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

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

For the transition period from to

Commission file number 001-39990

Elicio Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**11-3430072**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
451 D Street, 5th Floor, Boston, Massachusetts	02210
(Address of Principal Executive Offices)	(Zip Code)

(857) 209-0050
Registrant's telephone number, including area code

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01	ELTX	The Nasdaq Global Select 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-(§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the Registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the Registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting stock and non-voting common stock held by non-affiliates of the registrant, based on the closing price of a share of the registrant’s common stock on June 30, 2023 as reported by the Nasdaq Global Select Market on such date, was approximately $47.1 million. Shares of common stock held by each executive officer and director and by each entity affiliated with an executive officer or director have been excluded

from this computation. The determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of shares of the issuer's common stock outstanding as of March 26, 2024, was 10,235,469.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed for its 2024 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Auditor Name: Baker Tilly US, LLP	Auditor Location: Tewksbury, Massachusetts	PCAOB ID: 23

Forward-Looking Statements

This Annual Report on Form 10-K, including the sections titled "Business", "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations", contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Annual Report on Form 10-K other than statements of historical fact, including statements concerning our business strategy and plans, future operating results and financial position, as well as our objectives and expectations for our future operations, are forward-looking statements.

In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "contemplate," "continue," "could," "due," "estimate," "expect," "goal," "intend," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "should," "target," "will," "would," and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our financial condition, including our ability to obtain the funding necessary to advance the development of ELI-002 and any other future product candidates, our ability to continue as a going concern and our cash runway;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- our ability to utilize our platform to develop a pipeline of product candidates to address unmet needs in cancer and infectious disease;
- the timing, progress and results of clinical trials for ELI-002, and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the studies or trials will become available, and research and development programs;
- the timing, scope and likelihood of regulatory filings and approvals, including timing of INDs (as defined below) and U.S. Food and Drug Administration ("FDA") approval of ELI-002 and any future product candidates;
- the timing, scope or likelihood of foreign regulatory filings and approvals;
- our ability to develop and advance current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- the size of the market opportunity for our product candidates, including estimates of the number of patients who suffer from the diseases we are targeting;
- expectations regarding the approval and use of our product candidates in combination with other drugs;
- expectations regarding potential for accelerated approval or other expedited regulatory designation;
- our competitive position and the success of competing therapies that are or may become available;
- our anticipated research and development activities and projected expenditures;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- the extent to which global economic and political developments, including the ongoing conflict between Ukraine and Russia, the conflicts in the Middle East, geopolitical tensions with China, and other geopolitical events, will affect our business operations, clinical trials, or financial condition;
- our expectations regarding other macroeconomic trends;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering ELI-002, other product candidates we may develop, including the

  extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for clinical trials;
- our ability to have manufactured sufficient supplies of drug product for clinical testing and commercialization;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

- our projected financial performance;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our planned operating expenses and capital expenditure requirements; and
- the impact of laws and regulations.

We caution you that the foregoing list may not contain all of the forward-looking statements made in this Annual Report on Form 10-K.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in the "Risk Factors" section in Part I, Item 1A of this Annual Report on Form 10-K. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report on Form 10-K. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this Annual Report on Form 10-K. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into or review of all relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely on these statements.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain drugs, including data regarding the estimated size of those markets, their projected growth rates and the incidence of certain medical conditions. Information that is based on estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

As used in this Annual Report on Form 10-K, unless otherwise stated or the context otherwise indicates, references to "Elicio," the "Company," "we," "our," "us" or similar terms refer to Elicio Therapeutics, Inc. and our wholly owned subsidiaries.

Part I

Item 1. Business

Overview

We are a clinical-stage biotechnology company pioneering the development of immunotherapies for patients with limited treatment options and poor outcomes suffering from cancer and infectious disease. Our proprietary Amphiphile ("AMP") technology is designed to mobilize the body's immune response by preferentially targeting our product candidates to the lymph nodes with the goal of generating a robust T cell response. Recent advances have identified T cell responses as a key component of effective cancer immunotherapy and we believe our AMP technology can generate a robust T cell response that can potentially provide meaningful clinical benefit.

We believe the therapeutic utility of currently approved and development stage immunotherapies are limited in many cases due to their inability to sufficiently localize to lymph nodes and adequately engage with the critical immune cells responsible for stimulating adaptive immunity. Our AMP technology is specifically intended to localize payloads to lymph nodes leading to the generation of a robust T cell response that we believe is critical to generate an anticancer immune response.

We have developed our cancer vaccine product candidates to target biologically validated tumor mutation drivers using known neoantigens. This strategy results in an "off-the-shelf" therapeutic option allowing patients to receive treatment without delay due to manufacturing timelines and costs associated with personalized vaccine approaches.

Our clinical and preclinical pipeline includes the lymph node targeted therapeutic cancer vaccines ELI-002, currently being evaluated in a Phase 2 clinical program, designed to stimulate an immune response against mutant KRAS cancers, ELI-007, currently being evaluated in a preclinical study for the treatment of mutant v-raf murine sarcoma viral oncogene homolog B1 ("BRAF") -driven cancers, and ELI-008, currently being evaluated in a preclinical study for use in the treatment of mutated tumor protein p53 ("TP53") expressing cancers. We believe that each of our cancer vaccine product candidates, if approved, have the potential to improve the lives of patients suffering from solid tumors arising due to specific oncogenic driver mutations.

Our Strategy

We are focused on mobilizing the immune response to defeat cancer and infectious diseases through the development and commercialization of lymph node targeted immunotherapies. Key elements of our strategy are to:

- **Continue advancing ELI-002 through the ongoing randomized Phase 2 trial in pancreatic ductal adenocarcinoma ("PDAC")** . We are initially developing our first product candidate, ELI-002, for the treatment of patients with solid tumors carrying mutated KRAS. By targeting immunotherapy to the lymph nodes and generating a robust and differentiated T cell response, we believe ELI-002 could improve the long-term prognosis and quality of life for patients suffering from solid tumors. We are currently conducting AMPLIFY-7P, a randomized Phase 2 trial to evaluate the efficacy and safety of ELI-002 in patients with PDAC.
- **Expand ELI-002 clinical development for the treatment of other KRAS driven cancers.** Our ongoing Phase 2 trial is in PDAC, but our Phase 1 trials included patients with colorectal cancer and the preliminary safety, immunogenicity and efficacy data were encouraging in both PDAC and CRC patients. In addition to CRC, there are large groups of patients with lung cancer, bile duct and other gastrointestinal cancers driven by KRAS mutations. We are evaluating opportunities to advance ELI-002 in clinical trials for CRC including in collaboration with other organizations.
- **Advance development of our internal pipeline for additional oncology targets.** We have two preclinical programs that employ our AMP technology targeting other key tumor driver mutations, BRAF and TP53. ELI-007, for mutant BRAF-driven cancers, and ELI-008 for mutant TP53-expressing cancers, are AMP immunotherapies targeting biologically validated neoantigens expressed in high proportions of solid tumors. We have received grants to fund the preclinical development of ELI-007 and ELI-008 and will continue to seek collaboration opportunities to advance their development.
- **Realize the full value of the AMP technology through collaborations.** We and others have published several preclinical proof-of-concept applications where our AMP technology has demonstrated meaningful improvements when applied to prophylactic or therapeutic vaccines, CAR-T and TCR-T cell therapies, and

therapies for auto-immune disease. We will look to form collaborations to capitalize on the potential of the technology in these applications.

Overview of Immune System and Cancer Immunotherapy

The immune system is a large network of organs, tissues, white blood cells, proteins and chemicals working together to protect and repair the body from infections, injuries and cellular changes that can result in disease. One component of the immune system is the adaptive immune response which is responsible for mounting highly specific responses to substances deemed to be foreign. The adaptive immune response is carried out by white blood cells including B lymphocytes and T lymphocytes. B lymphocytes ("B cells") are involved in the humoral immune response, differentiating into antibody-secreting plasma cells on activation and recognition of a foreign-specific molecular structure known as an antigen. T lymphocytes ("T cells") participate primarily in the cell-mediated immune response and are capable of specific antigen-directed recognition and elimination of aberrant cells arising from pathogenic infection or genetic transformation. T cells can be further segregated into distinct cell types, with the primary types being CD8+ T cells, which are also referred to as cytotoxic lymphocytes ("CTLs") and CD4+ "helper" T cells. CD8+ T cells specifically recognize and eliminate cells infected with viruses, other pathogens, or cancer-associated mutations. In contrast, CD4+ T cells, which can also exhibit cytotoxic activity, primarily participate in the immune response by directing the activity of other cells, in particular B cells and CD8+ T cells.

The lymphatic system plays a major role in the production, differentiation, and proliferation of both B cells and T cells, and lymph nodes serve a critical role in lymphocytes' activation and acquisition of essential functionality. The lymph nodes act as the "school house" of the adaptive immune response playing an essential role in the generation of B cells and T cells possessing the specificity and functionality required for effective disease modification. Specifically, signaling delivered between immune cells residing in the lymph nodes is critical for the generation of a T cell response with the magnitude, potency, persistence, functionality, specificity, and memory capacity required for an effective cell-mediated immune response.

As cancer is the result of genetic transformation of normal cells resulting in uncontrolled growth, the immune system doesn't always recognize cancer cells as foreign. In addition, cancer cells can adopt mechanisms to evade immune system recognition or defenses rendering the adaptive immune response ineffective. However, researchers have found that immune cells, referred to as tumor-infiltrating lymphocytes ("TILs"), are sometimes found in and around tumors and patients with TILs often have a better prognosis than patients without TILs. Following this observation, immunotherapy has been envisioned as a treatment approach intended to enhance the ability of the immune system to eliminate disease including cancer.

In the last few decades, immunotherapy has become an important part of treating certain cancers. Several approaches to cancer immunotherapy have been attempted all with the goal of eliciting or enhancing an immune response to identify and attack tumor cells. One immunotherapy approach attempted with limited success to date is the development of therapeutic cancer vaccines. Cancer cells often contain tumor-specific antigens, or neoantigens, not present in normal cells that could facilitate the immune system recognition and response to these neoantigens and ultimately, elimination of the cancer cells. In addition, because an adaptive immune response includes a mechanism to create life-long lymphocytes, cancer vaccines may prevent relapse of cancer long after initial treatment.

While general neoantigen-specific immune activity has been demonstrated by previous cancer vaccine efforts, reduction in tumor loads has not been frequently observed resulting in only two FDA-approved cancer vaccines. Researchers investigating this lack of historical cancer vaccine efficacy have suggested a key reason is the limited generation of tumor-specific T cells as well as impaired fitness of the elicited anti-tumor T cells.

We believe improved delivery of immunotherapies to the lymph nodes is required to generate the robust and multifunctional adaptive immune response, specifically T cell responses, needed for therapeutic efficacy. Elicio's AMP technology is designed to deliver therapeutic payloads of interest to lymph nodes.

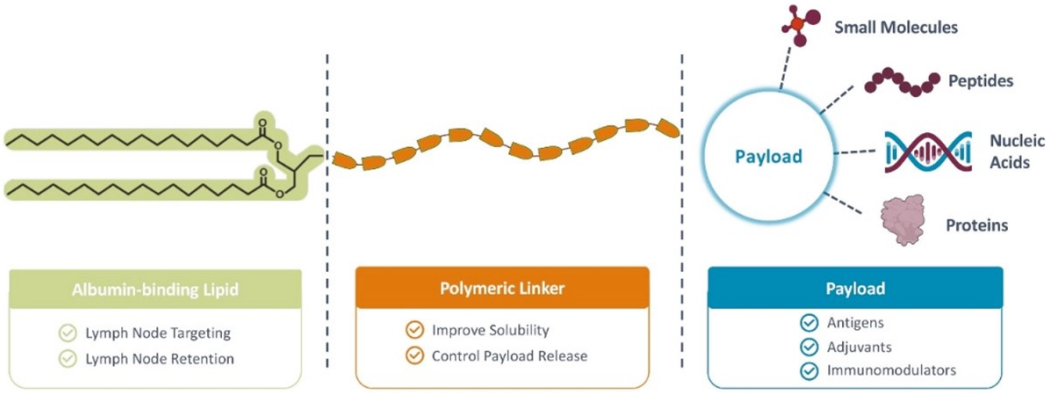
Our Approach

The fundamental underpinning of our innovative approach to induce an immune response capable of meaningful clinical benefit is delivering payloads to lymph nodes. Our AMP technology is designed to rapidly deliver peptides, proteins, nucleic acids and small molecules to lymph nodes through reversible interactions with endogenous albumin. Our AMP technology has been flexibly designed to be manufactured with various peptide lengths and sequences optimizing the localization of the AMP-modified molecules to lymph nodes and the subsequent cellular processing required to generate robust T cell response.

AMP Technology: Lymph node targeting via albumin hitchhiking

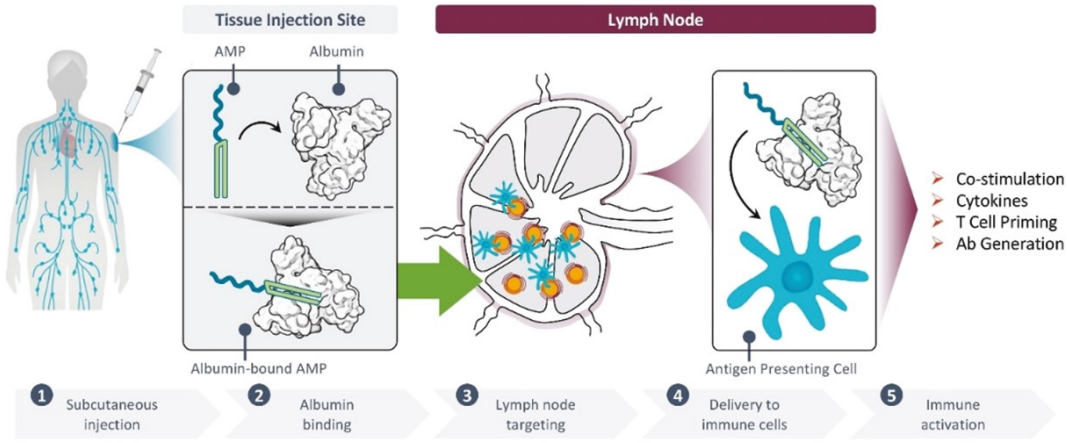
Our proprietary AMP technology, and combined expertise in immunology and materials science allows us to develop AMP immunotherapies capable of generating robust and differentiated immune responses. Our AMP immunotherapies utilize modular conjugation chemistry, potentially allowing for application to multiple therapeutic modalities, including peptides, proteins, nucleic acids, and small molecules as illustrated in the figure below:

AMP construction: A molecular conjugation approach for delivery of immune therapeutics to lymph nodes



AMP molecules are multifunctional constructs with lipid tails linked to a therapeutic payload designed to accumulate in the lymph nodes through the body's existing surveillance mechanisms. AMP molecules are designed to interact with endogenous albumin, an abundant protein present in tissues that drains through lymphatic capillaries and accumulates in lymph nodes where foreign substances are collected for risk-assessment by sentinel immune cells. AMP molecules use their lipid tails to target the lymph nodes by hitchhiking on endogenous albumin after subcutaneous injection resulting in precise delivery to immune cells responsible for coordinating protective immune responses. Albumin hitchhiking is a well-established method for targeting molecules to lymph nodes. Our AMP technology preferentially traffics immuno-modulatory molecules to lymph nodes enhancing the magnitude, potency, functionality, and durability of the immune response. We believe this lymph node-targeting technology has the potential to be broadly applicable to address significant unmet medical needs.

AMP Facilitated Albumin Hitchhiking



Targeting Common Validated Tumor Neoantigens

We believe a critical strategic benefit of our approach is utilizing common neoantigens that when combined with the AMP-modification could generate an effective T cell-mediated anti-tumor response. Common neoantigens represent an elite class of tumor-specific antigens derived from recurrently mutated driver genes shared across certain types of cancer. Neoantigens are newly formed antigens generated by tumor cells as a result of various tumor-specific alterations, such as genomic mutation or dysregulated protein synthesis. Neoantigens are recognized as non-self and can readily trigger an immune response.

Our most advanced clinical product candidate is a cancer vaccine that targets the tumor driver gene KRAS, which is mutated in more than 25% of all solid tumors. Our preclinical cancer vaccine candidates target two other key neoantigens TP53, the most commonly mutated cancer driver gene, and BRAF, a cancer driver gene found frequently in melanoma, thyroid, and colon cancers.

Utilizing potent adjuvants

In addition to utilizing well-known neoantigens we incorporate potent adjuvants as our AMP immunotherapy's rapid localization to the lymph nodes supports enhanced delivery to immune cells potentially resulting in higher, more robust immune responses with potentially fewer side effects. Adjuvants are any substance included in an immunotherapy intended to activate immune cells to elicit a stronger immune response. Our current product candidates utilize a synthetic oligodeoxynucleotides adjuvant, CpG 7909, intended to mimic bacterial DNA that has been extensively studied and incorporated into FDA-approved products.

In previous clinical studies conducted by third parties, CpG-containing oligonucleotides have been shown to be both well tolerated and to exert immune-stimulatory effects. Our AMP-modification is designed to concentrate and retain the CpG adjuvant in the lymphatic system potentially allowing more effective delivery to immune cells and/or reduced side effects.

The result of our approach is the development of therapeutic cancer vaccines targeting common tumor neoantigens found in a significant portion of patients with cancer. Our AMP immunotherapies are manufactured through traditional pharmaceutical methods resulting in an "off-the-shelf" drug product.

