLD and it assigns a therapeutic equivalence rating to the approved generic drug in its publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” also referred to as the “Orange Book.” Physicians and pharmacists consider an “AB” therapeutic equivalence rating to mean that a generic drug is fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA’s designation of an “AB” rating often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

The FDCA provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity. In cases where such exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication.

Hatch-Waxman Patent Certification and the 30-Month Stay

Upon approval of an NDA or a supplement thereto, NDA sponsors are required to list with the FDA each patent with claims that cover the applicant’s product or a method of using the product. Each of the patents listed by the NDA sponsor is published in the Orange Book. When an ANDA applicant files its application with the FDA, the applicant is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book, except for patents covering methods of use for which the ANDA applicant is not seeking approval.

Specifically, the applicant must certify with respect to each patent that:

- the required patent information has not been filed;
- the listed patent has expired;
- the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or
- the listed patent is invalid, unenforceable or will not be infringed by the new product.

A certification that the new product will not infringe the already approved product’s listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the applicant does not challenge the listed patents or indicates that it is not seeking approval of a patented method of use, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant.

European Union/Rest of World Government Regulation

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. The cost of establishing a regulatory compliance system for numerous varying jurisdictions can be very significant. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union (“EU”) and in other jurisdictions, the approval process varies between countries and jurisdictions and can involve additional product

testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Whether or not we obtain FDA approval for a product candidate, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial authorization application (“CTA”) must be submitted for each clinical protocol to each country’s national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is accepted in accordance with a country’s requirements, the clinical trial may proceed.

The requirements and process governing the conduct of clinical trials vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP the applicable regulatory requirements, and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational medicinal product under EU regulatory systems, we must submit a marketing authorization application. The content of the BLA or NDA filed in the United States is like that required in the EU, except, among other things, country-specific document requirements

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing, and reimbursement vary from country to country.

Countries that are part of the EU, as well as countries outside of the European Union, have their own governing bodies, requirements, and processes with respect to the approval of pharmaceutical and biologic products. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Authorization Procedures in the EU

Medicines can be authorized in the EU by using either the centralized authorization procedure or national authorization procedures.

- Centralized procedure. The EMA implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the European Economic Area (“EEA”). This procedure results in a single marketing authorization issued by the EMA that is valid across the EEA. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines.
- For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the European Commission following a favorable opinion by the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.
- National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure:
- Decentralized procedure. Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
- Mutual recognition procedure. In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In some cases, a Pediatric Investigation Plan (“PIP”) or a request for waiver or deferral, is required for submission prior to submitting a marketing authorization application. A PIP describes, among other things, proposed pediatric trials and their timing relative to clinical trials in adults. A PIP will be submitted to EMA and other EU countries, as required. The PIP will need to be submitted early during product development before marketing authorization applications are submitted. The timing of PIP submission cannot be after initiation of pivotal trials or confirmatory (phase 3) trials. In the future we may seek pediatric approval for AT-1501 applications in connection with renal and islet cell transplants, which may require the submission of a PIP.

Exclusivity of New Chemical Entities and New Fixed Dose Combinations

In the EU, new chemical entities, sometimes referred to as new active substances as well as new fixed dose combinations, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. This data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator’s data to assess a generic (abbreviated) application for eight years, after which a generic application can be submitted, and the innovator’s data may be referenced, but not approved for two years. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Exceptional Circumstances/Conditional Approval

Orphan drugs or drugs with unmet medical needs may be eligible for EU approval under exceptional circumstances or with conditional approval. Approval under exceptional circumstances may be applicable to orphan products and is used when an applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use because the indication for which the product is intended is encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, when the present state of scientific knowledge does not allow comprehensive information to be provided, or when it is medically unethical to collect such information. Conditional marketing authorization may be applicable to orphan medicinal products, medicinal products for seriously debilitating or life-threatening diseases, or medicinal products to be used in emergency situations in response to recognized public threats. Conditional marketing authorization can be granted on the basis of less complete data than is normally required in order to meet unmet medical needs and in the interest of public health, provided the risk-benefit balance is positive, it is likely that the applicant will be able to provide the comprehensive clinical data, and unmet medical needs will be fulfilled. Conditional marketing authorization is subject to certain specific obligations to be reviewed annually.

Accelerated Review

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the EMA’s Committee for Medicinal Products for Human Use, or CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. In this circumstance, EMA ensures that the opinion of the CHMP is given within 150 days, excluding clock stops.

Pharmaceutical Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we obtain regulatory approval. In the United States and in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Moreover, a payor’s decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any

product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. By way of example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and congressional challenges. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Congress also could consider subsequent legislation to replace elements of the Affordable Care Act that are repealed. Thus, the full impact of the Affordable Care Act, any law replacing elements of it, or the political uncertainty surrounding its repeal or replacement on our business remains unclear. Adoption of government controls, measures and tightening of restrictive policies in jurisdictions with existing controls and measures could limit payments for pharmaceuticals.

In European countries, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any products for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, the emphasis on cost containment measures in the United States and other countries has increased, and we expect will continue to increase the pressure on pharmaceutical pricing. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other Healthcare Laws and Compliance Requirements

If we obtain regulatory approval for any of our product candidates, we may be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, (“HIPAA”), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- the federal transparency laws, including the provision of the Affordable Care Act referred to as the federal Physician Payment Sunshine Act, that requires drug and biologics manufacturers to disclose payments and other transfers of value provided to physicians and teaching hospitals and ownership interests of physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

The Affordable Care Act broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. § 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

We are also subject to the U.S. Foreign Corrupt Practices Act (“FCPA”) which prohibits improper payments or offers of payments to foreign governments and their officials for the purpose of obtaining or retaining business. Safeguards we implement to discourage improper payments or offers of payments by our employees, consultants, and others may be ineffective, and violations of the FCPA and similar laws may result in severe criminal or civil sanctions, or other liabilities or proceedings against us, any of which would likely harm our reputation, business, financial condition and result of operations.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, exclusion from participation in government healthcare programs, such as Medicare and Medicaid and imprisonment, damages, fines and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Employees

As of March 26, 2021, Eledon had ten full-time employees. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

On September 14, 2020, the Company acquired Anelixis Therapeutics, Inc. (“Anelixis”), a Delaware Corporation, after which Anelixis became a wholly-owned subsidiary of the Company. On January 4, 2021, the Company changed its name from Novus Therapeutics, Inc. to Eledon Pharmaceuticals, Inc.

Our executive offices are located at 19900 MacArthur Boulevard, Suite 550, Irvine, California 92612. The Company also has research and development facilities in the Boston, Massachusetts area. Our telephone number is (949) 238-8090 and our website is eledon.com. We do not incorporate the information on or accessible through our website into this Annual Report, and you should not consider any information on, or that can be accessed through, our website as part of this Annual Report on Form 10-K.

You are advised to read this Annual Report on Form 10-K in conjunction with other reports and documents that we file from time to time with the Securities and Exchange Commission (“SEC”). In particular, please read our definitive proxy statement, which will be filed with the SEC in connection with our 2021 annual meeting of stockholders, our quarterly reports on Form 10-Q and any current reports on Form 8-K that we may file from time to time. You may obtain copies of

these reports after the date of this annual report directly from us or from the SEC at its website at www.sec.gov. We make our periodic and current reports available on our internet website, free of charge, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

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 Annual Report on Form 10-K, 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.

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 year ended December 31, 2020 is \$22.8 million. As of December 31, 2020, the Company had cash and cash equivalents of \$114.2 million, working capital of \$113.1 million and an accumulated deficit of \$80.4 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 States 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 Vela 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 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our executive offices are located in Irvine, California. We lease approximately 5,197 square feet of office space under an operating lease that expires in September 2021. Additionally, the Company has operating leases for four serviced office spaces in Burlington, Massachusetts that expire on June 30, 2021.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

None.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Capital Market under the symbol "ELDN".

As of March 23, 2021, there were approximately 87 stockholders of record of our common stock.

Dividends

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our common stock. Future determination as to the declaration and payment of dividends, if any, will be at the discretion of our board of directors and will depend on then existing conditions, including our operating results, financial condition, contractual restrictions, capital requirements, business prospects and other factors that our board of directors may deem relevant.

Item 6. Selected Financial Data.

Per §229.301 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 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to help the reader understand the results of operations and financial condition of the Company. The Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2020. In addition to historical information, this Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the safe harbors created thereby. See "Cautionary Note Regarding Forward-Looking Statements" in this report. Our actual results and the timing of events could differ materially from those discussed in our forward-looking statements as a result of many factors, including those set forth under the Part I, Item 1A. Risk Factors section and elsewhere in this report, as well as, in other reports and documents we file with the Securities and Exchange Commission from time to time. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances occurring after the date of this Annual Report on Form 10-K.

RECENT DEVELOPMENTS

Legacy Operations and Acquisition of Anelixis Therapeutics, Inc.

On September 14, 2020, the Company completed the acquisition of 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 ALS. Concurrent with the Company's acquisition of Anelixis on September 14, 2020, the Company entered into a Stock Purchase Agreement (the "Stock Purchase Agreement") with certain institutional and accredited investors (the "PIPE Investors"), pursuant to which the Company issued and sold approximately 217,200 shares of Series X1 Preferred Stock (the "PIPE Shares") for an aggregate purchase price of approximately \$108.15 million (the "Financing"). The Financing was exempt from registration pursuant to Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. At the closing of the Financing, the Company entered into a Registration Rights Agreement (the "Registration Rights Agreement") with the Investors. Pursuant to the Registration Rights Agreement, on December 22, 2020 the Company registered 12,065,875 shares of common stock, which may be issued upon conversion of the PIPE Shares on its under its effective shelf registration statement on Form S-3 (File No. 333-251305). The proceeds from the private placement will be used to fund the Company's operations, including to advance up to Phase 2 clinical trials of AT-1501, a humanized IgG1 anti-CD40L antibody.

Prior to our acquisition of Anelixis, we had been focused on developing novel products 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 and expected need to reformulate the investigational drug, we suspended the clinical development of our legacy ENT assets while we assess alternate development strategies, including out-licensing or a sale of these assets. 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.

Other Developments

Equity Distribution Agreement

On July 23, 2018, the Company filed a prospectus supplement (the "2018 Prospectus Supplement") under which the Company may offer and sell, from time to time, through Piper Jaffray, up to \$9.8 million in shares of its common stock. During the year ended December 31, 2019, 1,401 shares were sold under the 2018 Prospectus Supplement for gross proceeds of approximately \$110,000. No shares were sold during the year ended December 31, 2020. This agreement was terminated in 2020. Accordingly, as of December 31, 2020, no additional amounts remained available to be offered and sold under the 2018 Prospectus Supplement.

2019 Equity Offering

On April 30, 2019, the Company agreed to sell in a registered direct offering, an aggregate 191,617 shares of its common stock to certain investors for gross proceeds of approximately \$10.7 million under its effective shelf registration statement on Form S-3 (File No. 333-226286). In a concurrent private placement, the Company also agreed to issue to such investors Series A warrants to purchase up to 191,617 shares of its common stock at an exercise price of \$72.00 with a term

of eighteen months (the “Series A Warrants”) and Series B warrants to purchase up 191,6172 shares of its common stock at an exercise price of \$72.00 with a term of five years (the “Series B Warrants”). The Series B Warrants become exercisable only upon the exercise of the Series A Warrants. In addition, the Company agreed to issue to H.C. Wainwright & Co., LLC, the placement agent for the transaction, warrants to purchase up to 9,580 shares of common stock. The placement agent warrants have substantially the same terms as the Series A Warrants, except that the placement agent warrants have an exercise price equal to \$69.6375 and will expire on April 20, 2024. We refer to the registered direct offering and the concurrent private placement collectively as the “2019 Equity Offering.”

Warrant Exercise Transaction

On January 10, 2020 and January 15, 2020, the Company entered into warrant exercise agreements (the “Exercise Agreements”) with the holders (the “Holders”) of its Series A Warrants and Series B Warrants (collectively, the “Warrants”), issued in the 2019 Equity Offering, pursuant to which the Holders agreed to exercise in cash their Warrants to purchase an aggregate of 383,234 shares of the Company’s common stock at a reduced exercise price of \$12.87 per share, plus an additional \$2.25 per share for the issuance of the private placement warrants for gross proceeds (before placement agent fees and expenses) to the Company of approximately \$5.8 million (the “Exercise Transaction”).

Under the Exercise Agreements, the Company also agreed to issue to the Holders new warrants to purchase up to 383,234 shares of the Company’s common stock at an exercise price of \$12.96 per share, with an exercise period of five and a half years (the “Private Placement Warrants”). The Private Placement Warrants transaction subsequently closed and the Private Placement Warrants were issued on January 14, 2020 with respect to the Warrants exercised on January 10, 2020 and on or about January 17, 2020, with respect to the Warrants exercised on January 15, 2020. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 19,162 shares of common stock, representing 5.0% of the aggregate number of shares of common stock issued in the Exercise Transaction. The placement agent warrants have substantially the same terms as the Private Placement Warrants issued to the Holders, except that the placement agent warrants have an exercise price equal to \$18.90. A warrant inducement expense of \$4.8 million was incurred which was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the Warrants prior to, and immediately after, the reduction in the exercise price on the date of repricing in addition to the fair value of the Private Placement Warrants issued.

Common Stock Exchange Agreements

On February 13, 2020, the Company entered into an exchange agreement (the “Exchange Agreement”) with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Trading Fund OS, L.P. (the “Exchanging Stockholders”), pursuant to which the Exchanging Stockholders exchanged (the “February Exchange”) 210,888 shares of the Company’s common stock, par value \$0.001 per share, for 3,796 shares of newly designated Series X Convertible Preferred Stock (the “Series X Preferred Stock”). The Company agreed to reimburse the Exchanging Stockholders for their expenses in connection with the Exchange up to a total of \$25,000, which was recorded as operating expense in the Company’s condensed consolidated statements of operations and comprehensive loss.

On February 13, 2020, in connection with the February Exchange, the Company filed a Certificate of Designation setting forth the preferences, rights and limitations of the Series X Preferred Stock with the Secretary of State of the State of Delaware. Each share of Series X Preferred Stock will be convertible into 55.5556 shares of common stock at the option of the holder at any time; subject to certain limitations, including, that the holder will be prohibited from converting Series X Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock. In the event of the Company’s liquidation, dissolution or winding up, holders of Series X Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal (on an as-if-converted-to-common stock basis) to and in the same form as dividends actually paid on the common stock or other junior securities of the Company. Shares of Series X Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series X Preferred Stock will be required to amend the terms of the Series X Preferred Stock.

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. (the “BVF Exchanging Stockholders”) and Cormorant Global Healthcare Master Fund, LP (together with the BVF Exchanging Stockholders, the “Exchanging Stockholders”), pursuant to which the Exchanging Stockholders

exchanged (the “Series X Exchange”) 344,666 shares of the Company’s common stock, for 6,203.98 shares of Series X 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”).

Following the Exchanges, the Company will have 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)

September 2020 Stock Purchase Agreement

On September 14, 2020, Eledon entered into a Stock Purchase Agreement (the “Purchase Agreement”) with certain institutional and accredited investors (the “Investors”). Pursuant to the Purchase Agreement, Eledon 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 (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 stockholder approval of the issuance of the Company’s common stock upon the conversion of the Company’s X¹ Preferred Stock and the effective registration of its common stock. Subject to stockholder approval, each share of Series X¹ Preferred Stock was convertible into 55.5556 shares of Common Stock, as described below. 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. The Financing was exempt from registration pursuant to Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. The Investors have acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends have been affixed to the securities issued in this transaction.

On December 18, 2020, the Company held a special meeting of stockholders (the “Special Meeting”). At the Special Meeting, 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.

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.

Reverse Stock-Split

On October 5, 2020, the Company effected a reverse stock-split of its issued and outstanding common stock and options for common stock at a ratio of one-for-eighteen. The Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware effecting the reverse stock-split. The discussion in this Management’s Discussion and Analysis of Financial Condition and Results of Operations gives retroactive effect to the reverse stock-split for all periods presented.

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 work-from-home policies for all of our employees, resulting in reduced productivity and 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.

Business Combinations

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development ("IPR&D") and liabilities assumed. Additionally, the Company must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. The Company accounted for the acquisition of Anelixis as a business combination under the acquisition method of accounting. Consideration paid to acquire Anelixis was measured at fair value and included the exchange of Anelixis' common stock. The allocation of the purchase price resulted in recognition of intangible assets related to goodwill and IPR&D. Acquired IPR&D is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. The operating activity for Anelixis, the acquiree for accounting purposes, was immediately integrated with Eledon post-acquisition, therefore it is not practical to segregate results of operations related specifically to Anelixis since the date of acquisition.

During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the consolidated statements of operations as operating expenses or income.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment as of October 1 of each year or earlier if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount. For the year ended December 31, 2019, the Company recognized \$1.9 million of goodwill impairment which was included in the consolidated statements of operations. No impairment was recorded for the year ended December 31, 2020.

The Company performs its goodwill impairment analysis at the reporting unit level, which aligns with the Company's reporting structure and availability of discrete financial information. The Company performs its annual impairment analysis by either comparing the reporting unit's estimated fair value to its carrying amount or doing a qualitative assessment of a reporting unit's fair value from the last quantitative assessment to determine if there is potential impairment. The Company may do a qualitative assessment when the results of the previous quantitative test indicated the reporting unit's estimated fair value was significantly in excess of the carrying value of its net assets and it does not believe there have been significant changes in the reporting unit's operations that would significantly decrease its estimated fair value or significantly increase its net assets. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Key assumptions for these projections include revenue growth, future gross and operating margin growth, and its weighted cost of capital and terminal growth rates. The revenue and margin growth are based on increased sales of new products as the Company maintains investments in research and development. Additional assumed value creators may include increased efficiencies from capital spending. The resulting cash flows are discounted using a weighted average cost of capital. Operating mechanisms and requirements to ensure that growth and efficiency assumptions will ultimately be

realized are also considered in the evaluation, including timing and probability of regulatory approvals for Company products to be commercialized. The Company's market capitalization is also considered as a part of its analysis.

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's contracts with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to its vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. The Company's accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. These contracts may be terminated by the Company upon written notice and the Company is generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances the Company may be further responsible for termination fees and penalties. The Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through December 31, 2020.

Stock-Based Compensation

For stock options granted to employees and directors, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical industry. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options ordinary vesting period and the contractual term. For stock options granted to the 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.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the estimated fair value of the stock options on their grant date, determined using the Black-Scholes option pricing model. The awards generally vest over the period the Company expects to receive services from the nonemployees. Similar to stock options granted to employees, the fair value of stock options granted nonemployees, determined using the Black-Scholes option pricing model, involves 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 on stock options granted to nonemployees, the Company determined the contractual term is the appropriate period for expected life on stock options granted to nonemployees. 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.

RESULTS OF OPERATIONS

Comparison of the Years Ended December 31, 2020 and 2019

The following table provides comparative results of operations for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,		\$ Variance	% Variance
	2020	2019		
Operating expenses:				
Research and development	\$ 6,131	\$ 8,128	\$ (1,997)	-25%
General and administrative	10,052	6,056	3,996	66%
Restructuring expense	2,282	—	2,282	100%
Goodwill impairment	—	1,867	(1,867)	-100%
Total operating expenses	18,465	16,051	2,414	15%
Loss from operations	(18,465)	(16,051)	(2,414)	15%
Other income (expense), net	79	40	39	98%
Warrant inducement expense	(4,829)	—	(4,829)	100%
Loss before income tax benefit	(23,215)	(16,011)	(7,204)	45%
Income tax benefit	404	—	404	100%
Net loss and other comprehensive loss	\$ (22,811)	\$ (16,011)	\$ (6,800)	42%

Research and Development Expenses

The decrease in research and development expenses of \$2.0 million for the year ended December 31, 2020 was primarily due to decreases in clinical costs of \$1.5 million and formulation development costs of \$1.5 million, as well as decreases in personnel costs of \$84,000, travel and meetings expense of \$82,000, and miscellaneous operating costs of \$2,000. The decreases were partially offset by increases in stock-based compensation expense and consulting costs of \$911,000 and \$247,000, respectively. The decreases were made following the completion of our Phase 2a study of our legacy lead program in acute otitis media and the subsequent suspension of development as we assessed strategic options. We expect our research and development costs to increase in future periods as we proceed with the development of AT-1501.

General and Administrative Expenses

The increase in general and administrative expenses of \$4.0 million for the year ended December 31, 2020 was primarily due to increases in merger related costs of \$2.9 million as a result of the Anelixis acquisition and \$441,000 in administrative costs associated with operating a public company, as well as increases in stock-based compensation expense and general operating costs of \$953,000 and \$80,000, respectively. The increases were offset by a decrease in litigation costs of \$281,000, as well as decreases in travel and meetings expense and personnel costs of \$44,000 and \$5,000, respectively. Following the completion of Anelixis acquisition, we expect our general and administrative expenses to increase in future periods, as we have a larger headcount and incur expenses relating to the development of a larger product pipeline.

Restructuring Expense

On June 11, 2020, following the prior announcement of topline results of the Phase 2a Clinical Trial of OP0201 in acute otitis media, the Board of the Company approved a reduction in force. The restructuring was completed on June 30, 2020. Additionally, on September 3, 2020, the Board of the Company accepted the resignation of Gregory Flesher as the Company's Chief Executive Officer and a member of the Board, effective as of the close of business on September 4, 2020. Furthermore, following the acquisition of Anelixis, the severance terms of certain terminated employees were modified. The Company incurred charges totaling \$2.3 million for the estimated cash payments related to employee separation costs, including severance and post-employment health benefits.

Goodwill Impairment

The Company performed a goodwill impairment test as of December 31, 2019 and determined that the fair value of its goodwill was below its carrying value. As a result, the Company recognized \$1.9 million of goodwill impairment. No impairment was recorded for the year ended December 31, 2020.

Other Income, Net

The change in other income, net was due to miscellaneous income of \$35,000 related to disgorgement of profits on prohibited stock transactions by an investor, a decrease in realized losses on foreign currency translation of \$22,000, and a decrease in VAT tax of \$3,000, partially offset by a decrease in interest income of \$21,000 for the year ended December 31, 2020.

Warrant Inducement Expense

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. (See Note 7 to the consolidated financial statements included elsewhere in this filing).

Income Tax Benefit

The Company recognized an income tax benefit of \$404,000 for the year ended December 31, 2020 due to the current year change in deferred tax liability for the acquired IPR&D related to the Anelixis acquisition.

Pro Forma Comparison of the Years Ended December 31, 2020 and 2019

The following table provides pro forma combined financial information presented to illustrate the estimated effects of the Anelixis acquisition based on the historical financial statements and accounting records of the Company and Anelixis after giving effect to the acquisition. This pro forma information is not necessarily indicative either of the combined results of operations that actually would have been realized by us had the Anelixis acquisition been consummated at the beginning of the period for which the pro forma information is presented, or of future results. Additionally, the pro forma combined financial information does not reflect any merger-related expenses.