Our Product Candidates

ELI-002: *AMP Immunotherapy for mutant KRAS-driven Cancers*

ELI-002 is a multivalent lymph node–targeted AMP peptide vaccine being developed to target seven KRAS driver mutations that are present in 25% of all solid tumor cancers including 88% of PDAC, 36% of colorectal cancer ("CRC"), and 25% of non-small cell lung cancer ("NSCLC"). Other cancers with significant proportions of KRAS mutations include bile duct and ovarian cancers. The KRAS protein relays signals from outside of the cell membrane to the cell nucleus influencing expression of downstream genes involved in the regulation of cell growth, cell differentiation, and cell death (also referred to as apoptosis). Mutations to the KRAS gene result in expression of overactive KRAS protein, driving aberrant signaling and unregulated cell growth, which are hallmarks of cancer.

Targeting mutated KRAS using immunotherapy presents several potential advantages. KRAS mutations are categorized as truncal mutations serving as a genetic driver of malignant changes where each tumor cell must maintain the expression of the mutated KRAS protein to remain viable. Such uniform expression across every transformed cell in a particular tumor holds the promise that immunological approaches may enable complete tumor eradication. Mutated KRAS proteins are neoantigens, found exclusively in tumor cells, potentially limiting immunotherapy activity to the targeted tumor cells limiting side effects. ELI-002 is chemically synthesized with traditional manufacturing methods that allow the drug product to be readily available as an "off-the-shelf" treatment providing potential cost and time-to-treatment advantages compared to personalized vaccine or cell-therapy treatments.

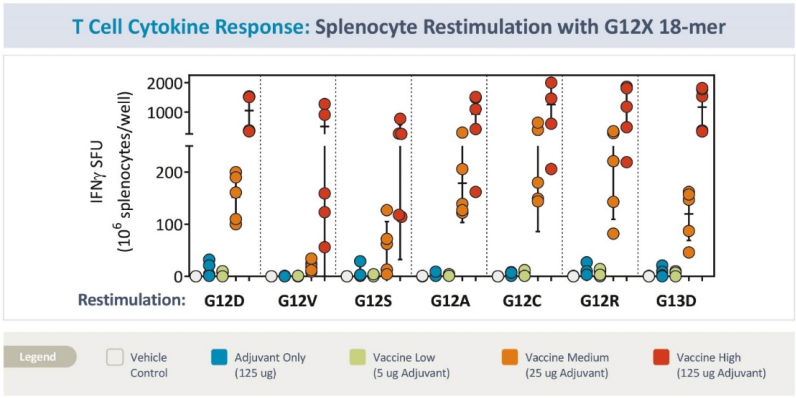
ELI-002 Preclinical Data

Preclinical studies of ELI-002 highlighted the therapeutic potential of the AMP platform and supported ELI-002's advancement into clinical trials. Data from the preclinical studies demonstrated:

- AMP-modified CpG induced significantly higher frequencies of activated immune cells within the lymph nodes compared to soluble CpG.
- AMP-modified peptide sequences generated 40x – 400x increased immune response compared to non-modified peptide sequences suggesting localizing peptides in the lymph nodes produce a robust immune response.
- mKRAS-specific T cells were polyfunctional and able to elicit a cytotoxic response.

- Escalating doses of ELI-002 induced dose-dependent and consistent immune responses targeting all seven mKRAS epitopes.

AMP therapy induces strong immune responses targeting seven common KRAS mutations



AMPLIFY-201: Our First-in-human Phase 1 trial (NCT04853017)

In October 2021, we initiated dosing of the 2-peptide version of ELI-002 in a Phase 1 study of AMP-CpG 7909 dose escalation study intended to evaluate the safety and tolerability of ELI-002, as well as provide immunologic and anti-tumor proof of concept in patients with high relapse risk mKRAS-driven solid tumors, following surgery and chemotherapy. In April 2023, we completed enrollment of 25 patients with PDAC or CRC and will continue to follow patients for up to 30 months. Results published in Nature Medicine in January 2024 from a September 6, 2023 data cutoff demonstrated:

- ELI-002 2P is generally well-tolerated with no dose limiting toxicities or serious adverse events
- Selection of a recommended Phase 2 dose of 10.0mg Amph-CpG-7909
- 84% of patients generated mKRAS-specific T cell responses with a 58x average fold-change compared to baseline
- 59% of patient responses included both CD4 and CD8 T cells
- 84% of patients had a decline in their tumor biomarker from baseline
- 100% of the above median T cell group achieved tumor biomarker responses to ELI-002; in the below median group 67% (8/12) responded to ELI-002
- At a median follow up of 8.5 months, the median RFS was not reached for above median T cell responders compared to 4.01 months among below median T cell responders (HR 0.14, 95% CI 0.03-0.63, P=0.0167)
- 86% Reduction in Risk of Progression or Death in the above median T cell responders to ELI-002
- Median overall survival was not reached for either group
- Median relapse free survival of 16.3 months for 25 patient cohort

With the return of contract manufacturing capacity in 2022 and resulting availability of the 7-peptide version of ELI-002, that covers seven of the most common KRAS mutations thereby increasing the eligible patient population for ELI-002 and potentially reducing the chance of tumor bypass resistance mechanisms, we do not intend further studies of the 2-peptide version of ELI-002.

AMPLIFY-7P Phase 1/2 clinical trial (NCT05726864)

This trial is to assess the safety and efficacy of the 7-peptide version of ELI-002 as adjuvant monotherapy treatment in patients with solid tumors carrying mutated KRAS. In April 2023, we initiated dosing of the Phase 1A portion of the trial enrolling 14 patients through October 2023 who will be evaluated for safety and efficacy of two ELI-002 AMP-peptide total dose levels (1.4mg and 4.9mg) in combination with the 10.0mg Phase 2 dose of Amph-CpG-7909. In September 2023 the Independent Data Monitoring Committee (“IDMC”) reviewed the available Phase

1A data and determined enrollment for the Phase 2 portion of the study could be opened. Preliminary results from the Phase 1A trial are expected in the second quarter of 2024.

In January 2024, we announced the first patient had been dosed in the randomized Phase 2 trial of ELI-002 7P as an adjuvant monotherapy treatment for patients with KRAS-mutated PDAC. The Phase 2 trial will assess disease free survival (DFS) in ~90 patients with PDAC who receive ELI-002 7P (10.0 mg AMP-CpG and 4.9 mg AMP-peptides 7P) as compared to ~45 patients with PDAC who receive standard of care (observation) with crossover of the observation arm permitted at the time of confirmed radiographic relapse via iRECIST. We expect enrollment of the 135 patients to complete by year-end 2024 with interim analysis results in the first quarter of 2025.

ELI-007: ***AMP Immunotherapy for mutant BRAF-driven Cancers***

ELI-007 is a multivalent lymph node–targeted AMP peptide vaccine developed to target 95% of the BRAF gene mutations found in solid tumors. The BRAF gene is part of an intracellular signaling pathway that drives cell growth and division. BRAF mutations can lead to uncontrolled cell growth and are present in multiple types of cancer, including 40% in melanoma, 9% in CRC, and 2% in lung cancer. High levels of BRAF protein expression in these tumors suggest susceptibility to T cells targeting the mutated protein. We received funding for the initial development of ELI-007 through two grants from the Gastro-Intestinal (“GI”) Research Foundation.

At the November 2023 Society for Immunotherapy of Cancer annual meeting, we presented preclinical data demonstrating ELI-007 can generate robust mutant BRAF-specific polyfunctional T cell responses in a murine model. We are currently evaluating opportunities to advance ELI-007 through partnerships, collaborations or additional grants.

ELI-008: ***AMP Immunotherapy for mutant TP53-expressing Cancers***

ELI-008 is a multivalent lymph node–targeted AMP peptide vaccine developed to target p53 hotspot mutations. p53 is a tumor-suppressing protein that controls DNA replication processes where mutated p53 protein contributes to uncontrolled cell growth and tumor progression. We designed ELI-008 to target ~30% of the p53 hotspot mutations found in solid tumor cancers including melanoma, CRC, and NSCLC. We received funding for the initial development of ELI-008 through two grants from the GI Research Foundation.

At the November 2023 Society for Immunotherapy of Cancer annual meeting, we presented preclinical data demonstrating ELI-008 can generate robust mutant p53-specific polyfunctional T cell responses in a murine model. We are currently evaluating opportunities to advance ELI-008 through partnerships, collaborations or additional grants.

AMP Platform Potential Beyond Cancer Vaccines

Our AMP platform has broad potential applications for the treatment or prevention of cancer, infectious diseases and other diseases. These other applications include immune cell therapy AMP-lifiers for CAR T cell therapeutics and TCR T cell therapeutics. We have also completed preclinical proof-of-concept assessments related to the intranasal and subcutaneous use of the AMP platform to prevent infectious diseases, including COVID-19. We intend to advance additional applications of the AMP platform via out-licensing, co-development, or other partnership arrangements.

TCR T Cell Therapy Preclinical Data

In January 2024, data from preclinical studies was published in Cancer Immunology Research demonstrating our AMP immunotherapy in combination with TCR-T cell therapy led to complete eradication and durable responses against established murine solid tumors refractory to TCR-T cell monotherapy. Our AMP immunotherapy led to enhanced lymph node delivery and correlated with pro-inflammatory lymph node transcriptional reprogramming and increased antigen-presenting cell maturation, resulting in TCR-T cell expansion and functional enhancement. Addition of AMP immunotherapy enhanced the infiltration and function of TCR-T cells in the tumor microenvironment and led to antigen spreading against diverse tumor targets. We are currently evaluating opportunities to advance our AMP immunotherapy application to TCR-T cell therapy through partnerships or collaborations.

Licensing, Collaboration and Partnership Agreements

MIT License Agreement

On January 27, 2016, we entered into an Exclusive Patent License Agreement with Massachusetts Institute of Technology (“MIT”), which has been amended from time to time (the “MIT License Agreement”). Pursuant to the MIT License Agreement, we were granted an exclusive, worldwide license, with the right to sublicense, to certain patents and patent applications owned by MIT related to the AMP technology for the diagnosis, treatment or prevention of diseases. The licensed patent claims cover vaccine products in development by us for our current lead programs in tumor indications where mutant KRAS, rearranged Anaplastic lymphoma kinase (“ALK”), or certain other proteins are a driver of disease, as well as programs using CpG as an adjuvant for immune activation in conjunction with an immunostimulatory agent. The MIT License Agreement established annual license payment obligations and

intellectual property cost reimbursement obligations for which we are responsible, specific product categories (including immunotherapeutic products and adjuvant products) for which we are required to invest specified minimum amounts of research funding and the timing of such investment, specified development and commercialization milestone obligations, and payments due with respect to the achievement of these milestones.

On October 21, 2016, the MIT License Agreement was amended to update language around patent rights and MIT procedures. On February 22, 2018, the MIT License Agreement was amended to extend certain milestone dates. On each of January 31, 2019, June 23, 2020 and January 7, 2021, the MIT License Agreement was amended to add certain patent applications owned by MIT and include an additional fee, updates to patent application fees and to annual license maintenance fees. The amendments on June 23, 2020 and January 7, 2021 also adjusted milestone dates and diligence requirements under the MIT License Agreement.

Under the terms of the MIT License Agreement, we are obligated to use commercially reasonable diligent efforts to develop and commercialize licensed products, and to use such efforts to accomplish specified development and commercial launch objectives in accordance with a specified timeline as well as to expend specified resources in the development and commercialization of immunotherapeutic products and adjuvant products. We are obligated to pay an annual license maintenance fee, which can be credited against royalties paid to MIT during the same calendar year. We are also obligated to make milestone payments upon the occurrence of specific development and commercialization achievements on a product-by-product basis during the term of the MIT License Agreement, including those relating to the making of certain regulatory filings, the initiation of certain clinical trials and the achievement of certain sales thresholds. The achievement of each milestone triggers the payment of a set dollar amount to MIT by us. These milestone payments could, in the aggregate, reach a maximum of $27.5 million. We are obligated to make royalty payments based on net sales by it and its sublicensees equal to (i) a fractional to low single digit percentage of net sales of products that would infringe the MIT patent rights and (ii) a fractional percentage of net sales of products that could not have been identified, selected, or determined to have biological activity but for the use or modification of products that would infringe the MIT patent rights. These royalty rates are subject to an upward adjustment if we or a sublicensee commence an action against MIT to declare or render invalid or unenforceable any of the licensed patent rights; and the amount of royalties payable to MIT are subject to a downward adjustment if we are required to secure certain patent licenses from third parties to avoid infringement by the practice of the licensed patent rights. These royalties are payable (1) until the expiration of the last to expire of the MIT patent rights with respect to products that would infringe the MIT patent rights and (2) for 12 years following the first commercial sale of products that could not have been identified, selected, or determined to have biological activity but for the use or modification of products that would infringe the MIT patent rights.

We are also obligated to pay a percentage of any revenue that it or its sublicensees earn from the provision of services using licensed products or that utilizes a process that would infringe the MIT patent rights. We are also obligated to pay a percentage of any payments it receives from its sublicenses, with certain exceptions. We are also required to share a portion of any funds it or a sublicensee receives in respect of the sale of a regulatory voucher that is granted by any regulatory authority based upon the regulatory approval of a product subject to the MIT License Agreement for the treatment of a neglected disease. MIT controls the prosecution and maintenance of the licensed patent rights, and we are required to pay all costs and fees associated with patent prosecution and maintenance of the licensed patents. Patent protection for the MIT licensed patents is being sought in the United States and elsewhere, including Australia, Canada, Europe, Hong Kong and Japan.

The term of the MIT License Agreement will continue in effect until the expiration or abandonment of all issued patents and filed patent applications within the licensed patent rights, unless earlier terminated. MIT may terminate the MIT License Agreement upon our uncured material breach of the MIT License Agreement or upon the occurrence of certain events, including if we or a sublicensee commence an action against MIT to declare or render invalid or unenforceable any of the licensed patent rights, or upon specified insolvency or bankruptcy events concerning us. We may terminate the MIT License Agreement without cause upon six months advance written notice to MIT and upon payment of all amounts due MIT through the date such termination takes effect.

Intellectual Property

Intellectual property is of vital importance in our field and in biotechnology generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We will also seek to rely on regulatory protection afforded through inclusion in expedited development and review, data exclusivity, market exclusivity and patent term extensions where available.

We have sought patent protection in the United States and internationally related to the AMP platform technology as well as the mKRAS and universal adjuvant programs. We have issued patents in Japan, Nigeria, Russia, and Singapore covering clinical product candidates but the patent portfolio owned by us currently largely

comprises pending applications. Such applications may not result in issued patents and, even if patents do issue, such patents may not be in a form or scope that will provide us with meaningful protection for our product candidates. We also rely on trade secrets that may be important to the development of our business. Trade secrets are difficult to protect and provide us with only limited protection, as trade secrets do not protect against independent development of a technology by third parties.

We expect to file additional patent applications in support of current and new clinical candidates as well as new platform and core technologies. Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of current and future product candidates and the methods used to develop and manufacture them, as well as successfully defending any such patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates will depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any patents that may be granted in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The terms of individual patents depend upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (“USPTO”) in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for extension, which permits patent term restoration to account for the patent term lost during the FDA regulatory review process. The Hatch-Waxman Act permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the subject drug candidate is under regulatory review. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions to extend the term of a patent that covers an approved drug are available in Europe and other foreign jurisdictions. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek patent term extensions to any issued patents we may obtain in any jurisdiction where such patent term extensions are available, however there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment that such extensions should be granted, and if granted, the length of such extensions.

In some instances, we have submitted and expect to submit patent applications directly to the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty (“PCT”) applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Office. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We seek to file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses that we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to pursue maximum coverage and value for our processes, and compositions, given existing patent office rules and

regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee's use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions.

The patent positions of biotechnology companies are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Third-party patents could require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see "Risk Factors—Risks Related to Intellectual Property."

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or product candidates.

Company-owned Intellectual Property

We own the following patent families and applications:

We have an issued U.S. patent and pending U.S. and Canadian patent applications titled "ALK polypeptides and methods of use thereof", which are related to our products in development for tumor indications where rearranged ALK is a driver of disease.

We also have a patent family titled "Compounds including a mutant KRAS sequence and a lipid and uses thereof" with granted patents in Japan, Russia and Singapore and pending applications in the United States, the United Arab Emirates, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Mexico, Malaysia, Nigeria, New Zealand, Saudi Arabia, Thailand, Ukraine, and South Africa. This patent family relates to our products in development for tumor indications where mutant KRAS is a driver of disease.

We also have a patent family titled "CpG amphiphiles and uses thereof" with granted patents in Nigeria and Singapore and pending applications in the United States, the United Arab Emirates, Australia, Brazil, Canada, China, Europe, Hong Kong, Israel, India, Japan, South Korea, Mexico, Malaysia, New Zealand, Russia, Saudi Arabia, Thailand, Ukraine, and South Africa. This patent family relates to our products in development for tumor indications where expression of human papillomavirus protein(s) is a driver of disease.

We also have a patent family titled “Compositions and methods for inducing an immune response against coronavirus” with pending applications in the United States, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, South Korea, and Mexico. This patent family relates to the use of our AMP technology, including products in development, in methods of inducing an immune response against coronavirus.

We also have a patent family titled “Uses of amphiphiles in immune cell therapy and compositions therefor” with pending applications in the United States, Australia, Canada, Europe, Japan, and New Zealand. This application relates to the use of our AMP technology, including products in development, in immune cell therapy.