	Year Ended December 31,		\$ Variance	% Variance
	2020	2019		
Revenue	\$ 120	\$ 500	(380)	(76)%
Operating expenses				
Research and development	9,489	11,441	(1,952)	(17)%
General and administrative	8,317	7,585	732	10%
Restructuring expense	2,282	—	2,282	100%
Goodwill impairment	—	1,867	(1,867)	100%
Total operating expenses	20,088	20,893	(805)	(4)%
Loss from operations	(19,968)	(20,393)	425	(2)%
Other income, net	79	40	39	98%
Warrant inducement expense	(4,829)	—	(4,829)	100%
Loss before income tax provision	(24,718)	(20,353)	(4,365)	21%
Income tax benefit	404	—	404	100%
Net loss and other comprehensive loss	\$ (24,314)	\$ (20,353)	\$ (3,961)	19%

Revenue

The decrease in revenue of \$380,000 for the year ended December 31, 2020 was due to the difference in amount Anelixis earned from a research grant. Anelixis had a \$944,000 research grant agreement, which contained four research and productivity milestones. The current phase, which earned Anelixis \$120,000, was the fourth and final phase of this agreement.

Research and Development Expenses

The decrease in research and development expenses of approximately \$2.0 million for the year ended December 31, 2020 was primarily due to decreases in clinical costs and formulation development costs of approximately \$2.2 million and \$1.2 million, respectively, as well as a decrease in travel and meetings expense of \$82,000. The decreases were partially offset by an increase in stock-based compensation costs of \$911,000, personnel costs of \$343,000, consulting services of \$232,000, and \$13,000 in general operating costs. As noted above, we expect research and development expenses to increase in future periods.

General and Administrative Expenses

The increase in general and administrative expenses of \$732,000 for the year ended December 31, 2020 was primarily due to increases in stock-based compensation costs of \$953,000 and costs associated with operating a publicly traded company of \$510,000. The increase was offset by decreases in litigation costs of \$281,000, general operating costs of \$245,000, personnel costs of \$161,000, and travel and meetings expense of \$44,000. As noted above, we expect our general and administrative expenses to increase in future periods.

Restructuring Expense

On June 11, 2020, following the prior announcement of topline results of the Phase 2a Clinical Trial of OP0201 in acute otitis media, the Board of the Company approved a reduction in force. The restructuring was completed on June 30, 2020. Additionally, on September 3, 2020, the Board of the Company accepted the resignation of Gregory Flesher as the Company's Chief Executive Officer and a member of the Board, effective as of the close of business on September 4, 2020. Furthermore, following the acquisition of Anelixis, the severance terms of certain terminated employees were modified. The Company incurred charges totaling \$2.3 million for the estimated cash payments related to employee separation costs, including severance and post-employment health benefits.

Other Income, Net

The change in other income, net was due to miscellaneous income of \$35,000 related to disgorgement of profits on prohibited stock transactions by an investor, a decrease in realized losses on foreign currency translation of \$22,000, and a decrease in VAT tax of \$3,000, offset by a decrease in interest income of \$21,000 for the year ended December 31, 2020.

Warrant Inducement Expense

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. (See Note 7 to the consolidated financial statements included elsewhere in this filing).

Income Tax Benefit

The Company recognized an income tax benefit of \$404,000 for the year ended December 31, 2020 due to the current year change in deferred tax liability.

LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2020, we had cash and cash equivalents of approximately \$114.2 million, consisting of readily available cash and cash equivalents in bank accounts and an accumulated deficit of \$80.4 million. While we believe our cash and cash equivalents are not subject to excessive risk, we maintain significant amounts of cash and cash equivalents 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 and warrants, 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 drug product through clinical development, to manufacture, obtain regulatory approval for and to commercialize our product candidates, to develop, acquire or in-license other potential product candidates, and to fund operations for the foreseeable future. Therefore, we will seek to raise additional capital through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. 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 the section of this Annual Report titled "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.

See Item 7, *Management's Discussion and Analysis of Financial Condition and Results of Operations* in this Annual Report on Form 10-K under the caption "Recent Developments" for a discussion of additional sources of liquidity, including the 2019 Equity Offering, the Exercise Transaction and the Financing.

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 for the years ended December 31, 2020 and 2019 (in thousands):

	Year Ended December 31,	
	2020	2019
Net cash used in operating activities	\$ (15,212)	\$ (13,857)
Net cash provided by investing activities	11,035	—
Net cash provided by financing activities	109,581	9,676
Net change in cash and cash equivalents	\$ 105,404	\$ (4,181)

Comparison of the Years Ended December 31, 2020 and 2019

Net cash used in operating activities for the year ended December 31, 2020 consisted primarily of our net loss of \$22.8 million, partially offset by non-cash items consisting primarily of depreciation and amortization of \$183,000, warrant inducement expense of \$4.8 million, net deferred income taxes of \$404,000, and stock-based compensation totaling \$3.2 million. Additionally, cash used in operating activities for the year ended December 31, 2020 reflected a net decrease in cash from changes in operating assets and liabilities of \$180,000, due to a decrease in operating lease liability.

Net cash used in operating activities for the year ended December 31, 2019 consisted primarily of our net loss of \$16.0 million, partially offset by non-cash items consisting primarily of depreciation and amortization of \$182,000, a goodwill impairment charge of \$1.9 million, and stock-based compensation totaling \$1.3 million. Additionally, cash used in operating activities for the year ended December 31, 2019 reflected a net decrease in cash from changes in operating assets and liabilities of \$1.2 million, due to a decrease in our accounts payable and accrued liabilities of \$1.4 million and a decrease in our operating lease liability of \$165,000, offset by a decrease in prepaid expenses and other assets of \$354,000.

Net cash provided by investing activities for the year ended December 31, 2020 consisted of cash and cash equivalents received from the acquisition of Anelixis.

There was no cash provided by or used in investing activities for the year ended December 31, 2019.

Net cash provided by financing activities for the year ended December 31, 2020 was comprised of \$95.2 million in net proceeds from the 2020 Purchase Agreement for the sale of 199,112 shares of Series X1 preferred stock, \$5.4 million in net proceeds from the exercise of warrants by stockholders to purchase approximately 0.4 million shares of common stock, and \$9.0 million in net proceeds for the sale of approximately 1.0 million shares of common stock, offset by \$25,000 of cash paid in connection with the cancellation of common stock related to the Company's reverse stock-split.

Net cash provided by financing activities for the year ended December 31, 2019 was comprised of \$9.6 million in net proceeds from the 2019 Equity Offering for the sale of approximately 3.4 million shares of common stock and \$107,000 in net proceeds from the 2018 Prospectus for the sale of approximately 25,000 shares of common stock.

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 7A. 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 8. Financial Statements and Supplementary Data.

The Report of Independent Registered Public Accounting Firm, our consolidated financial statements and accompanying notes listed under Part IV, Item 15. *Exhibits, Financial Statement Schedules* of this Annual Report on Form 10-K are set forth beginning on page F-1 immediately following the signature page hereof and incorporated by reference herein.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost benefit relationship of possible controls and procedures. Based on this evaluation, management concluded that our disclosure controls and procedures were effective in alerting them in a timely manner to material information required to be disclosed in our periodic reports filed with the SEC.

Internal Control Over Financial Reporting

Management’s Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Exchange Act. Our internal control system is designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO Framework”) in its 2013 *Internal Control—Integrated Framework*. Management believes that the COSO Framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.

Based on this assessment, our management has concluded that as of December 31, 2020, our internal control over financial reporting is effective.

As a non-accelerated filer, we are not required to provide an attestation report on our internal control over financial reporting issued by the Company’s independent registered accounting firm.

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 December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On March 30, 2021, the Company entered into an Open Market Sale Agreement (the “Sale Agreement”) with Jefferies LLC (“Jefferies”) to sell shares of the Company’s common stock, par value \$0.001 per share, having aggregate sales proceeds of up to \$75,000,000, from time to time, through an “at the market” equity offering program under which Jefferies will act as sales agent.

Under the Sale Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sale Agreement, Jefferies may sell the shares by methods deemed to be an “at the market offering” as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or on any other existing trading market for the common stock. The Company and Jefferies may each terminate the Sale Agreement at any time as set forth in the Sale Agreement. Under the terms of the Sale Agreement, the Company may also sell shares to Jefferies acting as principal for Jefferies’ own account.

The compensation to Jefferies for sales of the Company’s common stock will be an amount equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sale Agreement. The Company has no obligation to sell any shares under the Sale Agreement, and may at any time suspend solicitation and offers under the Sale Agreement.

The shares will be issued pursuant to a shelf registration statement on Form S-3 to be filed with the SEC. No sales may be made under the registration statement until it has been declared effective by the SEC.

The foregoing description of the Sale Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 1.1 to this Annual Report on Form 10-K and is incorporated herein by reference.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 is incorporated herein by reference to information in our proxy statement for our 2021 Annual Meeting of Stockholders (the “2021 Proxy Statement”), which we expect to be filed with the SEC within 120 days of the end of our fiscal year ended December 31, 2020, including under headings “Board of Directors and Corporate Governance—Election of Directors,” “Executive Officers and Executive Compensation—Executive Officers,” “Board of Directors and Corporate Governance—Code of Business Conduct and Ethics,” “Board of Directors and Corporate Governance—Director Nomination Process” and “Board of Directors and Corporate Governance—Committees of the Board of Directors”.

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is available on the Corporate Governance section of our website, which is located at <http://ir.eledon.com/corporate-governance/governance-overview>. We intend to disclose on our website any amendments to, or waivers from, the code of business conduct and ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation.

The information required by this Item 11 is incorporated herein by reference to information in our 2021 Proxy Statement, including under headings “Executive Compensation,” “Director Compensation,” “Board of Directors and Corporate Governance—Compensation Committee Interlocks and Insider Participation,” “Board of Directors and Corporate Governance—Oversight of Risk”.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 is incorporated herein by reference to information in our 2021 Proxy Statement, including under headings “Security Ownership of Certain Beneficial Owners and Management” and “Securities Authorized for Issuance Under Equity Compensation Plans”.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 is incorporated herein by reference to information in our 2021 Proxy Statement, including under headings “Board of Directors and Corporate Governance—Related Person Transactions,” “Board of Directors and Corporate Governance,” and “Board of Directors and Corporate Governance—Committees of the Board of Directors”.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 is incorporated herein by reference to information in our 2021 Proxy Statement, including under headings “Proposal No. 2—Ratification of the Appointment of Independent Registered Public Accounting Firm”.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

The Report of Independent Registered Public Accounting Firm, our consolidated financial statements and accompanying notes are set forth beginning on page F-1 immediately following the signature page of this Annual Report on Form 10-K.

(2) Financial Statement Schedules:

The financial statement schedules are omitted as they are either not applicable or the information required is presented in the financial statements and notes thereto under Part II, Item 8. *Financial Statements and Supplementary Data*.