We also have a patent family titled “Compositions containing polynucleotide amphiphiles and methods of use thereof”with pending applications in the United States, Australia, Canada, Europe, Japan, and New Zealand. This application relates to aspects of our AMP technology platform.

We also have a pending U.S. provisional application titled “Compositions containing polynucleotide and polypeptide amphiphiles and methods of use thereof.” This application relates to aspects of our AMP technology platform.

We also have two pending U.S. provisional applications titled “Compositions containing mutant p53 peptide amphiphiles and methods of use thereof.” These applications relate to aspects of our AMP technology platform.

We have sole ownership of the above patents and patent applications. For these patents and for any patents granted on the pending applications, we anticipate that patent expiration would occur between 2037 and 2044 without taking into consideration patent term adjustments or extensions.

We also have a pending PCT international application titled “Uses of amphiphiles in immune cell therapy and compositions therefor.” This application relates to aspects of our AMP technology platform in connection with immune cell therapy. This application is co-owned with the University of Pennsylvania. If we are granted patents on this pending application, it is anticipated that patent expiration would occur in 2043 without taking into consideration patent term adjustments or extensions.

We also have two pending U.S. provisional applications titled “Compositions containing BRAF peptide amphiphiles and methods of use thereof.” These applications relate to aspects of our AMP technology platform. These applications are co-owned with Cornell University. If we are granted patents on non-provisional applications based on these pending applications, it is anticipated that patent expiration would occur in 2044 without taking into consideration patent term adjustments or extensions.

Licensed Intellectual Property

We have an exclusive license from MIT for six patent families related to aspects of our AMP technology platform:

- “Immunostimulatory compositions and methods of use thereof”, which contains three patents granted in the United States, patents granted in Europe, Hong Kong, and Japan, as well as pending applications in the United States, Europe, Hong Kong, and Japan, which relates to aspects of our AMP platform technology;
- “Albumin binding peptide conjugates and methods thereof,” which contains two patents granted in the United States, as well as pending applications in the United States, China, Hong Kong, Japan, and Europe, which relates to certain additional aspects of our AMP platform technology;
- “Chimeric antigen receptor-targeting ligands and uses thereof” with a pending application in the United States, which relates to further aspects of our AMP platform technology;
- “Compositions for chimeric antigen receptor T cell therapy and uses thereof” with pending applications in the United States, Australia, Canada, China, Europe, Hong Kong, Japan, South Korea, Mexico, New Zealand, and Russia, which relates to the use of our AMP platform technology in connection with CAR T therapy;
- “Uses of amphiphiles in immune cell therapy and compositions therefor” with pending application in the United States, Europe, Hong Kong, and Japan, which relates to use of our AMP platform technology in connection with immune cell therapy; and
- “Methods for identifying chimeric antigen receptor-targeting ligands and uses thereof” with a pending application in the United States, which relates to methods of identifying further ligands for use in our AMP platform technology.

For these patents and for any patents granted on the pending applications, we anticipate patent expiration to occur between 2033 and 2041, without taking into consideration patent term adjustments or extensions.

We also have an exclusive license from Dr. Roberto Chiarle for a patent family titled Anaplastic lymphoma kinase (ALK) as oncoantigen for lymphoma vaccination," which contains two granted U.S. patents. This patent family relates to ALK antigen sequences that may be used in connection with our AMP platform technology. We anticipate patent expiration to occur in 2028 and 2031 without taking into consideration patent term extension.

Manufacturing

We do not own or operate facilities for clinical drug manufacturing, storage, distribution or quality testing. Currently, all of our clinical manufacturing is outsourced to third-party contract manufacturing organizations. We currently obtain our supplies from these manufacturers on a purchase order basis and do not have long-term committed supply arrangements with respect to our product candidates and other materials. Our product candidates are manufactured using reliable and reproducible synthetic processes from readily available starting materials and are based on chemistry that is amenable to scale up. We expect to continue to develop product candidates that can be produced cost effectively at contract manufacturing facilities. See the risk factor entitled "*We rely on CMOs to manufacture our nonclinical and clinical pharmaceutical supplies and expect to continue to rely on CMOs to produce commercial supplies of any approved product candidate, and our dependence on CMOs could adversely impact its business*."

Competition

The biotechnology and pharmaceutical industries are characterized by rapid evolution of technologies, fierce competition, and strong defense of intellectual property. While we believe our technology, expertise, scientific knowledge, and intellectual property estate provide competitive advantages, we face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical, biotechnology companies, academic institutions, governmental agencies, and public and private research institutions that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may directly compete with our current or future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, technologies, and data emerge within the field of immunotherapy and, furthermore, within the treatment of infectious diseases and cancers.

In addition to the current standard of care treatments for patients, numerous commercial and academic preclinical studies and clinical trials are being undertaken by many parties to assess novel technologies and product candidates in the field of immunotherapy. In the treatment of mKRAS associated cancers there are two approved therapies for non-small cell lung cancer ("NSCLC") Amgen's LUMAKRAS and Mirati Therapeutics ' KRAZATI. Other companies developing clinical stage personalized cancer vaccine therapies or mKRAS-targeted therapies include BioNTech SE, BridgeBio Pharma Inc., Boehringer Ingelheim, Eli Lilly & Co., Inc., Gritstone bio, Inc., Hookipa Pharma, Roche Holding Ltd./Genentech, Inc., Revolution Medicines, Merck & Co., and Novartis AG.

Many of our competitors, either alone or in combination with their respective strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, the regulatory approval process, and marketing than we do. Mergers and acquisition activity in the pharmaceutical, biopharmaceutical and biotechnology sector is likely to result in greater resource concentration among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through sizeable collaborative arrangements with established companies. These competitors also compete with us in the recruiting and retaining of qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, better tolerated, or of greater convenience or economic benefit than any products we may develop. Our competitors also may be in a position to obtain FDA or other regulatory approval for their products more rapidly, resulting in a stronger or dominant market position before we are able to enter the market. The key competitive factors affecting the success of all of our programs are likely to be product safety, efficacy, convenience and treatment cost.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacturing, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, import, and export of biopharmaceutical products. In addition, sponsors of biopharmaceutical products participating in Medicaid,

Medicare, and other government health care programs are required to comply with mandatory price reporting, discount, and rebate requirements. We, along with our third-party contractors, will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with compliance with applicable statutes and regulations, requires the expenditure of substantial time and financial resources.

FDA Regulation

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act ("FDCA") the Public Health Services Act ("PHSA"), and their implementing regulations. The FDA further has issued a growing body of guidance documents, which, while not binding, provide the agency's current interpretation of its statutes and regulations. Failure to comply with the applicable U.S. requirements may subject an applicant to administrative or judicial sanctions, such as FDA refusal to approve pending biologics license applications ("BLAs") or the agency's issuance of warning letters, or the imposition of fines, civil penalties, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution brought by the FDA and the U.S. Department of Justice or other governmental entities.

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

- completion of preclinical (or nonclinical) laboratory tests and formulation studies in compliance with the FDA's good laboratory practice ("GLP") regulations;
- submission to the FDA of an Investigation New Drug application ("IND") which must become effective before human clinical trials may begin at United States clinical trial sites;
- approval by an institutional review board ("IRB") for each clinical site, or centrally, before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials to establish the product candidate's safety, purity, potency, and efficacy for its intended use, performed in accordance with good clinical practice ("GCP") as well as IND regulations and other clinical-trial related regulations;
- development of manufacturing processes to ensure the product candidate's identity, strength, quality, purity, and potency in compliance with current good manufacturing practice ("cGMP") regulations;
- submission to the FDA of a BLA;
- satisfactory completion of an FDA advisory committee review, if applicable;
- FDA review and approval of the BLA to permit commercial marketing for particular indications for use.

Preclinical Studies and IND Submission

The testing and approval process of product candidates requires substantial time, effort, and financial resources. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, and may involve *in vitro* testing or *in vivo* animal studies to assess the potential for toxicity, adverse events, and other safety characteristics of the product candidate, and in some cases to establish a rationale for therapeutic use. Such studies must generally be conducted in accordance with FDA GLP regulations. The Consolidated Appropriations Act for 2023, signed into law on December 29, 2022, (P.L. 117-328) amended the FDCA and the PHSA to specify that nonclinical testing for drugs and biologics may, but is not required to, include *in vivo* animal studies. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various *in vitro* assays (e.g., cell-based assays, organ chips, or microphysiological systems), *in silico* studies (i.e., computer modeling), other human or nonhuman biology-based tests (e.g., bioprinting), or *in vivo* animal studies.

Prior to commencing the first clinical trial at a U.S. investigational site with a product candidate, an IND sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or relevant scientific literature (including data from clinical trials conducted outside of the United States), and proposed clinical study protocols among other things, to the FDA as part of an IND. An IND is a request from a clinical study sponsor to obtain authorization from the FDA to administer an investigational drug or biologic product to humans in accordance with a specific clinical trial protocol. Some long-term nonclinical testing to

further establish the safety profile of the product candidate, as well as manufacturing process development and product quality evaluation, continues after the IND is submitted.

An IND goes into effect upon notification by the FDA or automatically 30 days after receipt by the FDA, unless the FDA, within the 30–day-time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve all outstanding concerns or questions posed by the FDA before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical trials due to safety concerns or non-compliance with applicable regulations. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical Trials

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with federal regulations and GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as review and approval of the trial by an IRB. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the trial procedures, the parameters to be used in monitoring safety, the effectiveness criteria to be evaluated, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND. In addition, an IRB at each site participating in the clinical trial, or a central IRB, must review and approve the plan for any clinical trial, informed consent forms, and communications to trial subjects before a trial commences at that site. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. If a product candidate is being investigated for multiple intended indications, separate INDs may also be required. Status reports summarizing the progress of the clinical trials must be submitted at least annually to the FDA and the IRB and more frequently if suspected unexpected serious adverse reactions occur, findings from other studies suggest a significant risk to humans exposed to the investigational product, findings from animal or *in vitro* testing suggest a significant risk for human subjects, or other significant safety information is found.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions on various grounds, including if the agency believes that the clinical trial either is not being conducted in accordance with regulatory requirements or presents an unacceptable risk to the clinical trial subjects. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements or if the trial poses an unexpected serious harm to subjects. The FDA or an IRB may also impose conditions on the conduct of a clinical trial. Clinical trial sponsors may also choose to discontinue clinical trials as a result of risks to subjects, a lack of favorable results, or changing business priorities. Some clinical trials also include oversight by an independent group of qualified experts organized by the trial sponsor, known as an independent data monitoring committee ("IDMC") which provides authorization for whether a trial may move forward at designated check points based on review of certain data from the trial, to which only the IDMC has access, and may recommend halting the trial if it determines that there is an unacceptable safety risk for subjects or on other grounds, such as no demonstration of efficacy.

Sponsors of clinical trials of certain FDA-regulated products generally must register and disclose certain clinical trial information to a public registry maintained by the National Institutes of Health ("NIH"). In particular, information related to the investigational product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results may be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. Department of Health and Human Services' Final Rule and NIH's complementary policy on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against non-compliant clinical trial sponsors. Sponsors or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

The manufacture of investigational biologics for the conduct of human clinical trials is subject to cGMP requirements. Investigational biologics and their therapeutic substances that are imported into the United States are also subject to regulation by the FDA. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements under the FDCA.

In general, for purposes of BLA approval, human clinical trials are typically conducted in three sequential phases, which may overlap or be combined.

- *Phase 1*—The product candidate is initially administered to healthy human volunteers and tested for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. In the case of some products for severe or life-threatening diseases, such as cancer, especially when the product may be too inherently toxic to administer ethically to healthy volunteers, the initial human testing is often conducted in patients with the target disease or condition. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.
- *Phase 2*—Studies are conducted in limited subject populations with a specified disease or condition to evaluate preliminary efficacy, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety. Multiple Phase 2 clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more extensive clinical trials.
- *Phase 3*—Clinical trials are undertaken with expanded subject populations, generally at geographically dispersed clinical trial sites, to generate sufficient data to provide statistically significant evidence of clinical efficacy and safety of the product candidate, to establish the overall risk-benefit profile of the product candidate, and to provide adequate information for the labeling of the product candidate. Typically, two adequate, well-controlled trials are required by the FDA for biological product approval. Under some limited circumstances, however, the FDA may approve a BLA based upon a single clinical trial plus confirmatory evidence from a post-market trial or, alternatively, a single large, robust, well-controlled multicenter trial without confirmatory evidence.

Additional kinds of data may also help to support a BLA, such as patient experience and real-world data. For appropriate indications sought through supplemental BLAs, data summaries may provide marketing application support. For genetically targeted products and variant protein targeted products intended to address an unmet medical need in one or more patient subgroups with a serious or life threatening rare disease or condition, the FDA may allow a sponsor to rely upon data and information previously developed by the sponsor or for which the sponsor has a right of reference, that was submitted previously to support an approved application for a product that incorporates or utilizes the same or similar genetically targeted technology or a product that is the same or utilizes the same variant protein targeted therapeutic agent as the product that is the subject of the application.

The FDA may also require, or companies may voluntarily conduct, additional clinical trials for the same indication after a product is approved. These post-approval trials, referred to as Phase 4 clinical trials, are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 trials as a condition of approval of a BLA. The results of Phase 4 studies can confirm or refute the effectiveness of a product candidate and can provide important safety information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, manufacturers must develop methods for testing the identity, strength, quality, potency, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require sponsors of a Phase 3 clinical trial, or other “pivotal study” of a new medical product to support marketing authorization, to submit a diversity action plan for such clinical trial. The action plan must include the sponsor’s diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. A sponsor must submit a diversity action plan to FDA by the time the sponsor submits the trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect Phase 3 trial planning and timing or what specific information FDA will expect in such plans, but if FDA objects to a sponsor’s diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

Marketing Application Submission, Review by the FDA, and Marketing Approval

Assuming successful completion of the required clinical and preclinical testing in accordance with all applicable regulatory requirements, the results of product development, including chemistry, manufacture, and controls information, nonclinical studies, and clinical trial results, including negative or ambiguous results as well as positive

findings, are all submitted to the FDA, along with the proposed labeling, as part of a BLA requesting approval to market the product for one or more indications. A BLA must contain sufficient evidence of the biological product candidate's safety, purity, potency and efficacy for its proposed indication or indications. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended("PDUFA"), each BLA submission is subject to a substantial application user fee, and the sponsor of an approved BLA is also subject to an annual program fee. The FDA adjusts the PDUFA user fees on an annual basis. The application user fee must be paid at the time of the first submission of the application, even if the application is being submitted on a rolling basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Product candidates that are designated as orphan products are also not subject to application user fees, unless the application also includes a non-orphan indication.

In addition, under the Pediatric Research Equity Act ("PREA"), a BLA or supplement to a BLA for a new active ingredient, indication, dosage form, dosage regimen, or route of administration, must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. 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 from the pediatric data requirements. A sponsor who is planning to submit a marketing application for a 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 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial 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 and the sponsor must reach an 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 or other clinical development programs. Orphan products are exempt from the PREA requirements.

The FDA Reauthorization Act of 2017 introduced a provision regarding required pediatric studies. Under this statute, for product candidates intended for the treatment of adult cancer which are directed at molecular targets that the FDA determines to be substantially relevant to the growth or progression of pediatric cancer, original application sponsors must submit, with the marketing application, reports from molecularly targeted pediatric cancer investigations designed to yield clinically meaningful pediatric study data, gathered using appropriate formulations for each applicable age group, to inform potential pediatric labeling. The FDA may, on its own initiative or at the request of the applicant, grant deferrals or waivers of some or all of this data, as above. Unlike PREA, orphan products are not exempt from this requirement.

The FDA also may require submission of a risk evaluation and mitigation strategy ("REMS") if it determines that a REMS is necessary to ensure that the benefits of the product candidate outweigh the risks and to assure safe use of the biological product. The REMS plan could include medication guides, physician communication plans, assessment plans and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required. An assessment of the REMS must also be conducted at set intervals. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the product outweigh the risks.

Once the FDA receives a marketing application for a biologic, it has 60 days to review the BLA to determine if it is substantially complete to permit a substantive review, before it accepts the application for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review.

Under the goals and policies agreed to by the FDA under PDUFA, the FDA has set the review goal of completing its review of 90% of BLAs within ten months of the filing date for a standard application and within six months of the filing date for an application with priority review. For all original BLAs, the ten and six-month time

periods run from the filing date; for all other submissions, including resubmissions, efficacy supplements and other supplements, the FDA's stated review time periods, ranging from two to ten months, run from the submission date. This review goal is referred to as the PDUFA date. The PDUFA date is only a goal, and it is not uncommon for FDA review of a BLA to extend beyond the PDUFA date. The review process and the PDUFA date may also be extended if the FDA requests, or the sponsor otherwise provides, substantial additional information or clarification regarding the submission.

The FDA may also refer certain applications to an advisory committee. Before approving a product candidate for which no active ingredient has previously been approved by the FDA, the FDA must either refer that product candidate to an external advisory committee or provide in an action letter a summary of the reasons why the FDA did not refer the product candidate to an advisory committee. The FDA may also refer other product candidates to an advisory committee if FDA believes that the advisory committee's expertise would be beneficial. An advisory committee is typically a panel that includes clinicians and other experts, which review, evaluate, and make 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 product approval decisions.