(3) Exhibits:

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
1.1	Open Market Sales Agreement by and between the Registrant and Jefferies, LLC dated March 30, 2021					X
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.	8-K	001-36620	2.1	September 15, 2020	
3.1	Restated Certificate of Incorporation of Novus Therapeutics, Inc., a Delaware corporation, dated September 22, 2014	8-K	001-36620	3.1	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	8-K	001-36620	3.1	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	8-K	001-36620	3.2	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	8-K	001-36620	3.1	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	8-K	001-36620	3.1	January 5, 2021	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
3.6	Amended and Restated Bylaws of Eledon Pharmaceuticals, Inc.	8-K	001-36620	3.2	January 5, 2021	
3.7	Certificate of Designations of Series X Convertible Preferred Stock	8-K	001-36620	3.1	February 19, 2020	
3.8	Certificate of Designations of Series X1 Convertible Preferred Stock	8-K	001-36620	3.1	September 15, 2020	
4.1	Form of Common Stock Certificate	8-A/A	001-36620	4.1	June 23, 2017	
4.2	Form of Warrant	8-K	001-36620	4.1	May 2, 2019	
4.3	Form of Placement Agent Warrant	8-K	001-36620	4.2	May 2, 2019	
4.4	Form of Common Stock Purchase Warrant	8-K	001-36620	4.1	January 16, 2020	
4.5	Description of Securities					X
10.2*	Form of Indemnification Agreement	8-K	001-36620	10.1	September 15, 2020	
10.3	Lease Agreement, dated as of September 2, 2015, by and between The Irvine Company LLC and Otic Pharma, Inc.	10-Q	001-36620	10.2	August 9, 2017	
10.4	First Amendment to Lease Agreement, dated April 19, 2018, by and between The Irvine Company LLC and Novus Therapeutics, Inc.	10-Q	001-36620	10.1	August 7, 2018	
10.5	Tokai Pharmaceuticals, Inc. 2007 Stock Incentive Plan	10-K	001-36620	10.11	April 2, 2018	
10.6	Tokai Pharmaceuticals, Inc. 2014 Stock Incentive Plan	10-Q	001-36620	10.2	August 7, 2018	
10.7	Novus Therapeutics, Inc., 2014 Employee Stock Purchase Plan	10-Q	001-36620	10.3	August 7, 2018	
10.8*	Executive Employment Agreement, dated September 9, 2020, between Novus Therapeutics, Inc. and David-Alexandre C. Gros, M.D.					X
10.9	Executive Employment Agreement, dated March 1, 2021, between Eledon Pharmaceuticals, Inc. and Jon Kuwahara					X
10.10	Executive Employment Agreement, dated March 15, 2021, between Eledon Pharmaceuticals, Inc. and Paul Little					X
10.11	Novus Therapeutics, Inc., 2020 Long Term Incentive Plan					X
16.1	Letter from Ernst & Young LLP, dated July 11, 2019	8-K	001-36620	16.1	July 12, 2019	
21.1	Subsidiaries of the Registrant	10-K	001-36620	21.1	March 17, 2020	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filing Date	Filed Herewith
		Form	File No.	Exhibit		
23.1	<u>Consent of KMJ Corbin & Company LLP, independent registered public accounting firm</u>					X
31.1	<u>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</u>					X
31.2	<u>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</u>					X
32.1#	<u>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</u>					X
32.2#	<u>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</u>					X
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					
*	Indicates a management contract or compensatory plan					
†	Schedules to and certain portions of these exhibits have been omitted pursuant to Item 601 (b)(2) of Regulation S-K. The omitted information is not material and may cause competitive harm to the Registrant if publicly disclosed.					
#	These certifications are not deemed filed by the SEC and are not to be incorporated by reference in any filing we make under the Securities Act of 1933 or the Securities Exchange Act of 1934, irrespective of any general incorporation language in any filings.					

Item 16. Form 10-K Summary.

None.

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: March 30, 2021

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

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

Date: March 30, 2021

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

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ David-Alexandre C. Gros, M.D. David-Alexandre C. Gros, M.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2021
/s/ Paul Little Paul Little	Chief Financial Officer (Principal Financial Officer)	March 30, 2021
/s/ Jon S. Kuwahara Jon S. Kuwahara	Senior Vice President Finance & Administration (Principal Accounting Officer)	March 30, 2021
/s/ Keith A. Katkin Keith A. Katkin	Chairman of the Board of Directors	March 30, 2021
/s/ Gary A. Lyons Gary A. Lyons	Director	March 30, 2021
/s/ John S. McBride John S. McBride	Director	March 30, 2021
/s/ Walter Ogier Walter Ogier	Director	March 30, 2021
/s/ June Lee, M.D. June Lee, M.D.	Director	March 30, 2021
/s/ Steven Perrin Steven Perrin	President, Director	March 30, 2021

ELEDON PHARMACEUTICALS, INC.
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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Eledon Pharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Eledon Pharmaceuticals, Inc. (the “Company”) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders’ equity and cash flows for the each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which it relates.

Anelixis Therapeutics, Inc. Business Combination

Critical Audit Matter Description

As described in Notes 1, 2, 4, 7 and 10 to the consolidated financial statements, on September 14, 2020, the Company acquired Anelixis Therapeutics, Inc. (“Anelixis”) pursuant to a merger agreement. The Company issued to the stockholders of Anelixis 175,488 shares of common stock and 140,026 shares of Series X1 Non-Voting Convertible Preferred Stock (“Preferred Stock”). In addition, the Company assumed outstanding Anelixis stock options and warrants and replaced them with the Company’s warrants and stock options. The Company applied the acquisition method of accounting to the acquired assets and assumed liabilities of Anelixis. The allocation of the purchase price included an identified intangible asset that consisted of in-process research and development (“IPR&D”) with an estimated fair value of \$32.4 million related to

Anelixis' clinical development program of AT-1501. The estimated fair value of the IPR&D was determined by management based on an external valuation specialists' analysis of replacement costs to recreate AT-1501 in its current clinical stage.

Given that the accounting for the transaction required management to make significant judgments in (1) assessing whether the acquisition should be accounted for as a business combination or asset acquisition, (2) determining the accounting acquirer, and (3) estimating the fair value of the acquired IPR&D intangible asset, auditing the transaction was challenging and complex as it required a high degree of auditor judgment and an increased extent of effort, including the need to involve a valuation specialist.

How the Critical Audit Matter Was Addressed in the Audit

Our audit procedures related to the accounting for the transaction included the following, among others, obtaining an understanding of management's assessment of the accounting treatment for the transaction through inspection of the merger agreement and evaluation of the Company's analysis which considered the significant terms of the merger agreement and the relevant accounting guidance. To test the estimated fair value of the acquired IPR&D intangible asset, we evaluated the reasonableness of the valuation methodology, with the assistance of a valuation specialist, and tested the completeness and accuracy of the underlying data used by management to develop the assumptions. In addition, we assessed the appropriateness of management's disclosures of the Anelixis business combination.

Accounting and Presentation of Series X1 Non-Voting Convertible Preferred Stock

Critical Audit Matter Description

As described in Notes 2, 7 and 10 to the consolidated financial statements, on September 14, 2020, the Company sold 199,112 shares of Preferred Stock for gross proceeds of \$99.1 million and issued 140,026 shares of Preferred Stock in connection with the acquisition of Anelixis. The Preferred Stock was contingently convertible upon shareholder approval of the conversion of the Preferred Stock into 55.5556 shares of common stock and was redeemable if there was no shareholder approval.

Auditing management's accounting for the Preferred Stock and its appropriate classification was challenging due to the complex nature of the relevant accounting guidance, as well as the extent of management's judgements in the application of the guidance. Management determined that the Preferred Stock was neither mandatorily redeemable nor did it require settlement into a variable number of shares of common stock. Management also evaluated the embedded conversion features for bifurcation as embedded derivative instruments. This evaluation included determining if the economic characteristics and risks of the embedded conversion features were clearly and closely related to the economic characteristics of the Preferred Stock. Based on its terms, the Company determined that the Preferred Stock was akin to an equity-like host. As a result, the Company concluded that the embedded conversion features were clearly and closely related to the Preferred Stock. Management also analyzed the conversion provision and determined there was no beneficial conversion feature. In addition, management classified the Preferred Stock outside of stockholders' equity for the period prior to the shareholder approval of the conversion to common stock because the approval was outside of the control of the Company.

How the Critical Audit Matter Was Addressed in the Audit

We obtained an understanding of management's assessment of the accounting treatment of the transaction through inspection of the Certificate of Designations of the Preferred Stock and evaluation of the Company's analysis of the significant terms of the Preferred Stock, the related accounting guidance and its conclusions.

Our audit procedures related to the accounting for the transaction included, among others, the following: we evaluated management's conclusions regarding the classification and valuation of the Preferred Stock, tested the Company's determination of the fair value of the Preferred Stock, and assessed the appropriateness of management's disclosures of the Preferred Stock and related transactions.

/s/ KMJ Corbin & Company LLP

We have served as the Company's auditor since 2019.

Irvine, California
March 30, 2021

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

	December 31,	
	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 114,195	\$ 8,791
Prepaid expenses and other current assets	1,435	1,180
Total current assets	<u>115,630</u>	<u>9,971</u>
Property and equipment, net	—	5
Operating lease asset, net	138	316
Goodwill	48,648	—
In-process research and development	32,386	—
Other assets	383	639
Total assets	<u>\$ 197,185</u>	<u>\$ 10,931</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,366	\$ 329
Current operating lease liability	144	180
Accrued severance	12	—
Accrued expenses and other liabilities	<u>961</u>	<u>813</u>
Total current liabilities	<u>2,483</u>	<u>1,322</u>
Deferred tax liability	4,106	—
Non-current operating lease liability	—	144
Total liabilities	<u>6,589</u>	<u>1,466</u>
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Series X ¹ non-voting convertible preferred stock, \$0.001 par value, 515,000 shares authorized; 108,070 and no shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Series X preferred stock, \$0.001 par value, 10,000 shares authorized; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, \$0.001 par value, 200,000,000 shares authorized at December 31, 2020 and 2019; 15,160,397 and 720,408 shares issued and outstanding at December 31, 2020 and 2019, respectively	15	1
Additional paid-in capital	270,974	67,046
Accumulated deficit	(80,393)	(57,582)
Total stockholders' equity	<u>190,596</u>	<u>9,465</u>
Total liabilities and stockholders' equity	<u>\$ 197,185</u>	<u>\$ 10,931</u>

See accompanying notes to consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)

	Year Ended December 31,	
	2020	2019
Operating expenses		
Research and development	\$ 6,131	\$ 8,128
General and administrative	10,052	6,056
Restructuring expense	2,282	—
Goodwill impairment	—	1,867
Total operating expenses	18,465	16,051
Loss from operations	(18,465)	(16,051)
Other income, net	79	40
Warrant inducement expense	(4,829)	—
Loss before income tax benefit	(23,215)	(16,011)
Income tax benefit	404	—
Net loss and other comprehensive loss	\$ (22,811)	\$ (16,011)
Net loss per share, basic and diluted	\$ (15.72)	\$ (24.42)
Weighted-average common shares outstanding, basic and diluted	1,451,432	655,526

See accompanying notes to consolidated financial statements.

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

	Series X ¹ Non-Voting Convertible Preferred Stock		Series X Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount	Shares	Amount	\$ 1	\$ (57,582)	\$ 9,46
Balance as of December 31, 2019	—	\$ —	—	\$ —	720,408	\$ 1	\$ 67,046	\$ (57,582)	\$ 9,46
Issuance of common stock in connection with PIPE transaction, net of issuance costs	—	—	—	—	1,004,111	1	8,549	—	8,550
Issuance of common stock in connection with exercise of warrants, net of issuance costs	—	—	—	—	421,772	—	5,380	—	5,380
Issuance of common stock in connection with conversion of Series X preferred stock	—	—	(3,796)	—	210,888	—	—	—	—
Issuance of common stock in connection with conversion of Series X ¹ preferred stock	(231,068)	—	—	—	12,837,056	13	(13)	—	—
Issuance of common stock in connection with vesting of restricted stock units	—	—	—	—	3,056	—	—	—	—
Issuance of common stock in connection with acquisition	—	—	—	—	175,488	—	1,194	—	1,194
Cancellation of common stock in connection with exchange for preferred stock	—	—	3,796	—	(210,889)	—	—	—	—
Cancellation of common stock in connection with reverse split	—	—	—	—	(1,493)	—	(25)	—	(2)
Issuance of preferred stock in connection with acquisition	140,026	—	—	—	—	—	69,723	—	69,723
Issuance of preferred stock in connection with PIPE transaction, net of issuance costs	199,112	—	—	—	—	—	95,226	—	95,226
Fair value of options assumed in acquisition	—	—	—	—	—	—	2,950	—	2,950
Fair value of warrants assumed in acquisition	—	—	—	—	—	—	12,944	—	12,944
Warrant inducement expense	—	—	—	—	—	—	4,829	—	4,829
Stock-based compensation	—	—	—	—	—	—	3,171	—	3,171
Net loss and other comprehensive loss	—	—	—	—	—	—	(22,811)	—	(22,811)
Balance as of December 31, 2020	<u>108,070</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>15,160,397</u>	<u>\$ 15</u>	<u>\$ 270,974</u>	<u>\$ (80,393)</u>	<u>\$ 190,590</u>
Balance as of December 31, 2018	—	\$ —	—	\$ —	523,452	\$ 1	\$ 56,062	\$ (41,571)	\$ 14,490
Issuance of common stock at-the-market, net of issuance costs	—	—	—	—	1,401	—	107	—	10
Issuance of common stock and warrants in registered direct offering, net of issuance costs	—	—	—	—	191,617	—	9,569	—	9,569
Issuance of common stock in connection with vesting of restricted stock units	—	—	—	—	4,359	—	—	—	—
Cancellation of common stock	—	—	—	—	(421)	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	1,308	—	1,308
Net loss and other comprehensive loss	—	—	—	—	—	—	(16,011)	—	(16,011)
Balance as of December 31, 2019	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>720,408</u>	<u>\$ 1</u>	<u>\$ 67,046</u>	<u>\$ (57,582)</u>	<u>\$ 9,46</u>

See accompanying notes to consolidated financial statements.