The FDA reviews a BLA to determine, among other things, whether a product candidate meets the agency's approval standards, such as whether the application includes sufficient evidence that the product candidate is safe and effective for the proposed indications, and whether the manufacturing methods and controls are adequate to assure and preserve the product's identity, strength, quality, potency, and purity. As part of its review, the FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. Before approving a marketing application, the FDA typically will inspect the facility or facilities where the product is manufactured, referred to as a pre-approval inspection. The FDA will not approve an application unless it determines that the manufacturing processes and facilities, including contract manufacturers and subcontractors, are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a marketing application the FDA may inspect one or more clinical trial sites to assure compliance with applicable IND trial requirements and GCP. To assure cGMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

After evaluating the marketing application and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a Complete Response Letter ("CRL"). A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form, and it describes all of the specific deficiencies that the FDA identified. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of the marketing application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional Phase 3 clinical trials. If a CRL is issued, the applicant may either: resubmit the marketing application, addressing all of the deficiencies identified in the letter; withdraw the application; or request an opportunity for a hearing. The FDA has the goal of reviewing 90% of application resubmissions in either two or six months of the resubmission date, depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA may issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications or populations for use of the product, require that contraindications, warnings, or precautions be included in the product labeling, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety and efficacy after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA also may not approve label statements that are necessary for successful commercialization and marketing or may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs.

After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval. The FDA may also withdraw the product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the marketplace. Further, should new safety information arise, additional testing, product labeling, or FDA notification may be required.

Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of our biological product candidates, some of our U.S. patents may be eligible for limited patent term extension. These patent term extensions permit a patent restoration term of up to five years as compensation for any 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, plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension, and the extension must be applied for prior to expiration of the patent. The USPTO in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, a number of biosimilars have been licensed under the BPCIA, and numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be demonstrated through analytical studies, animal studies, and a clinical trial or trials. There must be no difference between the reference product and a biosimilar in mechanism of action, conditions of use, route of administration, dosage form, and strength. A biosimilar product may be deemed interchangeable with the reference product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product in any given patient and, for products administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic without such alternation or switching. Upon licensure by the FDA, an interchangeable biosimilar may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product. The FDA approved the first interchangeable biosimilars, including an interchangeable monoclonal antibody biosimilar, in 2021.

A reference biologic is granted 12 years of data exclusivity from the time of first licensure of the product, and the first approved interchangeable biological product will be granted an exclusivity period of up to one year after it is first commercially marketed. However, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. As part of the Consolidated Appropriations Act for 2023, Congress amended the PHSA in order to permit multiple interchangeable products approved on the same day to receive and benefit from this one-year exclusivity period. If pediatric studies are performed and accepted by the FDA as responsive to a written request, the 12-year exclusivity period will be extended for an additional six months. In addition, the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a supplement for the reference product for a subsequent application filed by the same sponsor or manufacturer of the reference product (or licensor, predecessor in interest or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength or for a modification to the structure of the biological product that does not result in a change in safety, purity or potency. Therefore, one must determine whether a new product includes a modification to the structure of a previously licensed product that results in a change in safety, purity or potency to assess whether the licensure of the new product is a first licensure that triggers its own period of exclusivity. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

Pediatric Exclusivity

Pediatric exclusivity is a type of non-patent marketing 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 or listed patents. This six-month exclusivity may be granted if a 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 requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover 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 approve another application. The issuance of a written request does not require the sponsor to undertake the described studies.

Orphan Product Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products for rare diseases or conditions. Specifically, sponsors may apply for and receive Orphan Drug Designation ("ODD") if a product candidate is intended to treat a rare disease or condition, which is generally a disease or condition affecting less than 200,000 individuals in the United States, or affecting more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States will be recovered from United States sales. Additionally, sponsors must present a plausible hypothesis for clinical superiority to obtain ODD if there is a product already approved by the FDA that that is considered by the FDA to be the same as the already approved product and is intended for the same indication. This hypothesis for clinical superiority must be demonstrated to obtain orphan exclusivity. Orphan drug designation must be requested before submitting a marketing application for the product candidate and does not convey any advantage in or shorten the duration of the regulatory review and approval process. If granted, ODD entitles the applicant to financial incentives such as opportunities for grant funding towards clinical study costs, tax advantages, and certain user-fee waivers. After the FDA grants ODD, the identity of the therapeutic agent and its potential orphan use will be disclosed publicly by the FDA; the posting will also indicate whether the drug or biologic is no longer designated as an orphan product. More than one product candidate may receive an orphan designation for the same indication.

If a product candidate receives FDA approval for the indication for which it has ODD, the product is generally entitled to orphan exclusivity, which means the FDA may not approve any other application to market a product containing the same active moiety 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. A product is clinically superior if it is safer, more effective or makes a major contribution to patient care. Thus, orphan drug exclusivity could block the approval of one of our potential products for seven years if a competitor obtains approval of the same product, as defined by the FDA, for the same orphan indication and we are not able to show the clinical superiority of our product candidate. In addition, the FDA will not recognize orphan drug exclusivity if a sponsor fails to demonstrate upon approval that the product is clinically superior to a previously approved product containing the same active moiety for the same orphan condition, regardless of whether or not the previously approved product was designated an orphan drug or had orphan drug exclusivity. A product that has received ODD may not receive orphan exclusivity if it is approved for a use that is broader than the indication for which it received the designation. Orphan exclusivity does not prevent the FDA from approving a different drug or biological product for the same disease or condition, or the same product for a different disease or condition. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Recent court cases have challenged the FDA's approach to determining the scope of orphan drug exclusivity; however, at this time the agency continues to apply its long-standing interpretation of the governing regulations and has stated that it does not plan to change any orphan drug implementing regulations.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited development or review if they are intended for the treatment of serious or life-threatening diseases or conditions, and demonstrate the potential to address unmet medical needs or present a significant improvement over existing therapy. These programs include fast track designation, breakthrough therapy designation and priority review designation.

To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a product candidate is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. Fast track designation provides opportunities for more frequent interactions with the FDA review team to expedite development and review of the product. In addition, the FDA may initiate review of sections of a marketing application before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the submission of the application sections and the sponsor pays any required user fees upon submission of the first section of the application. In some cases, a product with fast track designation may be eligible for accelerated approval or priority review if the relevant criteria are met. The FDA may rescind, or the sponsor may forfeit, fast track designation if the designation is no longer supported by data emerging from the clinical trial process.

Under the provisions of the Food and Drug Administration Safety and Innovation Act ("FDASIA") enacted in 2012, a sponsor may request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drug or biologic, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Products designated as breakthrough therapies are eligible for the same benefits described above for fast track designation, as well as intensive guidance on an efficient development program beginning as early as Phase 1 trials, and a commitment from the FDA to involve senior managers and experienced review staff in a proactive collaborative and cross-disciplinary review. Drugs or biologics designated as breakthrough therapies are also eligible for accelerated approval of their respective marketing applications.

Finally, the FDA may grant priority review designation to product candidates that are intended to treat serious conditions and, if approved, would provide significant improvements in the safety or effectiveness over existing therapies. The FDA determines at the time that the marketing application is submitted, on a case-by-case basis, whether the proposed drug or biologic represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months for an original application from the date of filing.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, breakthrough therapy designation and priority review do not change the standards for approval and may not ultimately expedite the development or approval process.

Accelerated Approval

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM") and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug or biologic.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug or biologic, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs and biologics for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to establish the effect on the clinical endpoint. Failure to

conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug or biologic. As part of the Consolidated Appropriations Act for 2023, Congress provided FDA additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs or biologics previously granted accelerated approval. Under the act's amendments to the FDCA, FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

Post-approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, monitoring and record-keeping requirements, reporting of adverse experiences with the product, periodic reporting requirements, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, as well as advertising and promotion requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as off-label uses), limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the Internet.

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 of a new BLA or a supplement, which may require the applicant to develop additional data or conduct additional pre-clinical studies and clinical trials. The FDA may also place other conditions on approvals, including the requirement for a REMS, to assure the safe use of the product. A REMS 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. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the quality and long-term stability of the product. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports and returned or salvaged products. The manufacturing facilities for our product candidates must meet cGMP requirements and satisfy the FDA or comparable foreign regulatory authorities before any product is approved and our commercial products can be manufactured. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These third-party manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers, including third-party manufacturers, and other entities involved in the manufacture and distribution of approved biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Future inspections by the FDA and other regulatory agencies may identify compliance issues at the facilities of our CMOs that may disrupt production or distribution or require substantial resources to correct. In addition, the discovery of conditions that violate these rules, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, voluntary recall and regulatory sanctions as described below.

The FDA also strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. A company can make only those claims relating to a product that are approved by the FDA. Physicians, in their independent professional medical judgment, may prescribe legally available products for unapproved indications that are not described in the product's labeling and that differ from those tested and approved by the FDA. Biopharmaceutical companies, however, are required to promote their products 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, including, but not limited to, criminal and civil penalties under the FDCA and False Claims Act, exclusion from participation in federal health care programs, mandatory compliance programs under corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts.

Moreover, the Drug Supply Chain Security Act ("DSCSA") was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA imposes phased-in and resource-intensive obligations on biopharmaceutical manufacturers, wholesale distributors, and dispensers related to product tracking and tracing over a 10-year period which culminated in November 2023. Among the requirements of this legislation, manufacturers are required to provide certain information regarding the products to wholesale distributors and dispensers to which product ownership is transferred, label products with a product identifier, and keep certain records regarding the product. A manufacturer must also verify that purchasers of the manufacturer's products are appropriately licensed. Further, under this legislation, manufacturers have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death. Most recently, the FDA announced a one-year stabilization period to November 2024, giving entities subject to the DSCSA additional time to finalize interoperable tracking systems and to ensure supply chain continuity.

FDA's post-market requirements are continuously evolving and additional requirements may apply. For instance, in March 2020, the U.S. Congress passed the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), which includes various provisions regarding FDA drug shortage reporting requirements, as well as provisions regarding supply chain security, such as risk management plan requirements, and the promotion of supply chain redundancy and domestic manufacturing. Any changes of law may require that we modify how we conduct our business and may require additional expenditure to ensure that we are in compliance.

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 significant regulatory actions. Such actions may include refusal to approve pending applications, license or approval suspension or revocation, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in federal and state health care programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and adverse publicity, among other adverse consequences.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Fraud and Abuse, Data Privacy and Security, and Transparency Laws and Regulations

Although we currently do not have any products on the market, our business activities and current and future arrangements with investigators, health care professionals, consultants, third-party payors and customers may be subject to regulation and enforcement by numerous federal and state regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Department of Justice, the Department of Health and Human Services and its various divisions, including the Centers for Medicare and Medicaid Services ("CMS") and the Health Resources and Services Administration, the Department of Veterans Affairs, the Department of Defense, and state and local governments. Our business activities must comply with numerous health care laws, including but not limited to, anti-kickback and false claims laws and regulations as well as data privacy and security

laws and regulations, which are described below, as well as state and federal consumer protection and unfair competition laws.

The federal Anti-Kickback Statute, which regulates, among other things, marketing practices, educational programs, pricing policies, and relationships with health care providers or other entities, prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order, or the referral to another for the furnishing or arranging for the furnishing of any item or service reimbursable under Medicare, Medicaid, or other federal health care programs, in whole or in part. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical industry members on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. There are certain statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, including purchases of products paid by federal health care programs, the statute has been violated. The Patient Protection and Affordable Care Act (" ACA") of 2010, as amended, also modified the intent requirement under the Anti-Kickback Statute to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA also provided that a violation of the federal Anti-Kickback Statute is grounds for the government or a whistleblower to assert that a claim for payment of items or services resulting from such violation constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal civil False Claims Act ("FCA") prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or avoiding, decreasing, or concealing an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. Intent to deceive is not required to establish liability under the FCA. Actions under the FCA may be brought by the government or may be brought by private individuals on behalf of the government, called "qui tam" actions. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement, which can aggregate into millions of dollars. For these reasons, since 2004, FCA lawsuits against biopharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices and promoting off label uses. FCA liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, conviction or civil judgment for violating the FCA may result in exclusion from federal health care programs, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

The government may further prosecute conduct constituting a false claim under the criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious, or fraudulent and, unlike the False Claims Act, requires proof of intent to submit a false claim.

The civil monetary penalties statute is another potential statute under which biopharmaceutical companies may be subject to enforcement. Among other things, the civil monetary penalties statue imposes fines against any person who is determined to have knowingly presented, or caused to be presented, claims to a federal health care program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a health care benefit program, regardless of whether the

payor is public or private, in connection with the delivery or payment for health care benefits, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care offense and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, health care benefits, items, or services relating to health care matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

Under the federal Physician Payments Sunshine Act and its implementing regulations, manufacturers of biologics for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program (with certain exceptions) must make annual reports to CMS regarding payments and other transfers of value made to or at the request of covered recipients, such as, but not limited to, physicians, certain advanced non-physician health care providers, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family. Certain payments for clinical trials are included within the ambit of this law. CMS makes the reported information publicly available.

Further, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (the "HITECH Act") and its respective implementing regulations impose requirements on covered entities relating to the privacy, security, and transmission of individually identifiable health information, known as protected health information. Among other things, the HITECH Act, through its implementing regulations, makes HIPAA's security standards and certain privacy standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains, or transmits protected health information on behalf of a covered entity for a function or activity regulated by HIPAA. The HITECH Act also strengthened the civil and criminal penalties that may be imposed against covered entities, business associates, and individuals, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. We are not a covered entity or a business associate under HIPAA, however, we are indirectly affected by HIPAA because the protected health information held by investigators conducting our clinical trials is subject to HIPAA and can only be used for our research consistent with HIPAA requirements imposed on those investigators.

In addition, numerous federal and state laws and regulations, including state data breach notification laws, and federal and state consumer protection laws govern the collection, use, disclosure, and protection of health-related and other personal information. For example, California enacted the California Consumer Privacy Act ("CCPA"), which took effect on January 1, 2020, and in 2020, California voters passed the California Privacy Rights Act (the "CPRA"), which became effective as of January 1, 2023, and significantly amends the CCPA and imposes additional data protection obligations on companies doing business in California.

Many states have also adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws also regulate sponsors' use of prescriber-identifiable data. Certain states also require implementation of commercial compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments or the provision of other items of value that may be made to health care providers and other potential referral sources; impose restrictions on marketing practices; or require sponsors to track and report information related to payments, gifts, and other items of value to physicians and other health care providers. Furthermore, to distribute products commercially, we must comply with state laws requiring the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Recently, states have enacted or are considering legislation intended to make drug prices more transparent and deter significant price increases, typically as consumer protection laws. These laws may affect our future sales, marketing, and other promotional activities by imposing administrative and compliance burdens.

If our operations are found to be in violation of any of the laws or regulations described above or any other laws that apply to us, we may be subject to penalties or other enforcement actions, including criminal and significant civil monetary penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, corporate integrity agreements, suspension and debarment from government contracts and non-procurement transactions such as grants, and refusal of orders under existing government contracts, reputational harm, diminished profits and future earnings, 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. Any action against us for violation of these laws, even if we successfully defends against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

To the extent that any of our products are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to health care professionals.

Coverage and Reimbursement Generally

The commercial success of our product candidates and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental payor programs at the federal and state levels, including Medicare and Medicaid, private health insurers, and other third-party payors provide coverage for and establish adequate reimbursement levels for our product candidates. Government authorities, private health insurers, and other organizations generally decide which therapeutics they will pay for and establish reimbursement levels for health care. A growing trend in recent years is the containment of health care costs. Accordingly, governmental payors are increasingly trying control therapeutic prices through reimbursement restrictions, rebates, mandatory discounts, and formulary restrictions, among other strategies.

Medicare is a federal health care program administered by the federal government that covers individuals aged 65 and over as well as individuals with certain disabilities. Drugs and biologics may be covered under one or more sections of Medicare depending on the nature of the product and the conditions associated with and site of administration. For example, under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage for outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level.

Medicare Part B covers most injectable drugs and biologics given in an in-patient setting and some products administered by a licensed medical provider in hospital outpatient departments and doctors' offices. Medicare Part B is administered by Medicare Administrative Contractors, which generally have the responsibility of making coverage decisions. Subject to certain payment adjustments and limits, Medicare generally pays for a Part B-covered drug or biologic based on a percentage of manufacturer-reported Average Sales Price, which is regularly updated. We believe that our product candidates, which are intended to be administered by a health care professional in a clinical environment, will be subject to the Medicare Part B rules.

In the United States, the European Union, and other markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which often has resulted in average selling prices lower than they would otherwise be and sometimes at or below the provider's acquisition cost. In the United States, it is also common for government and private health plans to use coverage determinations to leverage rebates from sponsors in order to reduce the plans' net costs. These restrictions and limitations influence the purchase of health care services and products and lower the realization on sponsors' sales of prescription therapeutics. Third-party payors are developing increasingly sophisticated methods of controlling health care costs. Third-party payors may limit coverage to specific therapeutic products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication or might impose high copayment amounts to influence patient choice. Third-party payors also control costs by requiring prior authorization or imposing other dispensing restrictions before covering certain products and by broadening therapeutic classes to increase competition. 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. Absent clinical differentiators, third-party payors may treat products as therapeutically equivalent and base formulary decisions on net cost. To lower the prescription cost, sponsors frequently rebate a portion of the prescription price to the third-party payors. Recently, purchasers and third-party payors have begun to focus on value of new therapeutics and have sought agreements in which price is based on achievement of performance metrics.