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

	Year Ended December 31,	
	2020	2019
Operating activities		
Net loss	\$ (22,811)	\$ (16)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	5	
Amortization of operating lease asset	178	
Goodwill impairment	—	1
Warrant inducement expense	4,829	
Stock-based compensation	3,171	1
Deferred income taxes	(404)	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	39	
Accounts payable and accrued expenses	(39)	(1)
Operating lease liability	(180)	
Net cash used in operating activities	<u>(15,212)</u>	<u>(13)</u>
Investing activities		
Cash and cash equivalents received from acquisition	11,035	
Net cash provided by investing activities	<u>11,035</u>	
Financing activities		
Proceeds from issuance of common stock, net	9,000	9
Proceeds from issuance of non-voting preferred stock in connection with PIPE transaction, net	95,226	
Proceeds from exercise of warrants, net	5,380	
Cash paid for cancellation of common stock in connection with reverse split	(25)	
Net cash provided by financing activities	<u>109,581</u>	<u>9</u>
Net change in cash and cash equivalents	105,404	(4)
Cash and cash equivalents at beginning of year	8,791	12
Cash and cash equivalents at end of year	<u>\$ 114,195</u>	<u>\$ 8</u>
Supplemental disclosure of non-cash investing and financing activities		
Conversion of Series X ¹ preferred stock into common stock	\$ 13	\$
Issuance of common stock in acquisition	\$ 1,194	\$
Issuance of non-voting convertible preferred stock in acquisition	\$ 69,723	\$
Fair value of options assumed in acquisition	\$ 2,950	\$
Fair value of warrants assumed in acquisition	\$ 12,944	\$
Accrued offering costs	\$ 450	\$

See accompanying notes to consolidated financial statements.

ELEDON PHARMACEUTICALS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Note 1. Description of Business

Eledon Pharmaceuticals, Inc. (formerly Novus Therapeutics, Inc.) is a clinical stage biopharmaceutical company focused on developing life-changing, targeted medicines for persons living with an autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis (“ALS”). 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. 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, Novus Therapeutics, Inc. (“Novus”) 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 10). Following the acquisition of Anelixis, Novus changed its name to Eledon Pharmaceuticals, Inc. The Company has continued to maintain its corporate headquarters in Southern California and has research and development facilities in the Boston, Massachusetts area.

In 2017, Otic Pharma, Ltd. (“Otic”) consummated a reverse merger with Tokai Pharmaceuticals, Inc. (“Tokai”), pursuant to which, among other things, Tokai purchased from Otic and its stockholders all of the common and preferred shares of Otic in exchange for the issuance of a certain number of shares of common stock of Tokai (the “Reverse Merger”). Following the Reverse Merger, Tokai changed its name to Novus Therapeutics, Inc.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (“GAAP”). 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 consolidated financial statements.

All significant intercompany accounts and transactions among the entities have been eliminated in consolidation.

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 \$22.8 million and used \$15.2 million of cash in operating activities for the year ended December 31, 2020. As of December 31, 2020, the Company had cash and cash equivalents of \$114.2 million, working capital of \$113.1 million and an accumulated deficit of \$80.4 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 consolidated financial statements for the year ended December 31, 2020, 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 consolidated financial statements.

September 2020 Stock Purchase Agreement

On September 14, 2020, Eledon entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors (the "Investors"). Pursuant to the Purchase Agreement, Eledon agreed to sell an aggregate of approximately 199,112 shares of Series X¹ non-voting Preferred Stock ("Series X¹ Preferred Stock") for an aggregate purchase price of approximately \$99.1 million (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 stockholder 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. Subject to stockholder approval, each share of Series X¹ Preferred Stock was convertible into 55.5556 shares of common stock, as described within this document. 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. The Financing was exempt from registration pursuant to Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. The Investors have acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends have been affixed to the securities issued in this transaction.

On December 18, 2020, the Company held a special meeting of stockholders (the "Special Meeting"). At the Special Meeting, 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.

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.

Nasdaq Matters

On August 8, 2019, the Company received written notice (the "Notification Letter") from The Nasdaq Stock Market LLC ("Nasdaq") notifying the Company that it was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market. Nasdaq Listing Rule 5550(a)(2) requires listed securities maintain a minimum closing bid price of \$1.00 per share, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company's common stock for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement.

On October 19, 2020, the Company received written notice from Nasdaq notifying the Company that the closing bid price of the Company's common stock had been at \$1.00 per share or greater for a period of ten consecutive trading days. Accordingly, the Company has regained compliance with Listing Rule 5550(a)(2) and this matter is now closed.

Reverse Stock-Split

On October 5, 2020, Eledon effected a reverse stock-split of its issued and outstanding common stock and options for common stock at a ratio of one-for-eighteen. The Company filed an Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware effecting the reverse stock-split. The accompanying consolidated financial statements and notes, as well as other share and per-share data herein, give retroactive effect to the reverse stock-split for all periods presented.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions that affect the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes. The most significant estimates in the Company's consolidated financial statements relate to stock-based compensation, accruals for liabilities, 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 consolidated financial statements and related disclosures.

Actual results could differ materially from those estimates under different assumptions or conditions and the differences may be material to the consolidated financial statements.

Cash and Cash Equivalents

Cash represents cash deposits held at financial institutions. The Company considers all liquid investments purchased with an original maturity of three months or less and that can be liquidated without prior notice or penalty to be cash equivalents. The carrying value of cash equivalents approximates their fair value due to the short-term maturities of these instruments. Cash equivalents are held for the purpose of meeting short-term liquidity requirements, rather than for investment purposes. The Company had \$9.2 million and \$0 cash equivalents at December 31, 2020 and 2019, respectively.

Fair Value Measurements

Financial assets and liabilities are recorded at fair value.

The Company measures the fair value of certain of its financial instruments on a recurring basis. A fair value hierarchy is used to rank the quality and reliability of the information used to determine fair values. Financial assets and liabilities carried at fair value will be classified and disclosed in one of the following three categories:

Level 1—Quoted prices (unadjusted) in active markets for identical assets and liabilities.

Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as unadjusted quoted prices for similar assets and liabilities, unadjusted quoted prices in the markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

There have been no transfers of assets for liabilities between these fair value measurement classifications during the periods presented.

The Company had no financial instruments, assets or liabilities measured at fair value on a recurring basis at December 31, 2020 and 2019.

Concentration of Credit Risk and Other Risks and Uncertainties

As of December 31, 2020 and 2019, all of the Company's long-lived assets were located in the United States.

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

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

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

Our facilities and equipment, including those of our suppliers and vendors, may be affected by natural or man-made disasters. Our administrative office is based in Irvine, California and we manage all our research and development activities through third parties that are located throughout the world. We have taken precautions to safeguard our facilities, equipment and systems, including insurance, health and safety protocols, and off-site storage of computer data. However, our facilities and systems, as well as those of our third-party suppliers and vendors, may be vulnerable to earthquakes, fire, storm, health emergencies, including the ongoing COVID-19 pandemic, 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.

Business Combinations

Accounting for acquisitions requires extensive use of estimates and judgment to measure the fair value of the identifiable tangible and intangible assets acquired, including in-process research and development (“IPR&D”) and liabilities assumed. Additionally, the Company must determine whether an acquired entity is considered a business or a set of net assets because the excess of the purchase price over the fair value of net assets acquired can only be recognized as goodwill in a business combination. The Company accounted for the acquisition of Anelixis as a business combination under the acquisition method of accounting. Consideration paid to acquire Anelixis was measured at fair value and included the exchange of Anelixis’ common stock. The allocation of the purchase price resulted in recognition of intangible assets related to goodwill and IPR&D. Acquired IPR&D is recognized at fair value and initially characterized as an indefinite-lived intangible asset, irrespective of whether the acquired IPR&D has an alternative future use. The operating activity for Anelixis, the acquiree for accounting purposes, was immediately integrated with Eledon post-acquisition, therefore it is not practical to segregate results of operations related specifically to Anelixis since the date of acquisition.

During the measurement period, which extends no later than one year from the acquisition date, the Company may record certain adjustments to the carrying value of the assets acquired and liabilities assumed with the corresponding offset to goodwill. After the measurement period, all adjustments are recorded in the consolidated statements of operations as operating expenses or income.

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.

Goodwill

Goodwill represents the difference between the consideration transferred and the fair value of the net assets acquired under the acquisition method of accounting. Goodwill is not amortized but is evaluated for impairment as of October 1 of each year or if indicators of impairment exist that would, more likely than not, reduce the fair value from its carrying amount.

The Company performs its goodwill impairment analysis at the reporting unit level, which aligns with the Company’s reporting structure and availability of discrete financial information. The Company performs its annual impairment analysis by either comparing the reporting unit’s estimated fair value to its carrying amount or doing a qualitative assessment of a reporting unit’s fair value from the last quantitative assessment to determine if there is potential impairment. The Company may do a qualitative assessment when the results of the previous quantitative test indicated the reporting unit’s estimated fair value was significantly in excess of the carrying value of its net assets and it does not believe there have been significant changes in the reporting unit’s operations that would significantly decrease its estimated fair value or significantly increase its net assets. If a quantitative assessment is performed the evaluation includes management estimates of cash flow projections based on internal future projections and/or use of a market approach by looking at market values of comparable companies. Key assumptions for these projections include revenue growth, future gross and operating margin growth, and its weighted cost of capital and terminal growth rates. The revenue and margin growth is based on increased sales of new products as the Company maintains investments in research and development. Additional assumed value creators may include increased efficiencies from capital spending. The resulting cash flows are discounted using a weighted average cost of capital. Operating mechanisms and requirements to ensure that growth and efficiency assumptions will ultimately be

realized are also considered in the evaluation, including timing and probability of regulatory approvals for Company products to be commercialized. The Company's market capitalization is also considered as a part of its analysis.

The Company's annual evaluation for impairment of goodwill consists of one reporting unit. In accordance with the Company's policy, the Company completed its annual evaluation for impairment as of October 1, 2020 using the qualitative assessment and determined that no impairment existed. However, since the acquisition of Anelixis was only 16 days prior to the goodwill impairment test date, the Company did not expect, and did not observe, any indicators of impairment of goodwill at September 30, 2020 and deemed it appropriate to update its analysis as of December 31, 2020 to ensure that the status had not changed over the three month period. It was determined that no impairment existed as of December 31, 2020. Due to declining market conditions in 2019, the Company performed an additional goodwill impairment test as of December 31, 2019 and determined that the fair value of its goodwill was below its carrying value. As a result, the Company recognized \$1.9 million of goodwill impairment which was included in the consolidated statement of operations for the year ended December 31, 2019. No impairment was recorded for the year ended December 31, 2020.

Long-Lived Assets

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over the estimated useful lives of the respective assets. Additions, major renewals and improvements are capitalized and repair and maintenance costs are charged to expense as incurred. Leasehold improvements are amortized over the remaining life of the initial lease term or the estimated useful lives of the assets, whichever is shorter.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated future undiscounted cash flows relating to the asset are less than its carrying amount. An impairment loss is measured as the amount by which the carrying amount of an asset exceeds its fair value. Significant management judgment is required in the forecast of future operating results that are used in the preparation of expected cash flows. No impairments of long-lived assets have been identified during the years presented.

In-Process Research and Development

The fair value of IPR&D acquired through a business combination is capitalized as an indefinite-lived intangible asset until the completion or abandonment of the related research and development activities. When the related research and development is completed, the asset will be assigned a useful life and amortized.

The fair value of an IPR&D intangible asset is determined using the replacement cost method. This method involves arriving at an asset's value by reference to the present-day cost, in an arms-length transaction, of replacing that asset with a similar asset in a similar condition.

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's contracts with third parties to perform various clinical trial activities in the on-going development of potential products. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows to its vendors. Payments under the contracts depend on factors such as the achievement of certain events, successful enrollment of patients, and completion of portions of the clinical trial or similar conditions. The Company's accrual for clinical trials is based on estimates of the services received and efforts expended pursuant to contracts with clinical trial centers and clinical research organizations. These contracts may be terminated by the Company upon written notice and the Company is generally only liable for actual effort expended by the organizations to the date of termination, although in certain instances the Company may be further responsible for termination fees and penalties. The Company estimates its research and development expenses and the related accrual as of each balance sheet date based on the

facts and circumstances known to the Company at that time. There have been no material adjustments to the Company's prior period accrued estimates for clinical trial activities through December 31, 2020.

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, and stock options and warrants are considered to be potentially dilutive securities and are excluded from the calculation of diluted net loss per share because their effect would be anti-dilutive. Therefore, basic and diluted net loss per share was the same for the periods presented due to the Company's net loss position.

	Year Ended December 31,	
	2020	2019
	(In thousands, except share and per share data)	
Net loss	\$ (22,811)	\$ (16,011)
Net loss per share, basic and diluted	<u>\$ (15.72)</u>	<u>\$ (24.42)</u>
Weighted-average number of common shares	<u>1,451,432</u>	<u>655,526</u>

The computation of diluted earnings per share excludes stock options, warrants, and restricted stock units that are anti-dilutive. For the year ended December 31, 2020, common share equivalents of 3,959,302 shares were anti-dilutive. For the year ended December 31, 2019, common share equivalents of 487,275 shares were anti-dilutive.

Stock-Based Compensation

For stock options granted to employees and directors, the Company recognizes compensation expense for all stock-based awards based on the grant-date estimated fair value. The fair value of stock options is determined using the Black-Scholes option pricing model, using assumptions which are subjective and require significant judgment and estimation by management. The risk-free rate assumption was based on observed yields from governmental zero-coupon bonds with an equivalent term. The expected volatility assumption was based on historical volatilities of a group of comparable industry companies whose share prices are publicly available. The peer group was developed based on companies in the pharmaceutical industry. The expected term of stock options represents the weighted-average period that the stock options are expected to be outstanding. Because the Company does not have historical exercise behavior, the Company determined the expected life assumption using the simplified method for stock options granted to employees, which is an average of the options ordinary vesting period and the contractual term. For stock options granted to the 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 Stock Incentive Plan (the "2014 Plan") and 7,204 shares issuable under the 2014 Employee Stock Purchase Plan (the "ESPP").

On December 18, 2020, the Company held 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 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 4,167,044 and 24,077 shares, respectively, as of December 31, 2020.

Stock-based compensation expense related to stock options granted to nonemployees is recognized based on the estimated fair value of the stock options on their grant date, determined using the Black-Scholes option pricing model. The awards generally vest over the period the Company expects to receive services from the nonemployees. Similar to stock options granted to employees, the fair value of stock options granted to nonemployees, is determined using the Black-Scholes option pricing model, involves 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 on stock options granted to nonemployees, the Company determined the contractual term is the appropriate period for expected life on stock options granted to nonemployees. 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.

Income Taxes

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. We assess the likelihood that deferred tax assets will be recovered as deductions from future taxable income. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. We have provided a valuation allowance on our deferred tax assets as of December 31, 2020 and 2019 because we believe it is more likely than not that a majority of our deferred tax assets will not be realized as of this date.

The Company evaluates the accounting for uncertainty in income tax recognized in its consolidated financial statements and determines whether it is more likely than not that a tax position will be sustained upon examination by the appropriate taxing authorities before any part of the benefit is recorded in its consolidated financial statements. For those tax positions where it is "not more likely than not" that a tax benefit will be sustained, no tax benefit is recognized. Where applicable, associated interest and penalties are also recorded. The Company has not accrued any liabilities for any such uncertain tax positions as of December 31, 2020 and 2019. The Company is subject to U.S. federal and state tax authority examinations for all the years since inception due to net operating loss and tax credit carryforwards. The net operating losses and tax credits are subject to adjustment until the statute closes on the year the attributes are ultimately utilized.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known. For additional information, see Note 7, *Income Taxes* in the notes to the consolidated financial statements.

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 consolidated financial statements or disclosures.

Note 3. Prepaid Expenses, Other Assets, Accrued Expenses and Other Liabilities

Prepaid expenses and other current assets consisted of the following as of December 31, 2020 and 2019 (in thousands):

	As of December 31,	
	2020	2019
Prepaid insurance	\$ 1,157	\$ 734
Prepaid clinical	89	102
Prepaid other	41	45
Insurance receivable	110	245
Other current assets	38	54
Total prepaid expenses and other current assets	<u>\$ 1,435</u>	<u>\$ 1,180</u>

Accrued expenses and other liabilities consisted of the following as of December 31, 2020 and 2019 (in thousands):

	As of December 31,	
	2020	2019
Accrued compensation and related expenses	\$ 31	\$ 40
Accrued clinical	258	437
Accrued professional services	9	130
Accrued vacation	67	199
Accrued costs associated with PIPE financing	450	—
Accrued other	146	7
Total accrued expenses and other liabilities	<u>\$ 961</u>	<u>\$ 813</u>

Note 4. Goodwill

On September 14, 2020, the Company acquired Anelixis (see Note 10).

The changes in the carrying amount of goodwill consisted of the following for the years ended December 31, 2020 and 2019 (in thousands):

	Total
Balance as of January 1, 2019	\$ 1,867
Impairments	<u>(1,867)</u>
Balance as of December 31, 2019	—
Acquisition of Anelixis	48,648
Balance as of December 31, 2020	<u>\$ 48,648</u>

The Company performed a goodwill impairment test as of December 31, 2019 and determined that the fair value of its goodwill was below its carrying value. As a result, the Company recognized \$1.9 million of goodwill impairment. No impairment was recorded for the year ended December 31, 2020.

Note 5. Commitments and Contingencies

Operating Leases

The Company leases office space under various operating leases. Total rent expense for all operating leases in the consolidated statements of operations and comprehensive loss was approximately \$207,000 and \$188,000 for the years ended December 31, 2020 and 2019, 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 consolidated balance sheet.

The Company determines if a contract contains a lease at inception. Our office leases have a remaining term ranging from nine months to one year 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 consolidated balance sheet.

The components of lease expense were as follows:

	<u>For the Year Ended December 31, 2020</u>
Operating lease cost ^(a)	\$ 195

(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):

	<u>For the Year Ended December 31, 2020</u>
Supplemental Cash Flows Information	
Cash paid for amounts included in the measurement of lease liability:	
Operating cash flows from operating lease	\$ 188
Operating lease asset obtained in exchange for lease liability:	
Operating lease	\$ —
Remaining lease term	
Operating lease	0.75 years
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 succeeding fiscal year and thereafter (in thousands):

Year ending	
2021	146
Total minimum lease payments	146
Less imputed interest	(2)
Present value of lease liabilities	144
Less current portion	(144)
	\$ -

Future payments under short term leases with an initial term of 12 months or less total approximately \$33,000 for 2021.

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 2020 and 2019.

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 as royalties from sales of the products developed by the Company from their 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 had not yet generated sales as of December 31, 2020; therefore, no liability was recorded for the repayment in the accompanying 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 it 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 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 intellectual property and will be the sole owner of improvements. Under the agreement with the Licensors, the Company paid license fees totaling \$750,000 and issued 9,780 common shares to the Licensors, which was expensed to research and development during the year ended December 31, 2015.

In December 2015, the Licensors completed transfer of all technology, including the active IND application 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 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, which is included in research and development expenses in 2019. There were no other milestones achieved during the years ended December 31, 2020 or 2019.

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, enter 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 December 31, 2020 and 2019.

Note 6. Income Taxes

Loss before income taxes are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Losses before income taxes:		
U.S.	\$ (23,408)	\$ (16,174)
Non-U.S.	193	163
Total	<u>\$ (23,215)</u>	<u>\$ (16,011)</u>

The provision (benefit) for income taxes are as follows (in thousands):

	Year Ended December 31,	
	2020	2019
Current:		
Federal	\$ —	\$ —
State	—	—
Foreign	—	—
	—	—
Deferred:		
Federal	(404)	—
State	—	—
Foreign	—	—
	(404)	—
Provision (benefit) for income taxes	\$ (404)	\$ —

The Company is subject to income taxes under U.S. tax laws. The Company is subject to an Israeli corporate tax rate of 23% in 2020 and thereafter. The Company was subject to a blended U.S. tax rate (federal as well as state corporate tax) of 21% in 2019 and 2020.

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting.

Based on its review, the Company concluded that it was more likely than not that they would not realize the benefit of a portion of its deferred tax assets in the future. This conclusion was based on historical and projected operating performance, as well as the Company's expectation that its operations will not generate sufficient taxable income in future periods to realize the tax benefits associated with the deferred tax assets within the statutory carryover periods. Therefore, the Company has a valuation allowance on its deferred tax assets as of December 31, 2020.

The Company will continue to assess the need for a valuation allowance on its deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2020	2019
Statutory Federal income tax rate	\$ (4,875)	\$ (3,362)
Tax credits	(215)	(207)
Change in warrant fair market value	1,014	—
Stock-based compensation	252	141
Goodwill impairment	—	392
Permanent items	627	4
Section 382 limitation on net operating losses and credits	10,562	—
Other	89	38
Change in valuation allowance	(7,858)	2,994
Total provision (benefit) for income taxes	\$ (404)	\$ —

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2020 and 2019 consisted of the following (in thousands):

	Year Ended December 31,	
	2020	2019
Net operating loss carryforwards	\$ 5,151	\$ 9,947
Research and development tax credits	705	506
Accruals and reserves	14	43
Stock compensation	802	391
Depreciation and amortization	1,905	116
Lease liability	30	68
Total deferred tax assets	8,607	11,071
Right-of-use asset	(29)	(66)
Acquired IPR&D	(6,801)	—
Total deferred tax liabilities	(6,830)	(66)
Less: valuation allowance	(5,883)	(11,005)
Net deferred tax liabilities	<u><u>\$ (4,106)</u></u>	<u><u>\$ —</u></u>

The following table reconciles the beginning and ending amounts of unrecognized tax benefits for the years presented (in thousands):

	Year Ended December 31,	
	2020	2019
Gross unrecognized tax benefits at the beginning of the year	\$ 548	\$ 328
Additions from tax positions taken in the current year	233	214
Additions from tax positions taken in prior years	531	6
Reductions from tax positions taken in prior years	(548)	—
Tax settlements	—	—
Gross unrecognized tax benefits at the end of the year	<u><u>\$ 764</u></u>	<u><u>\$ 548</u></u>

The deferred income tax assets have been offset by a valuation allowance, as realization is dependent on future earnings, if any, the timing and amount of which are uncertain. The net valuation allowance decreased by \$5.1 million.

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood, and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At present, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a valuation allowance has been established.