Federal programs also impose price controls through mandatory ceiling prices on purchases by federal agencies and federally funded hospitals and clinics and mandatory rebates on retail pharmacy prescriptions paid by Medicaid and Tricare. By example, payment or reimbursement of prescription therapeutics by Medicaid or Medicare requires sponsors to submit certified pricing information to CMS. The Medicaid Drug Rebate statute and state statutes requires sponsors to calculate and report price points, which are used to determine mandatory rebate payments or negotiate supplemental rebate payments on both the state and federal level and Medicaid payment rates for certain therapeutics. For therapeutics paid under Medicare Part B, sponsors must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate. Furthermore, as a condition of receiving Medicare Part B reimbursement for eligible drugs or biologicals, the manufacturer is required to participate in other government health care programs, including the Medicaid Drug Rebate Program and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires biopharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of Department of Health & Human

Services (“DHHS”) as a condition for states to receive federal matching funds for the manufacturer’s outpatient therapeutic products furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program. In addition, therapeutics covered by certain government payor programs are subject to an additional inflation penalty which can substantially increase rebate payments. Certain states have also enacted laws that require that manufacturers report certain pricing information, including drug price increases. States laws may also limit the amount that prices may be increased or require negotiation of supplemental rebates for new drugs entering the market at price points determined to be high. Refusal to negotiate supplemental rebates can negatively affect market access and provider reimbursement.

Private payors often rely on the lead of the governmental payors in rendering coverage and reimbursement determinations. Therefore, achieving favorable CMS coverage and reimbursement is usually a significant gating issue for successful introduction of a new product. In addition, government programs as a condition of participation mandate fixed discounts or rebates from sponsors regardless of formulary position or utilization and may utilize mechanisms such as formulary placement to attain further price reductions, which can greatly reduce realization on the sale.

Further, the increased emphasis on managed health care in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement, and utilization, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, competition within therapeutic classes, judicial decisions and governmental laws and regulations related to Medicare, Medicaid, and health care reform, biopharmaceutical coverage and reimbursement policies, and pricing in general. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated health care costs. Sales of our product candidates will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or reimbursed by government health administration authorities, such as Medicare and Medicaid, private health insurers, and other third-party payors.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of our product candidate to currently available therapies (so called health technology assessment (“HTA”)) in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Other member states allow companies to fix their own prices for drug products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States, and prices generally tend to be significantly lower in the European Union.

As a result of the above, 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 marketing approvals in the United States and in other jurisdictions. Our product candidates may not be considered medically necessary or cost-effective, or the rebate percentages required to secure coverage may not yield an adequate margin over cost. Additionally, companies are increasingly finding it necessary to establish bridge programs to assist patient access to new therapies during protracted initial coverage determination periods.

Moreover, a payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved or that significant price concessions will not be required to avoid restrictive conditions. High health plan co-payment requirements may result in patients refusing prescriptions or seeking alternative therapies. 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 therapeutic development. 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. Legislative proposals to reform health care or reduce costs under government insurance programs may result in lower reimbursement for our products and product candidates or exclusion of our products and product candidates from coverage. The cost containment measures that health care payors and providers are instituting and any health care reform could significantly reduce our revenues from the sale of any approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

Health Care Reform Measures

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Moreover, among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access.

For example, the ACA has had a significant impact on the health care industry in the United States. The ACA expanded coverage for the uninsured while at the same time containing overall health care costs. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. Additionally, the CREATES Act, which became law on December 20, 2019, aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on any of our future commercial products are unknown.

Legislative and regulatory changes under the ACA are possible, but it is unknown what form any such changes or any law would take and how or whether it may affect the biopharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. In May 2019, DHHS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified a DHHS policy change that was effective January 1, 2019.

More recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 (the "IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single-source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against

CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In mid-2022, the Federal Trade Commission also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for health care products and services, including any future drug products for which we secure marketing approval.

The Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party, or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. Activities that violate the FCPA, even if they occur wholly outside the United States, can result in criminal and civil fines, imprisonment, disgorgement, oversight, and suspension and debarment from government contracts, and refusal of orders under existing government contracts.

European Union Drug Development

In the European Union ("European Union" or the "EU"), our product candidates and products, should they receive marketing authorization in the EU, will be subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

In April 2014, the Clinical Trials Regulation, (EU) No 536/2014, was adopted and it became effective on January 31, 2022. The Clinical Trials Regulation will be directly applicable in all of the European Union Member States ("EU Member States"), repealing the current Clinical Trials Directive 2001/20/EC. The extent to which ongoing clinical trials will be governed by the Clinical Trials Regulation will depend on when the clinical trial is initiated or on the duration of an ongoing trial. As of January 2023, all new clinical trials must comply with the Clinical Trials Regulation. In addition, any clinical trial that was already under way as of January 1, 2023 and continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable (i.e., January 31, 2025), the Clinical Trials Regulation will at that time begin to apply to the clinical trial.

The Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU portal" or Clinical Trial Information System ("CTIS"); a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each EU Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant

ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State.

To obtain a marketing authorization of a medicinal product in the European Union, we may submit marketing authorization applications ("MAA") either under the so-called centralized or national authorization procedures. Before granting the marketing authorization under any such procedures, described below, the EMA or the competent authorities of the individual member states make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Centralized procedure

The centralized procedure provides for the grant of a single marketing authorization following a favorable opinion by the European Medicines Agency ("EMA") that is valid in all EU Member States, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for medicines produced by specified biotechnological processes, products designated as orphan medicinal products, advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) and products with a new active substance indicated for the treatment of specified diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions and viral diseases. The centralized procedure is optional for products that represent a significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public health. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA 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 Committee for Medicinal Products for Human Use ("CHMP"). Accelerated assessment 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. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding stop-clocks.

National authorization procedures

There are also two other possible routes to authorize medicinal products in several European Union 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 Member State of medicinal products that have not yet been authorized in any EU Member State 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 may be sought from other EU Member States in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

European Data Collection

The collection, use, disclosure, transfer or other processing of personal data, including personal health data, in the EU is governed by the General Data Protection Regulation ("GDPR"). The GDPR applies to any company established in the European Economic Area ("EEA") and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, special provisions affording greater protection to and requiring additional compliance measures for "special categories of personal data" including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), "privacy by design" requirements, and direct obligations on service providers acting as processors.

The GDPR also prohibits the international transfer of personal data from the EEA to "non-adequate" countries outside of the EEA unless a valid data transfer mechanism has been put in place to safeguard the personal data, such as the Standard Contractual Clauses or certification under the newly-adopted Data Privacy Framework.

The GDPR also enhances enforcement authority and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the infringer, whichever is greater. Additionally, the GDPR confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

United Kingdom Regulation

As of January 1, 2021, EU law no longer directly applies in the United Kingdom ("United Kingdom" or the "UK"). The United Kingdom has adopted existing EU medicines regulation as standalone UK legislation with some amendments to reflect procedural and other requirements with respect to marketing authorizations and other regulatory provisions.

In order to market medicines in the United Kingdom, manufacturers must hold a UK authorization. On January 1, 2021, all EU marketing authorizations were converted to UK marketing authorizations subject to a manufacturer opt-out. UK medicines legislation is subject to future regulatory change under the Medicines and Medical Devices Act 2021, which sets out a framework for the adoption of medicines regulation. Guidance issued by the Medicines and Healthcare products Regulatory Agency ("MHRA") states that the United Kingdom will have the power to take into account marketing authorizations made under the EU decentralized and mutual recognition procedures. In addition, the MHRA's guidance has been updated to refer to UK-specific licensing procedures including routes of evaluation for novel and biotechnological products.

In Northern Ireland, however, EU central marketing applications will continue to apply.

The Trade and Cooperation Agreement between the EU and the United Kingdom contains an Annex in relation to medicinal products with the objective of facilitating availability of medicines, promotion of public health and consumer protection in respect of medicinal products. The Annex provides for mutual recognition of cGMP inspections and certificates, meaning that manufacturing facilities do not need to undergo duplicate inspections for the two markets. The Annex establishes a Working Group on Medicinal Products to deal with matters under the Trade and Cooperation Agreement, facilitate co-operation and for the carrying out of technical discussions. It is expected that further bilateral discussions will continue with respect to regulatory areas not the subject of the Trade and Cooperation Agreement, including pharmacovigilance. The Trade and Cooperation Agreement also does not include reciprocal arrangements for the recognition of batch testing certification. However, the United Kingdom has listed approved countries, including the EEA which will enable UK importers and wholesales to recognize certain certification and regulatory standards. The European Commission has not adopted such recognition procedures.

Relatedly, following the United Kingdom's withdrawal from the EU, the GDPR's requirements have been implemented in the United Kingdom (referred to as the "UK GDPR"). The UK GDPR sits alongside the amended UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into United Kingdom law. Under the UK GDPR, companies not established in the United Kingdom but who process personal data in relation to the offering of goods or services to individuals in the United Kingdom, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover. In June 2021, the European Commission issued a decision, valid for four years from its entry into force, that the United Kingdom ensures an adequate level of protection for personal data transferred under the EU GDPR from the EU to the United Kingdom.

Rest of the World Regulation

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. Additionally, clinical trials to support applications for marketing authorization in such jurisdictions must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

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.

Human Capital

As of December 31, 2023, we had 32 employees, all of whom were full-time, and of whom 10 have Ph.D. or M.D. degrees, and 19 are engaged in research and development and manufacturing activities. We do not have any employees represented by a labor union or covered under a collective bargaining agreement.

Talent Acquisition and Retention

We are committed to pioneering the development of immunotherapies for patients with limited treatment options and poor outcomes suffering from cancer and infectious disease. To that end, we recognize that our industry is specialized and dynamic, and a significant aspect of our success is our continued ability to execute our human capital strategy of attracting, engaging, developing and retaining highly skilled talent. We offer competitive compensation packages including base salary, annual incentive bonuses, and long-term equity incentive awards.

We also offer comprehensive and robust employee benefits, such as life, disability, and health insurance, health savings and flexible spending accounts, paid time off, and a 401(k) plan. We pride ourselves on our strong company culture and initiatives aligned with our mission, vision, and values. In addition, we strive to provide a collegial atmosphere where teamwork and collaboration are emphasized and valued. We use internal and external resources to recruit highly skilled candidates for open positions. It is our express intent to be an employer of choice in our industry by providing market-competitive compensation and benefits packages and we believe we are able to attract and retain superior talent as measured by our minimal turnover rate and high employee service tenure.

Diversity, Equity, and Inclusion

We believe a diverse workforce is critical to our success. Our mission is to value differences in races, ethnicities, religions, nationalities, genders, ages, and sexual orientations, as well as education, skill sets, and experience. We have a set of policies explicitly setting forth our expectations for nondiscrimination and a harassment-free work environment. We are also focused on inclusive hiring practices, fair and equitable treatment, organizational flexibility, and training and resources. We are a proud equal opportunity employer and cultivate a highly collaborative and entrepreneurial culture.

Training and Development

We believe in encouraging employees to become lifelong learners by providing ongoing learning and leadership training opportunities. We strive to provide real-time recognition of employee performance. In addition, we have a formal annual review process to determine individual contributions that may lead to pay and equity adjustments. The annual review process also helps us identify areas where training and development may be needed.

Corporate Information

On June 1, 2023, Elicio Operating Company, Inc. (“Former Elicio”) completed a merger transaction in accordance with the terms and conditions of the Agreement and Plan of Merger and Reorganization, dated as of January 17, 2023 (the “Merger Agreement”), by and among the Delaware corporation formerly known as “Angion Biomedica Corp.” (“Angion”), Arkham Merger Sub, Inc., a wholly owned subsidiary of Angion (“Merger Sub”), and Former Elicio, pursuant to which Merger Sub merged with and into Former Elicio, with Former Elicio surviving the merger as a wholly owned subsidiary of Angion (the “Merger”). Additionally, on June 1, 2023, Angion changed its name from “Angion Biomedica Corp.” to “Elicio Therapeutics, Inc.”

We and Former Elicio each have a principal executive office at 451 D Street, Suite 501, Boston, MA 02210.

Available Information

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). The SEC maintains an Internet site that contains reports, proxy information and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is http://www.sec.gov.

We maintain a public website at https://www.elicio.com and use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Our website includes an Investors section through which we make available, free of charge, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements and Forms 3, 4 and 5 filed on behalf of directors and executive officers, as well as any amendments to those reports filed or furnished pursuant to the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The members of our Board of Directors are reflected on the signature page of this annual report on Form 10-K. We also make available on our website the charters for our Board of Directors' Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, as well as our Code of Business Conduct and Ethics, and other related materials. The information on our website is not part of this annual report.

Item 1A. Risk Factor

Investing in our securities involves a high degree of risk. You should carefully consider the risk factors set forth below as updated by our subsequent filings under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), before deciding whether to purchase our securities. The risks and uncertainties we describe below are not the only ones we face. Additional risks and uncertainties not presently known to us could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities, and the occurrence of any of these risks might cause you to lose all or part of your investment.

Summary Risk Factors

We are subject to a number of risks that if realized could affect our business, financial condition, results of operations and cash flows. As a clinical stage biopharmaceutical company, certain elements of risk are inherent to our business. Accordingly, we encounter risks as part of the normal course of our business. Some of the more significant challenges and risks include the following:

- We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed, on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our research and development programs, commercialization efforts or cease operations.
- We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited consolidated financial statements for the year ended December 31, 2023 included in this Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC").
- We have incurred losses since inception, have never generated any revenue from product sales, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.
- We have identified material weaknesses in our internal control over financial reporting related to our control environment. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.
- Our product candidates are at an early stage of development and, except for our current clinical trials, we have not previously conducted clinical trials with our product candidates. We may not be able to effectively design and execute a clinical trial that supports marketing approval and may not successfully develop or commercialize our product candidates.
- Our clinical trial results may not support approval by the U.S. Food and Drug Administration ("FDA") or comparable foreign regulatory authorities and such failure to obtain regulatory approval of our product candidates would significantly harm our business, results of operations, and prospects.
- We may be unable to use and expand our discovery engine to build a pipeline of product candidates and progress such product candidates through preclinical or clinical development, which may result in us abandoning our development efforts, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.
- Due to our limited financial and managerial resources, we may focus on research programs and product candidates we identify for specific indications and may forego or delay other opportunities that may have greater commercial potential.
- There are a number of factors that can impact the enrollment of patients in our clinical trials. If we experience difficulties in enrolling patients, we could experience significant delays and we may need to abandon one or more clinical trials, or we may need to increase development costs for our product candidates which could materially impair our ability to generate revenues.
- Our product candidates may cause undesirable side effects, may not achieve the desired efficacy threshold, or have other properties or characteristics that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We may form or seek strategic partnerships or collaborations or enter into additional licensing arrangements with third parties and we may not realize the benefits of such transactions or arrangements.
- We rely on contract manufacturing organizations ("CMOs") to manufacture our product candidates and perform other manufacturing-related services. If these third parties do not successfully carry out their contractual duties, meet expected timelines, or otherwise conduct the trials as required or perform and comply with regulatory requirements, we may not be able to successfully complete clinical development, obtain regulatory approval or commercialize our product candidates when expected or at all, and our business could be substantially harmed. We face significant competition, and our competitors may achieve regulatory approval before us or develop safer, more advanced or effective therapies than we might develop.
- Our AMP platform is novel and any current or future product candidates may be too complex to manufacture and such complexities could lead to regulatory delays or production problems that could harm our business.

- Our success depends on our ability to obtain and maintain our intellectual property for our product candidates and their formulations.
- We are substantially dependent on patents we license from the Massachusetts Institute of Technology ("MIT") and if the licensed patent rights lack legal effect or if there is a dispute under the license agreement or changes to the scope of the agreement, it could lead to a material adverse effect on our business, financial condition, results of operations and prospects.
- Even if we obtain regulatory approval for our product candidates, we will remain subject to ongoing regulatory requirements. Maintaining compliance with ongoing regulatory requirements may result in significant additional expense to us, and any failure to maintain such compliance could subject us to penalties and cause our business to suffer.
- Healthcare and other legislative reform measures may have a materially negative impact on our business.
- Cybersecurity incidents, loss of data and other disruptions, including from cyberattacks, could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.
- The instability of the global credit and financial markets may adversely affect our business strategy, including our ability to secure necessary and timely financings, which may impact our financial performance, stock price and development of our product candidates.
- We will continue to incur significant legal, accounting and other expenses in order to comply with the laws, rules, and regulations associated with being a public company.

The above list is not exhaustive, and we face additional challenges and risks. Please carefully consider all of the information in this Annual Report on Form 10-K including matters set forth in this "Risk Factors" section.

Risks Related to Our Operating History, Financial Position and Capital Requirements

We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our research and development programs, commercialization efforts or cease operations.

Our operations have consumed substantial amounts of cash. During the years ended December 31, 2023 and 2022, we incurred research and development expenses of $23.8 million and $18.1 million, respectively. We will require substantial additional funds to support our continued research and development activities, including the anticipated costs of nonclinical studies and clinical trials, regulatory approvals and potential commercialization. Additionally, our estimates on future financial needs may be based on assumptions that prove to be wrong, and we may spend our available financial resources much faster than we expect.

Until such time, if ever, that we can generate sufficient product revenue and achieve profitability, we expect to seek to finance future cash needs through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including licensing arrangements, partnerships and collaborations with other companies or other strategic transactions. We currently have no other commitments or agreements relating to any of these types of transactions and cannot be certain that additional funding will be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity, convertible debt or other securities convertible into equity, the ownership interest of our stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect rights of our stockholders. Debt financing, if available at all, would likely involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, completing acquisitions or declaring or paying dividends.