As of December 31, 2020 and 2019, the Company had federal net operating loss carryforwards of approximately \$14.4 million and \$38.6 million, respectively, available to reduce future taxable income. As of December 31, 2020 and 2019, the Company also has state net operating loss carryforwards of \$6.2 million and \$0.9 million, respectively. The federal net operating loss carryforwards incurred before 2018 begin expiring in 2035 if not utilized. The federal net operating losses incurred since 2018 of \$13.6 million do not expire. The state net operating losses begin to expire in 2035. As of December 31, 2020 and 2019, the Company had Israeli net operating losses of \$7.9 million and \$8.0 million, respectively, which carryforward indefinitely.

As of December 31, 2020 and 2019, the Company had federal research and development tax credit carryforwards of approximately \$966,000 and \$764,000, respectively. If not utilized, the carryforwards will begin expiring in 2035. As of December 31, 2020 and 2019, the Company has state research and development credit carryforwards of approximately \$562,000 and \$264,000, respectively, which will begin expiring in 2030 if not utilized.

Pursuant to Internal Revenue Code (“IRC) Sections 382 and 383, annual use of the Company’s net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. As part of the equity raise and acquisition, the Company had an IRC Section 382/383 ownership change during 2020. The Company has removed \$10.6 million of deferred tax assets related to NOL and R&D credit carryforwards due to the Section 382 limitations. The Company’s ability to use its remaining net operating loss and tax credit carryforwards may be further limited if the Company experiences additional Section 382 ownership change in connection with future changes in the Company’s stock ownership.

In the United States, the Company files income tax returns in the U.S. Federal jurisdiction, California and Massachusetts. The Company’s tax years for 2017 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The Company’s policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. There was no accrued interest and penalties associated with uncertain tax positions as of December 31, 2020 and 2019. The Company has not recorded any interest or penalties in 2020 or 2019.

Note 7. 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, 2019, 1,401 shares were sold under the 2018 Prospectus for gross proceeds of approximately \$110,000. No shares were sold during the year ended December 31, 2020.

2019 Equity Offering

On April 30, 2019, the Company agreed to sell in a registered direct offering, an aggregate 191,617 shares of its common stock to certain investors for gross proceeds of approximately \$10.7 million under its effective shelf registration statement on Form S-3 (File No. 333-226286). In a concurrent private placement, the Company also agreed to issue to such investors Series A warrants to purchase up to 191,617 shares of its common stock at an exercise price of \$72.00 with a term of eighteen months and Series B warrants to purchase up to 191,617 shares of its common stock at an exercise price of \$72.00 with a term of five years. The Series B warrants become exercisable only upon the exercise of the Series A warrants. In addition, the Company agreed to issue placement agent warrants to purchase up to 9,580 shares of common stock representing 5.0% of the aggregate number of shares of common stock sold in this offering. The placement agent warrants have substantially the same terms as the Series A Warrants, except that the placement agent warrants will have an exercise price equal to \$69.66 and will expire on April 30, 2024. We refer to the registered direct offering and the concurrent private placement collectively as the “2019 Equity Offering”.

All the warrants issued in connection with the 2019 Equity Offering contained put options that allow the holders of the warrants the right to receive, for each warrant share that would have been issuable upon an exercise immediately prior to the occurrence of an effective change in control event defined as a fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock for which this warrant is exercisable immediately prior to such fundamental transaction. The Company evaluated the embedded put option contained in the warrants under the guidance of Accounting Standards Codification (“ASC”) 815, *Derivatives and Hedging*, and concluded that the requirements for contingent exercise provisions as well as the settlement provision for scope exception in ASC 815-10-15-74 has been met. Accordingly, the put options contained in the warrants were not bi-furcated and accounted for as freestanding derivative instruments.

Warrant Exercise Transactions

On January 10, 2020 and January 15, 2020, the Company entered into warrant exercise agreements (the “Exercise Agreements”) with the holders (the “Holders”) of its Series A Warrants and Series B Warrants (collectively, the “Warrants”), issued in the 2019 Equity Offering, pursuant to which the Holders agreed to exercise in cash their Warrants to purchase an

aggregate of 383,234 shares of the Company's common stock at a reduced exercise price of \$12.87 per share, plus an additional \$2.25 per share for the issuance of the private placement warrants for gross proceeds (before placement agent fees and expenses) to the Company of approximately \$5.8 million (the "Exercise Transaction").

Under the Exercise Agreements, the Company also agreed to issue to the Holders new warrants to purchase up to 383,235 shares of the Company's common stock at an exercise price of \$12.96 per share, with an exercise period of five and a half years (the "Private Placement Warrants"). The Private Placement Warrants transaction subsequently closed and the Private Placement Warrants were issued on January 14, 2020 with respect to the Warrants exercised on January 10, 2020 and on or about January 17, 2020, with respect to the Warrants exercised on January 15, 2020. In addition, the Company agreed to issue to the placement agent warrants to purchase up to 19,162 shares of common stock, representing 5.0% of the aggregate number of shares of common stock issued in the Exercise Transaction. The placement agent warrants have substantially the same terms as the Private Placement Warrants issued to the Holders, except that the placement agent warrants have an exercise price equal to \$18.90. A warrant inducement expense of \$4.8 million was recorded which was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the Warrants prior to, and immediately after, the reduction in the exercise price on the date of repricing in addition to the fair value of the Private Placement Warrants issued.

For the year ended December 31, 2020, the Holders exercised approximately 64,171 Private Placement Warrants in a cashless exchange for 28,553 shares of the Company's common stock. Additionally, approximately 9,985 private placement warrants were exercised for 9,985 shares of the Company's common stock for gross proceeds of \$188,773.

As of December 31, 2020, 337,822 warrants were exercisable into common stock. The shares of common stock underlying the registered direct and private placement 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 Forms S-1.

The following table shows the warrant activity:

	Rollforward of Warrant Activity					
	Registered direct warrants, series A	Registered direct warrants, series B	Registered direct warrants, placement agent	Private placement warrants	Private placement warrants, placement agent	Total
Balance as of December 31, 2019	191,617	191,617	9,581	—	—	392,8
Issued	—	—	—	383,235	19,162	402,3
Exercised	(191,617)	(191,617)	—	(64,171)	(9,985)	(457,3)
Cancelled/Expired	—	—	—	—	—	—
Balance as of December 31, 2020	—	—	9,581	319,064	9,177	337,8

Anelixis Acquisition

On September 14, 2020, the Company acquired Anelixis, after which Anelixis became a wholly-owned subsidiary of the Company. Under the terms of the acquisition, the Company issued to the stockholders of Anelixis 175,488 shares of Company common stock and 140,026 shares of Series X1 Preferred Stock. In addition to the common stock and preferred stock issued in connection with the acquisition of Anelixis, certain outstanding warrants issued by Anelixis were not settled upon completion of the acquisition, and instead were assumed and then replaced with Company warrants. As part of the acquisition, the Company assumed and replaced options for the purchase of 1,346,398 shares of common stock with an estimated total fair value of approximately \$6.0 million and 55,583.875 warrants for Series X1 Preferred Stock with an estimated fair value of approximately \$12.9 million. The estimated fair value of the assumed and replaced options and warrants attributed to pre-merger services were approximately \$3.0 million and \$12.9 million, respectively, and is included in other consideration amounts transferred and added to goodwill (see Note 10).

On December 18, 2020, at the Special Meeting, 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 such, the shares of Series X1 Preferred Stock underlying the assumed and replaced warrants in connection with the Anelixis acquisition were converted into shares of Eledon common stock.

As of December 31, 2020, 55,853.875 warrants were exercisable into Series X1 Preferred 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, 2019	—	—
Assumed and replaced	55,583.875	55,583.875
Exercised	—	—
Cancelled/Expired	—	—
Balance as of December 31, 2020	<u>55,583.875</u>	<u>55,583.875</u>

Common Stock Exchange Agreement

On February 13, 2020, the Company entered into an exchange agreement (the "Exchange Agreement") with Biotechnology Value Fund, L.P., Biotechnology Value Fund II, L.P. and Biotechnology Value Trading Fund OS, L.P. (the "Exchanging Stockholders"), pursuant to which the Exchanging Stockholders exchanged (the "Exchange") 210,888 shares of the Company's common stock for 3,796 shares of newly designated Series X Convertible Preferred Stock (the "Series X Preferred Stock"). The Company agreed to reimburse the Exchanging Stockholders for their expenses in connection with the Exchange up to a total of \$25,000, which was recorded as operating expense in the Company's condensed consolidated statements of operations and comprehensive loss. The Exchange was completed on February 19, 2020.

On February 13, 2020, in connection with the Exchange, the Company filed a Certificate of Designation setting forth the preferences, rights and limitations of the Series X Preferred Stock with the Secretary of State of the State of Delaware. The number of shares so designated shall be 10,000 and Series X Preferred Stock shall have a par value of \$0.001 per share. Each share of Series X Preferred Stock will be convertible into 55.5556 shares of common stock at the option of the holder at any time; subject to certain limitations, including, that the holder will be prohibited from converting Series X Preferred Stock into common stock if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock. In the event of the Company's liquidation, dissolution or winding up, holders of Series X Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock. Holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal (on an as-if-converted-to-common stock basis) to and in the same form as dividends actually paid on the common stock or other junior securities of the Company. Shares of Series X Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series X Preferred Stock will be required to amend the terms of the Series X Preferred Stock.

SEC Accounting Series Release No. 268, *Presentation in Financial Statements of "Redeemable Preferred Stocks"* ("ASR 268") requires equity instruments with redemption features that are not solely within the control of the issuer to be classified outside of permanent equity, often referred to as classification in "temporary equity"). The Company evaluated Series X Preferred Stock redemption features and concluded that there are no redemption features with the Series X Preferred Stock that are not solely within the control of the Company and permanent equity classification was appropriate. Series X Preferred Stock has two (2) separate and distinct embedded features. They are: (1) optional conversion by holder and (2) redemption put feature upon fundamental transaction.

Each share of Series X Preferred Stock shall be convertible into 55.5556 shares of common stock, at the option of the holder, at any time after the date of issuance. The Company evaluated the embedded optional conversion feature in accordance with the guidance under ASC 815, *Derivatives and Hedging*, and determined it is exempt from derivative accounting as the embedded feature is deemed to be indexed to the Company's own stock and classified in stockholder's equity if freestanding. Further, because the conversion ratio is fixed and equal to the ratio of the original exchange of 55.5556 common stock to each share of Series X Preferred Stock, the Company concluded that there is no intrinsic value to the beneficial conversion feature.

Each share of Series X Preferred Stock contains redemption put features that allow the holders of the Series X Preferred Stock the right to receive, in lieu of the right to receive conversion shares, for each conversion share that would have been issuable upon such conversion immediately prior to the occurrence of an effective change in control ("Fundamental Transaction"), the same kind and amount of securities, cash or property as it would have been entitled to receive upon the occurrence of such Fundamental Transaction if it had been, immediately prior to such Fundamental Transaction, the holder of one share of common stock. The Company evaluated the redemption put feature contained in each Series X Preferred Stock under the guidance of ASC 815, *Derivatives and Hedging*, and concluded that the embedded redemption put feature do not meet the definition of a derivative, if freestanding, under ASC 815 as net settlement could not be achieved. Accordingly, the redemption put features contained in the Series X Preferred Stock were not bifurcated and accounted for as freestanding derivative instruments.

On June 1, 2020 and June 10, 2020, the Exchanging Stockholders converted a total of 3,285 shares of Series X Preferred Stock into 182,500 shares of common stock. On December 18, 2020, at the Special Meeting, the Company's stockholders approved the issuance of the Company's common stock, upon conversion of the Company's remaining 511 shares of Series X Preferred Stock, par value \$0.001 per share. As of December 31, 2020, no shares of Series X Preferred Stock remain outstanding.