Furthermore, the ongoing impact of COVID-19 and geopolitical instability, including the military conflict between Russia and Ukraine, the conflicts in the Middle East, and geopolitical tensions between the United States and China, as well as the impact of macroeconomic factors could make the terms of any available financing less attractive to us and more dilutive to our existing stockholders. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs or cease operations. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of our product candidates.

Our recurring losses from operations have raised substantial doubt regarding our ability to continue as a going concern.

We believe there is substantial doubt about our ability to continue as a going concern as of the date of this Annual Report on Form 10-K. Our independent registered public accounting firm has included an explanatory paragraph

relating to our ability to continue as a going concern in its report on our audited consolidated financial statements for the year ended December 31, 2023 included in this Annual Report on Form 10-K. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. We have incurred significant losses since our inception and have never been profitable, and it is possible we will never achieve profitability. We have devoted a majority of our resources to developing ELI-002, but this product candidate cannot be marketed until regulatory approvals have been obtained. Meaningful revenues will likely not be available unless ELI-002 or any of our current or future product candidates are approved by the FDA or comparable regulatory agencies in other countries and successfully marketed, either by us or a partner, an outcome which may not occur.

We believe that our cash on hand will enable us to fund our operations into the third quarter of 2024 based on our current plan. This period could be shortened if there are any significant increases in planned or actual spending on development programs or more rapid progress of development programs than anticipated. There is no assurance that financing will be available when needed to allow us to continue as a going concern. If we are unable to obtain additional capital and continue as a going concern, we might have to further scale back our operations or liquidate our assets and cease operations entirely, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. Our lack of capital resources and our conclusion that we may be unable to continue as a going concern may materially adversely affect our share price and our ability to raise new capital or to enter into critical contractual relations with third parties.

We may be unsuccessful in raising the capital necessary to address our going concern issues, or if we are successful, it may be on terms that are highly dilutive to existing stockholders.

Historically, we have funded our operations by raising capital from external sources and from the Merger. However, we are currently facing significant challenges to our ability to raise capital through the sale of common stock, including the following factors:

- in general, it is difficult for development stage companies to raise capital under current market conditions, especially those with early-stage programs like ours;
- the perception that we may be unable to continue as a going concern may impede our ability to attract further equity investment; and
- our common stock has limited trading volume, which limits the demand for our common stock.

Given these factors, there can be no assurances we will be successful at raising sufficient capital to address our going concern issues. Even if we are successful in raising capital, it may be on terms that are very highly dilutive to existing stockholders. In addition, if we are unable to raise additional capital, we may have to delay, curtail or eliminate one or more of our research and development programs or cease operations.

We have a history of operating losses that are expected to continue for the foreseeable future, and we are unable to predict the extent of future losses, or whether we will generate significant revenues or achieve or sustain profitability.

We are focused on product development and we have not generated any revenues to date. Additionally, we expect to continue to incur operating losses for the foreseeable future. These operating losses have adversely affected and are likely to continue to adversely affect our working capital, total assets and stockholders' deficit.

Since we are an early-stage company, our prospects must be considered in light of the uncertainties, risks, expenses, and difficulties frequently encountered by companies in their early stages of operations. Specifically, we have generated net losses each year since our inception, including $35.2 million and $28.2 million for the years ended December 31, 2023 and 2022, respectively. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit is expected to increase significantly as we expand development and clinical trial activities for our product candidates. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

We believe that our cash on hand will enable us to fund our operations into the third quarter of 2024 based on our current plan. We are dependent on obtaining, and are continuing to pursue, necessary funding from outside sources, including obtaining additional funding from the issuance of securities in order to continue our operations. Without adequate funding, we may not be able to meet our financial obligations.

We have not demonstrated an ability to perform the functions necessary for the successful commercialization of any products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

- continuing to undertake preclinical and clinical development;

- engaging in the development of product candidate formulations and manufacturing processes;
- interacting with the applicable regulatory authorities and pursuing other required steps for regulatory approval;
- engaging with payors and other pricing and reimbursement authorities;
- submitting marketing applications to and receiving approval from the applicable regulatory authorities; and
- manufacturing the applicable products and product candidates in accordance with regulatory requirements and, if ultimately approved, conducting sales and marketing activities in accordance with health care, FDA and similar foreign regulatory authority laws and regulations.

We have never generated revenue from product sales and may never become profitable.

We have no products approved for commercialization and have never generated any product revenue. Our ability to generate product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our current and future product candidates. We do not anticipate generating product sales for the next several years, if ever.

Our product candidates will require additional clinical, manufacturing, and non-clinical development, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before they generate any product sales. We cannot guarantee that we will meet our timelines for our development programs, which may be delayed or may not be completed for a number of reasons. Our ability to generate future revenues from product sales depends heavily on our, or our collaborators', ability to successfully:

- complete research and obtain favorable results from nonclinical and clinical development of our current and future product candidates, including addressing any clinical holds that may be placed on our development activities in the future by regulatory authorities;
- seek and obtain regulatory and marketing approvals for any of our product candidates for which we complete clinical trials, as well as their manufacturing facilities;
- launch and commercialize any of our product candidates for which we obtain regulatory and marketing approval by establishing a sales force, marketing, and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- qualify for coverage and establish adequate reimbursement by government and third-party payors for any of our product candidates for which we obtain regulatory and marketing approval;
- develop, maintain, and enhance a sustainable, scalable, reproducible, and transferable manufacturing process for the product candidates we may develop;
- establish and maintain supply and manufacturing capabilities or capacities internally or with third parties that can provide adequate, in both amount and quality, products, and services to support clinical development and the market demand for any of our product candidates for which we obtain regulatory and marketing approval;
- obtain market acceptance of current or any future product candidates as viable treatment options and effectively compete with other therapies to establish market share;
- maintain a continued acceptable safety and efficacy profile of our product candidates following launch;
- address competing technological and market developments;
- implement internal systems and infrastructure, as needed;
- negotiate favorable terms in any collaboration, licensing, or other arrangements into which we may enter and perform its obligations in such collaborations;
- maintain, protect, enforce, defend, and expand our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- avoid and defend against third-party interference, infringement, and other intellectual property claims; and
- attract, hire, and retain qualified personnel.

Even if one or more of our current and future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. If we are required to conduct additional clinical

trials or other testing of our product candidates that we develop beyond those that we currently expect, 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, or obtain more limited approvals. Even if we are able to generate revenues from the sale of any approved product candidates, we may not become profitable and may need to obtain additional funding to continue operations.

Even 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 our value and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in our value also could cause our stockholders to lose all or part of their investment.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology and preclinical and clinical development of our product candidates. We have not yet successfully completed any clinical trials for any of our product candidates, manufactured our product candidates at commercial scale or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates, if approved. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include other factors described elsewhere herein and also include, among other things:

- our ability to obtain additional funding to develop our product candidates;
- our ability to conduct and complete nonclinical studies and clinical trials;
- delays in the commencement, enrollment and timing of clinical trials;
- the success of our nonclinical studies and clinical trials through all phases of development;
- any delays in regulatory review and approval of product candidates in clinical development;
- our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions;
- potential toxicity and/or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved products, require the establishment of risk evaluation and mitigation strategies, cause an approved drug to be taken off the market or an inability to establish efficacy needed for approvals;
- our ability to establish or maintain partnerships, collaborations, licensing or other arrangements;
- market acceptance of our product candidates, if approved;
- competition from existing products, new products or new therapeutic approaches that may emerge;
- the ability of patients or health care providers to obtain coverage of or sufficient reimbursement for our products;
- our ability to leverage our proprietary AMP technology platform to discover and develop additional product candidates;
- our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; and
- potential product liability claims.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

We have identified material weaknesses in our internal control over financial reporting related to our control environment. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Pursuant to Section 404 ("Section 404") of the Sarbanes-Oxley Act of 2002,

as amended (the "Sarbanes-Oxley Act"), we are required to furnish a report by our management on our internal control over financial reporting in our periodic reports filed with the SEC. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify additional material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis.

We have identified material weaknesses in our internal control over financial reporting related to our control environment. More specifically, we have determined that we have not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate U.S. generally accepted accounting principles ("U.S. GAAP") technical expertise needed to identify, evaluate and account for complex and non-routine transactions. We have also determined that we have insufficient financial reporting and close controls to ensure that incurred expenses are accrued at period end. In addition, we have determined that we have not ensured calculations used in financial reporting are properly reviewed, including earnings per share ("EPS") and weighted average shares outstanding ("WASO") calculations as a result of a lack of finance and accounting staff with the appropriate U.S. GAAP technical expertise needed to identify, evaluate and review such calculations.

We have implemented, and over the next several months, we plan to implement additional measures to address the material weaknesses we have identified. We plan to design additional controls around identification, documentation and application of technical accounting guidance with particular emphasis on complex and non-routine transactions. These controls are expected to include an additional review process to ensure that the correct conclusions are reached with respect to complex and non-routine transactions and avoid the potential for a material misstatement of our financial statements. Additionally, we plan to engage SEC compliance and technical accounting consultants to assist in evaluating transactions for conformity with U.S. GAAP, as well as hire additional finance and accounting personnel to augment accounting staff and to provide more resources for complex accounting matters and financial reporting. However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

Any failure to remediate the material weaknesses we identified or any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to remediate the material weaknesses we identified or any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our stock price.

Section 404 of the Sarbanes-Oxley Act and the related rules and regulations of the SEC require annual management assessments of the effectiveness of our internal control over financial reporting. If we fail to maintain the adequacy of our internal control over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act and the related rules and regulations of the SEC. If we cannot favorably assess the effectiveness of our internal control over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts. The balance held in these accounts may exceed the Federal Deposit Insurance Corporation ("FDIC") standard deposit insurance limit of $250,000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

Changes in interpretation or application of U.S. GAAP may adversely affect our operating results.

We prepare our consolidated financial statements to conform to U.S. GAAP. These principles are subject to interpretation by the Financial Accounting Standards Board ("FASB"), American Institute of Certified Public Accountants, the SEC and various other regulatory and accounting bodies. A change in interpretations of, or our application of, these principles can have a significant effect on our reported results and may even affect our reporting of transactions completed before a change is announced. In addition, when we are required to adopt new accounting standards, our methods of accounting for certain items may change, which could cause our results of operations to fluctuate from period to period and make it more difficult to compare our financial results to prior periods.

Risks Related to the Development of our Product Candidates

Our product candidates are at an early stage of development and may not be successfully developed or commercialized.

In April 2023, we completed enrollment of the AMPLIFY-201 trial for ELI-002, our 2-peptide formulation, targeting Kirsten rat sarcoma viral oncogene homolog ("KRAS") gene mutations, which product candidate also includes ELI-004, our universal AMP-modified CpG adjuvant. In October 2023, we completed enrollment of the AMPLIFY-7P Phase 1 portion of the trial for ELI-002, our 7-peptide formulation, and initiated enrollment of the AMPLIFY-7P Phase 2 portion of the trial in January 2024. We have not previously conducted clinical trials with our product candidates. All of our other product candidates are in preclinical development and will require substantial further capital expenditures, development, testing, and regulatory approval prior to commercialization. With the limited data on ELI-002, we may not be able to effectively design and execute clinical studies that ultimately support marketing approval. In addition, we have not initiated or submitted for any marketing authorization to any health authorities.

The time required to obtain approval from the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. The outcome of studies is also inherently uncertain. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval process and are commercialized. The results of nonclinical studies, interim or top-line study results, and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. Nonclinical and early clinical studies may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies have suffered significant setbacks in advanced clinical trials, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in results between different clinical trials of the same product candidate due to numerous factors, including, among other things, differences in trial procedures set forth in protocols, differences in the type of the patient populations, changes in and adherence to the clinical trial protocols, the rate of dropout among clinical trial participants, and evolving standards of treatment from newly approved drugs.

Accordingly, even if we are able to obtain the requisite financing to fund our development programs, we cannot assure you that our product candidates will be successfully developed or commercialized. Our failure to develop, manufacture or receive regulatory approval for or successfully commercialize any of our product candidates could result in the failure of our business and a loss of all of our stockholders' investment.

Our product candidates are in various stages of development and we will not be able to commercialize our product candidates if our nonclinical and clinical studies do not produce successful results and/or our clinical trials do not demonstrate the safety and efficacy of our product candidates; early results and early understanding of product candidate potential may not be predictive of later success. Any product candidates currently in clinical development or that we advance into clinical development are subject to extensive regulation, which can be costly and time-consuming, and we may experience unanticipated delays or be unable to receive the required approvals to commercialize our product candidates.

Product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain. The results of nonclinical studies, preliminary clinical trial results, and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Our product candidates may not perform as we expect, may ultimately have a different than expected impact or no impact at all, may have a different mechanism of action than we initially understand or than we expect in humans, and may not ultimately prove to be safe or effective.

The nonclinical and clinical development, manufacturing, packaging, labeling, storage, record-keeping, advertising, promotion, post-approval monitoring and reporting, import, export, marketing and distribution, among other activities, of our product candidates are subject to extensive regulation by the FDA and by comparable health authorities in foreign markets. We are not permitted to market or promote our product candidates in the United States until we receive approval from the FDA of a Biologics License Application ("BLA"), or in any jurisdictions outside of the United States until we receive similar authorization from analogous foreign authorities, and we may never receive such regulatory approvals for any of our product candidates.

Some of our product candidates have only been tested in a nonclinical setting and while those studies have been subject to certain regulatory requirements in order to support product development and regulatory progression, as such product candidates progress they will require clinical trials (which are subject to much more extensive requirements, including good clinical practice standards), as well as additional manufacturing development, before we will be able to submit marketing applications to the applicable regulatory authorities. Even if our product candidates are approved, they may be subject to limitations on the indicated uses and populations for which they may be marketed. They may also be subject to other conditions of approval, may contain significant safety warnings, including boxed warnings, contraindications, and precautions, may not be approved with label statements necessary or desirable for successful commercialization, or may contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a risk evaluation and mitigation strategy ("REMS") to monitor the safety or efficacy of the products. If we do not receive regulatory authority approval for, and successfully commercialize our product candidates, we will not be able to generate revenue from these product candidates in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could have a material adverse impact on our business and financial condition.

The process of product candidate development and obtaining marketing approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved and the conditions that they are intended to treat. The number and nature of nonclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address and the regulations applicable to any particular product candidate. We have not previously submitted a marketing application to the FDA, or a similar marketing application to any comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval.

In addition to significant clinical testing requirements, our ability to obtain marketing approval for our product candidates depends on obtaining the final results of required nonclinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. Regulatory authorities may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations, or the type and amount of data necessary to gain approval, may change and may vary among jurisdictions. Moreover, regulatory authorities have substantial discretion in the biopharmaceutical approval process, including the ability to refuse to accept an application and to delay, limit or deny approval of a product candidate for many reasons, such as a determination that our data is insufficient for approval or that additional nonclinical studies, clinical trials or other data or development work is necessary. Despite the time and expense invested in the development of product candidates, regulatory approval is never guaranteed.

Our product candidates may fail at any stage of preclinical or clinical development, and may also reveal unfavorable product candidate characteristics, including safety concerns or the failure to demonstrate efficacy in initial clinical trials. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. Although we have completed preclinical validation, including toxicology testing, and anticipate completing the preclinical development necessary to file additional Investigational New Drug ("IND") applications for other product candidates in the future, we may experience numerous unforeseen events before, during, or as a result of clinical trials that could delay or prevent our ability to commence or complete development, commence or complete clinical trials, receive marketing approval or commercialize our product candidates, including:

- we may be unable to generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- regulators or institutional review boards ("IRBs") or Independent Ethics Committees ("IECs") may not authorize us or our investigators to commence or continue a clinical trial, conduct a clinical trial at a

prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;

- we, regulators, independent data monitoring committees ("IDMC"), IRBs, or IECs may recommend or require the suspension or termination of clinical research for various reasons, including non-compliance with regulatory requirements or a finding that participants are being exposed to unacceptable health risks, undesirable side effects, or a failure of the product candidate to demonstrate any benefit to subjects, or other unexpected characteristics (alone or in combination with other products) of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- new information may emerge regarding our product candidates or technology platform that result in continued development of some or all of our product candidates being deemed undesirable;
- we may have delays identifying, recruiting and training suitable clinical investigators or investigators may withdraw from our studies;
- we may experience delays in reaching, or failing to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or contract research organizations ("CROs"). Contractual terms can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- we may have delays in adding new clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- potential delays in patient enrollment for clinical trials due to public health emergencies pandemics, natural disasters, staffing shortages, or other events, which may affect our ability to initiate, conduct ongoing clinical trials, and delay initiation of planned and future clinical trials;
- 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 or be lost to follow-up at a higher rate than we anticipate for a number of reasons, such as adverse events, lack of treatment effectiveness, fatigue with the clinical trial process or personal issues, electing to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- patients who enroll in our studies may misrepresent their eligibility or may otherwise not comply with clinical trial protocols, resulting in the need to increase the enrollment size for those studies, or extend the duration of those studies;
- there may be flaws in our study design, which may not become apparent until a study is well advanced;
- our contractors may fail to comply with regulatory requirements or clinical trial protocols, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- regulatory authorities or IRBs or IECs may disagree with the design, including endpoints, scope, or implementation of our clinical trials, or regulatory authorities may disagree with the study patient population against our intended indications or our interpretation of data from nonclinical studies or clinical trials;
- regulatory authorities may disagree with the formulation for our product candidates, or our product candidate dose or dosing schedule;
- we may be unable to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe, pure, and potent for any indication;
- regulatory authorities may not accept, or we or our clinical trials may not meet, the criteria required to submit, clinical data from trials which are conducted outside of their jurisdictions;
- the results of clinical trials may be negative or inconclusive, may not meet the level of statistical significance required for, or may not otherwise be sufficient to support marketing approval, and we may decide, or regulatory authorities may require it, to conduct additional clinical trials, analyses, reports, data, or nonclinical studies, or abandon product development programs;
- our product candidates may have undesirable or unintended side effects, toxicities, or other properties or characteristics that preclude marketing approval or prevent or limit commercial use;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks or otherwise provide an advantage over current standard of care ("SOC") or current or future competitive therapies in development;

- the SOC for the indications we are investigating may change, which changes could impact the meaningfulness of our resulting study data or which may necessitate changes to our studies;
- regulatory authorities may disagree with our scope, design, including endpoints, implementation, or our interpretation of data from nonclinical studies or clinical trials;
- regulatory authorities may require us to amend our studies, perform additional or unanticipated clinical trials or nonclinical studies or manufacturing development work to obtain approval or initiate clinical trials, or we may decide to do so or abandon product development programs;
- regulatory authorities may find that we or our third-party manufacturers do not satisfy regulatory requirements and standards for the facilities and operations used in the manufacture of our product candidates;
- the cost of clinical trials of our product candidates may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA or other regulatory authorities upon the filing of a marketing application;
- 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;
- regulatory authorities may take longer than we anticipate to make a decision on our product candidates;
- we may be unable to demonstrate the efficacy and safety of our product candidates to the FDA or other regulatory authorities, due to inaccurate or inconsistent potency assessments, potentially resulting in regulatory delays, additional testing requirements, or even rejection of our product candidates;
- changes in regulatory guidelines of the FDA or other regulatory authorities may necessitate modifications to any future biological potency assays we may develop, requiring additional validation studies and potential delays in the development or commercialization of our product candidates; or
- changes in or the enactment of the approval policies, statutes, or regulations of the applicable regulatory authorities may significantly change in a manner rendering our nonclinical or clinical data insufficient for approval.

Additionally, our clinical trials, to date, have been open-label trials. Our Phase 2 study of AMPLIFY-7P is an open-label, randomized study, where both the patient and investigator know whether the patient is receiving our product candidate or is under observation, which may introduce study bias. Most typically, open-label clinical trials test only the product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received product candidate and may interpret the information of the treated group more favorably given this knowledge. Positive results observed in open-label trials may not be replicated in later clinical trials. Additionally, as patients become aware that they are not receiving our product candidate as part of the trial, they may elect to withdraw from our study and enroll in clinical trials sponsored by our competitors, which may extend our study timeline.

Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and, while we expect to enter into agreements governing their committed activities, we have limited influence over their actual performance.

A clinical trial may be suspended or terminated by us, our partners, the IRBs of the institutions in which such trials are being conducted, the IDMC for such trial or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug or therapeutic biologic, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of any of our potential future product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenue from such product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow our product development and approval process and jeopardize our ability to commence product sales and generate revenue, and we may not have the financial resources to continue development of the product candidate that is affected or any of our other product candidates. We may also lose, or be unable to enter into, collaborative arrangements for the affected product candidate and for other product candidates that we are developing. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our potential future product candidates.

Preliminary results from our nonclinical studies and clinical trials that we announce or publish from time to time may change as more patient data becomes available and as the data undergoes audit and verification procedures.

From time to time, we may publish interim, topline, or preliminary results from our nonclinical studies and clinical trials. Preliminary and interim results from our clinical trials are not necessarily predictive of final results and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary, interim and topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary, interim and topline data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the preliminary, interim or topline data could significantly harm our business prospects.

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

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans and we may fail to obtain regulatory approval of our product candidates.

The FDA standard for approval of a biologic generally requires two adequate, well-controlled clinical trials, each convincingly demonstrating the product candidate's safety and effectiveness, or one large and robust, well-controlled trial providing substantial evidence that the product candidate is safe and effective for its proposed indication. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. Product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA usually requires a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals.

Our clinical trial results may not support either accelerated or regular approval. The results of nonclinical studies and clinical trials may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;

- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to satisfy the FDA or comparable foreign regulatory authorities or to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer's facilities with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve our analytical testing methods, particularly with respect to bioassay potency testing;
- we may fail to develop a potency assay for ELI-002 that is satisfactory for the FDA or comparable foreign regulatory authorities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

We may not be successful in our efforts to use and expand our discovery engine to build a pipeline of product candidates.

A key element of our strategy is to use and expand our discovery engine to build a pipeline of product candidates and progress these product candidates through preclinical and clinical development for the treatment of various diseases. Although our research efforts to date suggest that complex amphiphilic molecules can deliver conventional immunomodulatory payloads including peptides, proteins and nucleic acids directly and preferentially to lymph nodes, this hypothesis may prove incorrect, or we may not be able to identify a product candidate that is safe or effective as a treatment for various cancers or for other diseases. We also may not be able to identify an amphiphile product candidate that we can demonstrate to be safe or effective, and we may not be able to develop any other product candidates. Our scientific research that forms the basis of our efforts to discover product candidates based on our discovery engine is ongoing. Further, the scientific evidence to support the feasibility of developing viable product candidates based on our platform has not been established. Our discovery engine may not be proven to be superior to competing technologies.

Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our platform may not be successful in identifying additional product candidates;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in nonclinical or clinical testing;
- a product candidate may upon further study demonstrate harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Even if we receive FDA approval to market additional product candidates, whether for the treatment of cancers or other diseases, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

Our ELI-002 clinical trials are designed to require, as part of screening to determine whether subjects meet inclusion criteria, the use of an investigational in vitro diagnostic device. If we are not able to successfully collaborate or partner with a third-party company for the development and authorization of such a device, we may not be able to receive marketing authorization for ELI-002.

The clinical trials for ELI-002 (AMPLIFY-201 and AMPLIFY-7P) employ an investigational in vitro diagnostic device ("IVD"), that identifies gene mutations in KRAS and neuroblastoma rat sarcoma viral oncogene homolog ("NRAS") genes and detects circulating tumor DNA ("ctDNA"), to identify patients who show signs of minimal residual disease in their blood, but before relapse is detected in traditional radiographic scans. Based on our Phase 1 and Phase 2 study design, we must account for and address the investigational status of this device from a regulatory perspective through the course of clinical development (for example, through the compliance with any applicable investigational device exemption requirements). An IVD used to select patients who may be appropriate to receive our commercial product will be considered a companion diagnostic device. Companion diagnostic devices are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and we anticipate that separate regulatory marketing authorization will be required for the device prior to commercialization of ELI-002. We plan to collaborate with appropriate companion diagnostic developers to seek marketing authorization from the FDA's Center for Devices and Radiological Health ("CDRH"). If our companion diagnostic partner experiences any delays in development or is not able to successfully develop and obtain marketing authorization for its companion diagnostic, or does not comply with the FDA's medical device regulations:

- the development and commercialization of ELI-002 may also be delayed because in most circumstances, FDA expects the companion diagnostic and its corresponding therapeutic product to be approved contemporaneously by the FDA;
- ELI-002 may not receive marketing approval if its safe and effective use depends on a companion diagnostic and none is commercially available; and
- We may not realize the full commercial potential of ELI-002 if it receives marketing approval and, among other reasons, we are unable to appropriately identify patients or types of tumors with the specific genetic alterations targeted by ELI-002.

Even if ELI-002 and any associated companion diagnostics are approved for marketing, the need for companion diagnostics may slow or limit adoption of ELI-002. Although we believe genetic testing is becoming more prevalent in the diagnosis and treatment of cancer, ELI-002 may be perceived negatively compared to alternative treatments that do not require the use of companion diagnostics, either due to the additional cost of the companion diagnostic or the need to complete additional procedures to identify relevant biomarkers prior to administering our product candidates.

If any of these events were to occur, our business and growth prospects would be harmed, possibly materially.

We may seek designations under FDA programs designed to facilitate and potentially expedite product candidate development, such as fast track or breakthrough therapy designation. Our product candidates may not receive any such designations or if they do receive such designations it may not lead to faster development or regulatory review or approval and it does not increase the likelihood that its product candidates will receive marketing approval.

We may seek designations under the FDA's expedited programs for serious conditions, such as fast track or breakthrough therapy designation, which are intended to facilitate and expedite the development or regulatory review or approval process for product candidates. Descriptions of the fast track and breakthrough therapy designations are included under "*Description of Our Business—Government Regulation and Product Approval—Fast Track, Breakthrough Therapy and Priority Review Designations*."

The granting of fast track or breakthrough therapy designation to an investigational product is entirely within the FDA's discretion. Accordingly, even if we believe one of our product candidates meets the criteria for a designation, the FDA may disagree and instead determine not to grant such designation. In any event, the receipt of a fast track

or breakthrough therapy designation for a product candidate may not result in a faster development process, review, or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate marketing approval by the FDA. In addition, the FDA may later decide that the product candidate no longer meets the designation conditions, in which case any granted designations may be revoked, or the agency may decide that the time period for review or approval of the product candidate will not be shortened.

If we are unable to obtain approval via the accelerated approval pathway, we may be required to conduct additional nonclinical studies or clinical trials. Even if we receive accelerated approval from the FDA, the FDA may seek to withdraw accelerated approval.

We may seek an accelerated approval development pathway for our product candidates. See "*Description of Our Business—Government Regulation and Product Approval—Accelerated Approval*" for a description of the accelerated approval pathway.

If we choose to pursue accelerated approval, we intend to seek feedback from the FDA or will otherwise evaluate our ability to seek and receive such accelerated approval. After our evaluation of the feedback from the FDA or other factors, we may decide not to pursue or submit a BLA for accelerated approval or any other form of expedited development, review or approval. Furthermore, if we submit an application for accelerated approval, there can be no assurance that such application will be accepted or that approval will be granted on a timely basis, or at all. The FDA also could require us to conduct further studies or trials prior to considering our application or granting approval of any type, and may require us to have a confirmatory trial to verify the clinical benefit of the product underway and partially or fully enrolled before granting approval. We might not be able to fulfill the FDA's requirements in a timely manner, which would cause delays, or approval might not be granted because our submission is deemed incomplete by the FDA.

Even if we receive accelerated approval from the FDA, we will be subject to rigorous post-marketing requirements, including the completion of confirmatory post-market clinical trials, submission to the FDA of periodic progress reports on confirmatory trials, and submission to the FDA of all promotional materials prior to their dissemination. The FDA could seek to withdraw accelerated approval for multiple reasons, including if we fail to conduct any required post-market study with due diligence; a post-market study does not confirm the predicted clinical benefit; other evidence shows that the product is not safe or effective under the conditions of use; or we disseminate promotional materials that are found by the FDA to be false and misleading. Under the Consolidated Appropriations Act for 2023, the FDA may use expedited procedures to withdraw any product for which we receive accelerated approval if our confirmatory trials fail to verify the purported clinical benefits.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for a product candidate that we may choose to develop would delay our commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

If we apply for orphan drug designation from the FDA, there is no guarantee that we will be able to obtain or maintain this designation, receive this designation for any of our other product candidates, or receive or maintain any corresponding benefits, including periods of exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation for a biologic must be requested before submitting a BLA. 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. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a biologic that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the product was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other drugs or biologics that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for some or all of our product candidates in specific orphan indications for which there is a medically plausible basis for their use, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Any future product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our amphiphile product candidates are expected to be regulated by the FDA as biological products, and we intend to seek approval for these product candidates pursuant to the BLA pathway. The enactment of the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) created an abbreviated pathway for the approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient’s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own nonclinical studies and clinical trials. In such a situation, any exclusivity for which our products candidates may be eligible under the BPCIA would not prevent the competitor from marketing a product similar or identical to our biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects who remain in the trial until its conclusion. We may not be able to initiate or continue conducting clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible subjects to participate in these trials. The enrollment of patients depends on many factors, including:

- the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for subjects and clinical trial sites;
- the severity of the disease under investigation and the existence of current treatments;
- the perceived risks and benefits of the product candidate, including the potential advantages or disadvantages of the product candidate being studied in relation to other available therapies;
- the subject eligibility criteria defined in the protocol, as well as our ability to compensate subjects for their time and effort;
- the size and nature of the patient population;
- the proximity and availability of clinical trial sites for prospective subjects;
- the design of the trial, including factors such as frequency of required assessments, length of the study and ongoing monitoring requirements;
- subjects' and investigators' ability to comply with the specific instructions related to the trial protocol, proper documentation, and use of the product candidate;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- patient referral practices of physicians and the effectiveness of publicity created by clinical trials sites regarding the trial;
- the ability to adequately monitor subjects during and after treatment and compensate them, as applicable, for their time and effort;
- the ability of our clinical study sites, CROs, and other applicable third parties to facilitate timely enrollment;
- the ability of clinical trial sites to enroll subjects that meet all inclusion criteria and any patient exclusion due to erroneous enrollment;
- our ability to obtain and maintain subject informed consents;
- the ability of clinical trial sites to enroll patients due to public health emergencies or pandemics, natural disasters, staffing shortages, or other events; and
- the risk that subjects enrolled in clinical trials will drop out of the trials before completion of the study or not return for post-study follow-up, especially subjects in control groups, due to reasons such as, adverse events, lack of treatment effectiveness, fatigue with the clinical trial process or personal issues, electing to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, rather than enroll patients in any of our future clinical trials.

Our inability to enroll a sufficient number of subjects for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Moreover, a significant number of withdrawn subjects would compromise the quality of our data. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, or the inability to complete development of our product candidates, which could cause our value to decline, limit our ability to obtain additional financing, and materially impair our ability to generate revenues.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent our regulatory approval or commercialization or limit our commercial potential.

As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects caused by any current or future product candidate could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. We initiated dosing of the AMPLIFY-201 trial of our 2-peptide formulation of ELI-002 in October 2021, our 7-peptide formulation of ELI-002, the AMPLIFY-7P trial, began dosing in April 2023. We initiated enrollment of the Phase 2 of the AMPLIFY-7P trial in January 2024 and we have not yet initiated clinical trials for any other product candidates. ELI-002, through the course of the AMPLIFY-201 and AMPLIFY-7P trials to date, has shown to induce mild to moderate side effects, such as fatigue, malaise, injections site reactions and myalgia. If we initiate future clinical trials for any other current or future product candidates or continue to advance the AMPLIFY-201 or AMPLIFY-7P studies, it is likely that there will be new or additional side effects associated with the use of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these side effects. In such an event, our trials could be suspended or terminated, and the FDA or other regulatory authorities could place a clinical hold or order us to cease further development of or deny approval of a product candidate for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business and financial condition and impair our ability to generate revenues.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

If one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approvals of such products;
- regulatory authorities may require the addition of labeling statements, specific warnings or contraindications;
- we may be required to create a REMS plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for health care providers, and/or other elements to assure safe use;
- we may be required to change the way such products are distributed or administered, or change the labeling of the products;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the products;
- we may decide to recall such products from the marketplace after they are approved;
- we could be sued and held liable for harm caused to individuals exposed to or taking our products; and
- our reputation may suffer.

In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

We may form or seek strategic partnerships or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

From time to time, we may form or seek strategic partnerships or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may

develop. Any such relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. These relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to our other development activities. Additionally, any collaborations, or licensing arrangements would be subject to the same product candidate development and compliance risks and obligations as we would be if we were to develop the product candidate on our own. Should any third party with which we enter into any of these arrangements not comply with the applicable regulatory requirements, we or they may be subject to regulatory enforcement action and we or they may be delayed or prevented from obtaining marketing approval for the applicable product candidate. Any collaborations, or licensing arrangements may pose a number of risks, including the following:

- any third party with which we enter into any of these arrangements often have significant discretion in determining the efforts and resources that they will apply to the arrangement and may not commit sufficient resources to the development, marketing or commercialization of the product or products that are subject to the arrangement;
- third parties may not perform their obligations as expected or may breach or terminate their agreements with us or otherwise fail to conduct their collaborative or licensing activities successfully and in a timely manner;
- any such collaboration, partnership, or licensing arrangement may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to us;
- third parties may cease to devote resources to the development or commercialization of our product candidates if the partners view our product candidates as competitive with their own products or product candidates;
- disagreements with third parties, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time consuming, distracting and expensive;
- third parties may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from the arrangement;
- third parties may infringe the intellectual property rights of other third parties, which may expose us to litigation and potential liability;
- the collaborations, partnerships, or licensing arrangements may not result in us achieving revenues sufficient to justify such transactions;
- by entering into certain collaborations, partnerships, or licensing arrangements, we may forego opportunities to collaborate with other third parties who do not wish to be associated with our existing third-party strategic partners; and
- such arrangements may be terminated and, if terminated, may result in a need for us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangement for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort, and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. Any licensed products or acquired businesses may also subject us to the risk of regulatory enforcement should the product or business not be compliant with applicable regulatory requirements. We cannot be certain that, following a strategic transaction or licensing arrangement, we will achieve the revenue or specific net income that justifies such a transaction.

We rely on CMOs to manufacture our nonclinical and clinical pharmaceutical supplies and expect to continue to rely on CMOs to produce commercial supplies of any approved product candidate, and our dependence on CMOs could adversely impact its business.

We rely on CMOs for the manufacture of nonclinical and clinical supplies of our product candidates and plan to continue to do so for commercial supplies should we receive marketing approval for any of our product candidates.

This reliance also results in our reduced control over the manufacture of our product candidates and the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure, which may adversely affect our future business prospects. Nevertheless, as the developer of the product candidates and sponsor of clinical trials involving such product candidates, we continue to have regulatory obligations to maintain oversight of the CMOs to ensure compliance with, among other things, contractual obligations, specifications, and current good manufacturing practices ("cGMP").