September 2020 Stock Purchase Agreement

On September 14, 2020, Eledon entered into the Purchase Agreement with the Investors. Pursuant to the Purchase Agreement, Novus 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, or net proceeds of approximately \$95.2 million after deducting offering costs, in 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 X¹ Preferred Stock and the effective registration of its common stock. Subject to stockholder approval, each share of Series X¹ Preferred Stock is convertible into 55.5556 shares of Common Stock, as described below. 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. The Financing is exempt from registration pursuant to Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder, as a transaction by an issuer not involving a public offering. The Investors have acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends have been affixed to the securities issued in this transaction.

The Company records shares of preferred stock at their respective fair values on the dates of issuance, net of issuance costs. Holders of Series X¹ Preferred Stock do not have voting rights and are entitled to receive dividends on shares of X¹ Preferred Stock on an as-if converted to common stock basis equal to dividends actually paid on shares of common stock. The shares of Series X¹ Preferred Stock shall automatically be converted into shares of common stock equal to the conversion ratio of 55.5556 upon stockholder approval of the conversion of the Series X¹ Preferred Stock into shares of common stock in accordance with the listing rules of the Nasdaq Stock Market.

The Company applied the guidance in ASC 480-10-S99-3A, SEC Staff Announcement: Classification and Measurement of Redeemable Securities, and classified the Series X¹ Preferred Stock outside of stockholders' equity for the period prior to the shareholder approval of the conversion to common stock because the Series X¹ Preferred Stock will be redeemable at the option of the holders for cash equal to the closing price of the common stock on the last trading day prior to the holder's redemption request, if there was no shareholder approval.

The Company analyzed the conversion provision related to the Series X¹ Preferred Stock and determined there was not a contingent beneficial conversion feature ("BCF") that would be recognized when the contingency of stockholder approval is resolved.

On December 18, 2020, the Company held a Special Meeting. At the Special Meeting, 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, 231,068 shares of Series X1 Preferred Stock were converted into 12,837,056 shares of the Company's common stock. As of December 31, 2020, 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.

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 will have 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).

Note 8. Stock-Based Compensation

The Company has three stock compensation plans, the 2020 Stock Incentive Plan (the "2020 Plan"), the 2014 Stock Incentive Plan (the "2014 Plan") and the 2007 Stock Incentive Plan (the "2007 Plan"). The 2020 Plan permits the Company to make grants of incentive stock options, non-statutory stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards to the Company's employees, officers, directors, consultants and advisors; however, incentive stock options may only be granted to the Company's employees. The number of shares initially reserved for issuance under the 2020 Plan was 4,860,000 shares of common 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. Options remain outstanding under the 2007, 2014 and the 2020 Plan. The number of shares subject to and the exercise prices applicable to these outstanding options were adjusted in connection with the one-for-eighteen reverse stock-split. As of December 31, 2020, there were 1,151 and 126,974 options outstanding under the 2007 Plan and 2014 Plan, respectively. Options granted under the 2007, 2014 and 2020 Plans generally expire ten years from the date of grant. The Company intends for the 2020 Plan to be its primary stock compensation plan in the future. As of December 31, 2020, there were 692,956 options outstanding and 4,167,044 shares available to issue under the 2020 Plan.

Stock Option and PRSU Activity

As of December 31, 2020, a total of 4,167,044 stock awards were available for grant under the 2020 Plan. The 2014 Plan was closed to new grants following the approval of the 2020 Plan, and therefore, there were no shares reserved for issuance under the 2014 Plan as of December 31, 2020.

The following table shows the stock option activity, as follows:

	<u>Shares Issuable Under Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (In years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding as of January 1, 2019	49,798	\$ 233.45	8.1	\$ —
Granted	42,244	28.87		
Exercised	—	—		
Forfeited / Canceled	(639)	79.38		
Outstanding as of December 31, 2019	91,403	139.96	8.2	\$ —
Granted	2,191,462	9.15		
Options assumed in connection with acquisition	1,346,398	7.58		
Exercised	—	—		
Forfeited / Canceled	(7,784)	586.16		
Outstanding as of December 31, 2020	<u>3,621,479</u>	\$ 10.63	8.9	\$ 23,938,701
Options vested and expected to vest as of December 31, 2020	3,621,479	\$ 15.21	8.9	\$ 23,938,701
Options exercisable as of December 31, 2020	878,033	\$ 16.00	8.2	\$ 6,297,510

The following table shows the PRSU activity, as follows:

	<u>Shares Issuable Under PRSUs</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term (In years)</u>	<u>Aggregate Intrinsic Value</u>
Outstanding as of January 1, 2019	4,358	\$ 86.94	9.2	\$ —
Granted	3,056	66.96		
PRSUs Vested	(4,358)	86.94		
Forfeited / Canceled	—	—		
Outstanding as of December 31, 2019	<u>3,056</u>	<u>66.96</u>	<u>9.2</u>	<u>\$ —</u>
Granted	—	—		
PRSUs Vested	(3,056)	66.96		
Forfeited / Canceled	—	—		
Outstanding as of December 31, 2020	<u>—</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
PRSUs vested and expected to vest as of December 31, 2020	—	\$ —	\$ —	\$ —
Options exercisable as of December 31, 2020	—	\$ —	\$ —	\$ —

As of December 31, 2020, the range of exercise prices was between \$0.96 and \$2,147 for options outstanding.

Intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that had exercise prices that were lower than the fair value per share of the common stock on the date of exercise. There was no aggregate intrinsic value of options exercised during the years ended December 31, 2020 and 2019.

As of December 31, 2020, total unrecognized stock-based compensation expense related to non-vested equity awards was \$17.1 million, which is expected to be recognized over an estimated weighted-average period of 2.7 years.

Stock-based Compensation Expense

Total compensation expense related to all of the Company's stock-based awards for the years ended December 31, 2020 and 2019 was comprised of the following (in thousands):

	Year Ended December 31,	
	2020	2019
Stock-based compensation classified as:		
Research and development expense	\$ 1,254	\$ 343
General and administrative expense	1,917	965
Total stock-based compensation expense	\$ 3,171	\$ 1,308

Stock-based compensation expense for the year ended December 31, 2020 included no stock-based compensation expense related to performance-based options granted during 2020.

During the year ended December 31, 2020, PRSUs awarded to employees totaling 3,059 shares vested and resulted in the recognition of \$205,000 in stock-based compensation expense.

Valuation Assumptions

The following table presents the assumptions used in the Black-Scholes option pricing model to determine the fair value of stock options granted in the periods presented, as follows:

	Year Ended December 31,	
	2020	2019
Expected stock price volatility	77% - 107%	74% - 87%
Risk-free interest rate	0% - 1%	1% - 3%
Expected life of option (in years)	4 - 6	6
Estimated dividend yield	0%	0%

Note 9. Restructuring Expense

On June 11, 2020, following the announcement regarding the topline results from the phase 2a clinical trial of OP0201, Eledon announced that its board of directors approved a plan to reduce the size of its workforce. The workforce reduction, which was completed in June 2020, was designed to reduce the Company's operating expenses while it is conducting a review of development and strategic alternatives.

On September 3, 2020, the board of directors (the "Board") of the Company accepted the resignation of Gregory Flesher as the Company's Chief Executive Officer and a member of the Board. Mr. Flesher's resignation was effective as of the close of business on September 4, 2020. The resignation of Mr. Flesher was not the result of any dispute or disagreement with the Company on any matter relating to the Company's operations, policies or practices. Concurrent with his resignation, Mr. Flesher entered into a consulting agreement with the Company pursuant to which he will provide consulting and transition-support services as requested by the Company at an hourly rate consistent with his target compensation.

For the year ended December 31, 2020, Eledon incurred \$2.3 million in expenses related to the workforce reduction and expects to pay these amounts in the next six months.

Total liability for restructuring expenses and their utilization are summarized as follows (in thousands):

	For the Year Ended December 31,
	2020
Accrued restructuring charges at beginning of period	\$ —
Charged	2,282
Paid	(2,270)
Accrued restructuring charges at end of period	\$ 12

Note 10. 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.

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 was 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 Novus 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. Eledon had commitments for an additional \$9.0 million in equity financing that was contingent upon the satisfaction of certain incremental closing conditions, including stockholder 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 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 the 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 the purchase price as of the September 14, 2020 acquisition closing date based upon a preliminary 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	(206)
Deferred tax liability	(4,510)
Net identifiable assets acquired	5,776
Goodwill	48,649
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.

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 an external valuation specialist's 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.

The unaudited pro forma combined statement of operations for the years ended December 31, 2020 and 2019 combine the historical statements of operations of Eledon and Anelixis, giving effect to the Merger as if it had occurred on January 1, 2019, the first day of the fiscal year ended December 31, 2019.

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 incurred by the Company or pre-merger Anelixis, which totaled approximately \$3.4 million and were removed from general and administrative expenses in the pro forma calculations below. The unaudited pro forma combined financial information also excludes certain other income and other expense items as part of the acquisition of Anelixis. For the year ended December 31, 2020, a gain of approximately \$655,000 due to the forgiveness of Anelixis debt was removed from pro forma other income. Approximately \$512,000 and \$395,000 was excluded from pro forma other expenses for the years ended December 31, 2020 and 2019, respectively, for interest expenses related to notes that were converted into equity interest in the Company.

	Year Ended December 31,	
	2020	2019
Revenue	\$ 120	\$ 500
Operating expenses		
Research and development	9,489	11,441
General and administrative	8,317	7,585
Restructuring expense	2,282	—
Goodwill impairment	—	1,867
Total operating expenses	<u>20,088</u>	<u>20,893</u>
Loss from operations	(19,968)	(20,393)
Other income (expense), net	79	40
Warrant inducement expense	(4,829)	—
Loss before provision for income taxes	(24,718)	(20,353)
Income tax benefit	404	—
Net loss and other comprehensive loss	<u>\$ (24,314)</u>	<u>\$ (20,353)</u>
Net loss per share, basic and diluted	<u>\$ (15.44)</u>	<u>\$ (24.49)</u>
Weighted-average shares outstanding, basic and diluted	<u>1,574,657</u>	<u>831,014</u>

Actual net loss and other comprehensive loss of Anelixis since September 14, 2020 that is included in our consolidated statement of operations for the year ended December 31, 2020, is approximately \$2.5 million. Anelixis did not recognize any revenue in 2020 since its acquisition by the Company.

Note 11. Subsequent Events

The Company has evaluated events subsequent to December 31, 2020 through the filing date of this Annual Report on Form 10-K. Any material subsequent events that occurred during this time have been properly recognized or disclosed in the consolidated financial statements and accompanying notes.

On March 15, 2021, the Company appointed Paul Little as the Company's Chief Financial Officer. In that role, Mr. Little will also serve as the Company's principal financial officer, replacing Jon Kuwahara in that role. Mr. Kuwahara will continue to serve as the Company's Senior Vice President of Finance and Administration and principal accounting officer.

On March 30, 2021, the Company entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies") to sell shares of the Company's common stock, par value \$0.001 per share, having aggregate sales proceeds of up to \$75,000,000, from time to time, through an "at the market" equity offering program under which Jefferies will act as sales agent.

Under the Sale Agreement, the Company will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Sale Agreement, Jefferies may sell the shares by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or on any other existing trading market for the common stock. The Company and Jefferies may each terminate the Sale Agreement at any time as set forth in the Sale Agreement. Under the terms of the Sale Agreement, the Company may also sell shares to Jefferies acting as principal for Jefferies' own account.

The compensation to Jefferies for sales of the Company's common stock will be an amount equal to 3.0% of the gross proceeds of any shares of common stock sold under the Sale Agreement. The Company has no obligation to sell any shares under the Sale Agreement, and may at any time suspend solicitation and offers under the Sale Agreement.

The shares will be issued pursuant to a shelf registration statement on Form S-3 to be filed with the SEC. No sales may be made under the registration statement until it has been declared effective by the SEC.

The foregoing description of the Sale Agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed herewith as Exhibit 1.1 to this Annual Report on Form 10-K and is incorporated herein by reference.