In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, including but not limited to, several complex release tests, including tests for biological potency, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. Although our agreements with our CMOs require them to perform according to certain cGMP, such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If our CMOs do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties, or if such parties are unable to support the commercialization of any of our product candidates for which we obtain marketing approval, we may not be able to produce, or may be delayed in producing sufficient product to meet our supply requirements. Any delays in obtaining adequate supplies on adequate terms with respect to our product candidates and components, due to manufacturing issues, global trade policies, or for other reasons, may delay the development, approval, or commercialization of our product candidates.

We may not succeed in our efforts to establish manufacturing relationships on commercially reasonable terms. Our product candidates may compete with other products and product candidates for access to manufacturing facilities, of which there are a limited number that operate under cGMP conditions and that are both capable of manufacturing our product candidates and willing to do so. Even if we do establish such collaborations or arrangements, our CMOs may breach, terminate, or not renew these agreements. These facilities may also be affected by general economic conditions, including but not limited to political unrest, global trade wars, natural disasters, such as floods or fires, acts of war, terrorism, or disease outbreaks, or such facilities could face manufacturing issues, such as contamination or adverse regulatory findings following a regulatory inspection. CMOs may also be subject to power failures and/or other utility failures or experience the breakdown, failure, substandard performance or improper installation or operation of equipment in the manufacturing process. Further, our CMOs may be temporarily unable to manufacture our product candidates due to government restrictions, requirements, or limitations. If our CMOs cease to manufacture our product candidates for any reason, we would experience delays in obtaining sufficient quantities of our product for us to meet commercial demand if we receive marketing approval or in advancing our development programs while we identify and qualify replacement suppliers. We could also incur added costs and delays in identifying and qualifying any such replacements and transferring any necessary technology and processes. The terms of a new arrangement may also be less favorable than any prior arrangements, if we are able to negotiate a new arrangement at all. The addition of a new or alternative CMO may also require FDA approval and may have a material adverse effect on our business.

We or our CMOs may also encounter shortages in the raw materials or substances necessary to produce our product candidates in the quantities and at the quality needed for our nonclinical studies and clinical trials or, if any of our product candidates are approved for commercialization, to produce our products on a commercial scale, meet an increase in demand, or compete effectively. Such shortages may occur for a variety of reasons, including capacity constraints, delays or disruptions in the market, and shortages caused by the purchase of such materials by our competitors or others. Our or our third-party manufacturers' failure to obtain the raw materials or substances necessary to manufacture sufficient quantities of our product candidates may have a material adverse effect on our business.

Moreover, any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate or component, including manufacturing validation, may result in a delay in a future marketing approval, if any, or commercial launch of any of our product candidates, should they receive regulatory approval, or may impair our ability to manufacture commercial quantities or manufacture such quantities at an acceptable cost, which could result in the delay, prevention, or impairment of commercialization of our product candidates, if approved, and could adversely affect our business. Furthermore, if the future manufacturers of the commercial supplies of our products, if approved, fail to deliver the required commercial quantities of our product candidates on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we could lose potential revenues. The manufacture of biological products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of biologics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, and compliance with strictly enforced federal, state, and foreign regulations. If our manufacturers were to encounter any of these difficulties and were unable to perform as agreed,

our ability to provide our product candidates for use in nonclinical studies or our current and planned clinical trials, or, if any of our product candidates are approved, our ability to produce our product for commercial use, could be jeopardized.

In addition, all manufacturers of our product candidates used in clinical trials and of our products for commercial supply, should any of our product candidates receive regulatory approval, must comply with cGMP regulations promulgated by the FDA and equivalent foreign regulatory authorities that are applicable to both finished products and their active components used both for clinical and commercial supply. Regulatory authorities enforce these requirements through facility inspections. CMO facilities must be satisfactory to the FDA and equivalent foreign regulatory authorities as determined by inspections that will be conducted after we submit our marketing applications to the appropriate agencies and prior to product approval and commercialization. Our CMOs will also be subject to continuing, periodic regulatory authority inspections should our product candidates receive marketing approval. Further, we, in cooperation with our CMOs, must supply all necessary chemistry, manufacturing, and control documentation to the FDA and equivalent foreign regulatory authorities in support of a marketing application on a timely basis.

The cGMP include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with our specifications, cGMP or with other applicable regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our CMOs cannot successfully manufacture material that conforms to our specifications and the applicable regulatory requirements, they may not be able to secure or maintain regulatory acceptance of their manufacturing facilities for the purpose of producing our product candidates.

Deviations from manufacturing requirements may also require reporting and remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales, if any of our product candidates receives regulatory approval, or the temporary or permanent closure of a facility. Any such remedial measure could materially harm our business. Any delay in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to nonclinical studies and clinical trials, or potential product approvals or commercialization. Any such delay may also require that we conduct additional studies.

While we are ultimately responsible for the manufacture and regulatory compliance of our products and product candidates, we have little control over our manufacturers' compliance with these regulations and standards other than through our contractual arrangements. If the FDA or a comparable foreign regulatory authority does not find these facilities satisfactory for the manufacture of our products, if approved, or product candidates, or if such authorities find such facilities to be noncompliant in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain and maintain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA or other relevant comparable regulatory authority approval for the use of any new manufacturers for commercial supply.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulatory requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, suspension of or restrictions on production, injunctions, delay, withdrawal or denial of product approval or supplements to approved products, clinical holds or termination of clinical studies, warning or untitled letters, regulatory authority communications warning the public about safety issues with a product, refusal to permit the import or export of a product, product seizure, detention, or recall, operating restrictions, civil penalties, criminal prosecution, corporate integrity agreements, or consent decrees and equivalent foreign sanctions. Depending on the severity of any potential regulatory action, supplies of our product candidates or products, if approved, could be interrupted or limited, which could have a material adverse effect on our business.

A portion of the manufacturing for our product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China, or a change in the regulatory framework in the United States or China, could materially adversely affect our business, financial condition and results of operations. The recently proposed BIOSECURE Act is aimed at discouraging federal contracting with certain Chinese biotechnology companies for biotechnology equipment or services and the enactment and implementation of the BIOSECURE Act has the potential to impact supply of our product candidates. Additionally, if following the enactment and implementation of the BIOSECURE ACT we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. We anticipate that the complexity of the manufacturing process may impact the amount of time it may take to secure a replacement manufacturer and such delays could negatively affect our ability to develop product candidates in a timely manner or within budget, which could materially adversely affect our business, financial condition and results of operations.

We rely on third parties to conduct some of our nonclinical studies and all of our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required, our development programs could be delayed or unsuccessful and we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We do not have the ability to conduct all aspects of our clinical trials ourselves and do not currently plan to independently conduct clinical trials. We use third parties, such as CROs, to conduct, supervise, and monitor the AMPLIFY-201 and AMPLIFY-7P trials and will rely upon such CROs, as well as medical institutions, investigators and consultants, to conduct these trials and any future clinical trials that we may conduct in accordance with our protocols and applicable laws and regulations. In addition, we occasionally use third parties to conduct our nonclinical studies. Our CROs, investigators and other service providers play a significant role in the conduct of these trials and the subsequent collection and analysis of data from such trials.

Our service providers are not our employees and, except for remedies available to us under our agreements with such third parties, we will have less control over the timing, quality and other aspects of such nonclinical studies and clinical trials than we would have if we were to conduct them on our own. If these third parties do not successfully carry out their contractual duties to us, meet our expected timelines or conduct our nonclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or applicable regulatory requirements or for other reasons, our trials may need to be repeated, extended, delayed, or terminated. Further, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, we may fail or be delayed in our efforts to successfully commercialize our product candidates, if approved. Such failures may also subject us or our third-party service providers to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates could be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of service providers in the future, our business may be materially and adversely affected. Our third-party service providers may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position.

Agreements with third parties conducting or otherwise assisting with our nonclinical studies or clinical trials might terminate for a variety of reasons, including a failure to perform by such parties. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with suitable alternative providers or do so on commercially reasonable terms. Switching or adding third parties involves additional cost and requires management time and focus. There is also a natural transition period when a new third party commences work. As a result, if we need to enter into alternative arrangements, we may need to delay our product development activities and our business could be adversely affected. Although we carefully manage our relationships with our third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects, and results of operations.

Our reliance on third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our oversight and regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for that trial. We must also ensure that our nonclinical studies are conducted in accordance with good laboratory practice (“GLP”) requirements, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with established good clinical practice (“GCP”) standards for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP conditions. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical and nonclinical investigators, manufacturers, and trial sites. If we or any of our third-party service providers fail to comply with applicable regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies, which may significantly delay our clinical development plans and the regulatory approval process. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that we, our third-party service providers, or clinical trial sites is in substantial compliance with the applicable regulatory requirements.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest. We are also required to register certain clinical trials and post the results of certain completed

clinical trials on a government-sponsored database, clinicaltrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

We rely on other third parties to store and distribute our product candidates for nonclinical studies and clinical trials that we conduct.

We also rely on other third parties to store and distribute our product candidates for the nonclinical studies and clinical trials that we are conducting or plan to conduct. Any performance failure, or failure to comply with applicable regulations, on the part of our distributors could delay development, the regulatory approval process, or potential commercialization of our product candidates, producing additional losses and depriving us of potential product revenue.

We may incur substantial product liability or indemnification claims relating to the clinical testing of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and claims could be brought against us if the use or misuse of one of our product candidates causes, or merely appears to have caused, personal injury or death. We will face an even greater risk of product liability if we receive marketing approval for and commercialize any of our product candidates. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and approved products, if any. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products.

There is a risk that our future product candidates may induce adverse events. Patients with the diseases targeted by our product candidates may already be in severe or advanced stages of disease and have both known and unknown significant preexisting and potentially life-threatening health risks. During the course of treatment, subjects may suffer adverse events, including death, for reasons that may be related to our product candidates. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured subjects, delay, negatively impact or end our opportunity to receive or maintain regulatory approval to market our products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which an adverse event is unrelated to our product candidates, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may delay our regulatory approval process or impact and limit the type of regulatory approvals our product candidates receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could have a material adverse effect on our business, financial condition or results of operations. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim. For instance, product liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- incurred costs and time of related litigation;
- substantial monetary awards to patients or other claimants, and loss of revenue;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decrease in our stock price;
- initiation of investigations, and enforcement actions by regulators; and/or
- product recalls, withdrawals, revocation of approvals, or labeling, marketing or promotional restrictions.

If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit development or commercialization of our products or product candidates. Although we maintain product liability and clinical trial insurance coverage, it may be inadequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as we continue clinical development of our product candidates and if we successfully commercialize any medicine. 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 Business, Industry and Future Commercialization

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, health care payors and the medical community, the revenues that we generate from sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, health care payors and the medical community. Market acceptance of our products by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond its control, including:

- the efficacy of our products and the prevalence and severity of any adverse events;
- any potential advantages or disadvantages when compared to alternative treatments;
- interactions of our products with other medicines patients are taking and any restrictions on the use of our products together with other medications;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for such product candidates, which could reduce the marketing impact of any claims that we could make following approval, if obtained;
- the safety, efficacy, and other potential advantages over alternative treatments, such as relative convenience and ease of administration of such products, and the availability of alternative treatments already used or that may later be approved;
- cost of treatment versus economic and clinical benefit in relation to alternative treatments or therapies;
- the availability of formulary coverage and adequate coverage or reimbursement by third parties, such as insurance companies and other health care payors, and by U.S. and international government health care programs, including Medicaid and Medicare;
- the price concessions required by third-party payors and government health care programs to obtain coverage and payment;
- the extent and strength of our marketing and distribution of such products;
- distribution and use restrictions imposed by the FDA and equivalent foreign regulatory authorities with respect to such products or to which we agree, for instance, as part of a REMS or voluntary risk management plan;
- the timing of market introduction of such products, as well as competitive products;
- our ability to offer such products for sale at competitive prices;
- our ability to offer programs to facilitate market acceptance and insurance coverage from public and private insurance companies, provide patient assistance, and transition patient coverage;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the approval of other new products, including biosimilar products that may be priced at a substantially lower price than we expect to offer our product candidates for, if approved;
- adverse publicity about the product or favorable publicity about competitive products;
- support from patient advocacy groups;
- the success of any efforts to educate the medical community and third-party payors regarding our products, which efforts may require significant resources and may not be successful; and
- potential product liability claims.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, health care payors and patients, we may not generate sufficient revenue from these products and may not become or remain profitable.

Our ability to negotiate, secure and maintain third-party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third-party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any drug or biologic candidate of ours that receives marketing approval in the future.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market any product candidates we may develop, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and we have limited experience in the sale, marketing, or distribution of pharmaceutical products. To achieve commercial success for any approved medicine for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to third parties. In the future, we may choose to build a focused sales, marketing, and commercial support infrastructure to sell, or participate in sales activities with our collaborators for, some of our current and future product candidates if and when they are approved.

There are risks involved with both establishing and managing our own commercial capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force or reimbursement specialists is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing and other commercialization capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our commercialization personnel.

Factors that may inhibit our efforts to commercialize product candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales, marketing, reimbursement, customer service, medical affairs, and other support personnel;
- the inability of sales personnel to obtain access to physicians to discuss our products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement, and other acceptance by payors, and to secure adequate coverage;
- reduced realization on government sales from mandatory discounts, rebates and fees, and from price concessions to private health plans and pharmacy benefit managers necessitated by competition for access to managed formularies;
- the clinical indications for which the products are approved and the claims that we may make for the products, as well as any limitations on use or warnings;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions, and any liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- restricted or closed distribution channels that make it difficult to distribute our products to different segments of the patient population;
- the lack of complementary medicines to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent commercialization organization.

If we enter into arrangements with third parties to perform sales, marketing, commercial support, and distribution services, our product revenues or the profitability of these product revenues to us may be lower than if we were to market and sell any product we may develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to commercialize our products or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish commercialization capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any products we may develop.

We face significant competition in an environment of rapid technological change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more

advanced or effective than ours, which may harm our financial condition and our ability to successfully market or commercialize any product candidates we may develop.

The development and commercialization of new therapeutic biologics is highly competitive. Moreover, the immunotherapy field is characterized by rapidly changing technologies, significant competition, and a strong emphasis on intellectual property. We will likely face competition with respect to any product candidates that we may seek to develop or commercialize in the future from numerous pharmaceutical and biotechnology organizations, as well as from academic institutions, government agencies and other public and private research organizations for our current and future product candidates. Our commercial success may be reduced or eliminated and our business, financial condition, results of operations, and prospects may be harmed if our competitors develop products that are safer, more effective or less costly than ours.

A number of well-resourced pharmaceutical and biotechnology companies with established relationships with patient organizations are developing products to inhibit RAS mutated cancers. These products, as well as marketing campaigns by competitors and clinical trial results with competitive products, could significantly diminish our ability to market and sell ELI-002 for RAS mutated cancers, if approved. For example, Amgen Inc. (“Amgen”), Mirati Therapeutics, Inc. (“Mirati”), a wholly owned subsidiary of Bristol Myers Squibb Co., and Revolution Medicines, Inc., among others, have developed small molecule therapies for the treatment of KRAS mutated cancer including G12C and other alleles. Other companies in the immunotherapy and cancer vaccine sector include BioNTech SE, Gilead Sciences Inc., Novartis International AG, Gritstone Oncology, Inc. (“Gritstone”), Hookipa Pharma Inc., Circio Holding ASA, Moderna, Inc. (“Moderna”), Roche Holding Ltd./Genentech, Inc., Merck & Co., Inc. (“Merck”), Bristol Myers Squibb Co., and AstraZeneca Plc. Closest in mechanism to ELI-002 is the Moderna mRNA-5671 cancer vaccine, which is currently in Phase 1 clinical development. While many of these programs are in preclinical stages or Phase 1 clinical trials, Amgen and Mirati have products that are approved by the FDA for the treatment of adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (“NSCLC”), who have received at least one prior systemic therapy. Additionally, Gritstone has product candidates in Phase 2 trials, including an “off the shelf” vaccine for solid tumors. Moderna and Merck are in a combined Phase 3 trial of their personalized cancer vaccine targeting melanoma (mRNA-4157) and BioNTech and Roche are in a combined Phase 2 trial of their personalized cancer vaccine targeting pancreatic cancer (BNT122, RO7198457). Although ELI-002 is being evaluated as an earlier line of therapy (before metastatic disease can be observed on radiographs), it may compete with existing and new therapies that may be approved in the future.

Many of our current or potential competitors, either alone or with their collaboration partners, may have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, 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 or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than the product candidates we may develop or that would render any of our product candidates obsolete or non-competitive. Our competitors also may obtain FDA or other regulatory approval for their product candidates more rapidly than we may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Our commercial opportunity may also be reduced or limited if our or our partners are unable to scale up the manufacture of our product candidates to meet clinical or commercial requirements. ELI-002 is comprised of eight active pharmaceutical ingredients (“APIs”), with peptides and nucleotides with a lipid modification. The compositions we seek to develop may exhibit poor pharmaceutical properties, and formulation, purification and stable storage could be challenging.

In addition, we could face litigation with respect to the validity and/or scope of patents relating to our competitors’ products. The availability of competitive products could limit the demand and the price we are able to charge for our products. Further, intellectual property protection for the amphiphile components of our product candidates is dynamic and rapidly evolving. The scope of intellectual property protection for our AMP platform may be limited, and its commercial opportunity may be reduced or limited if our competitors are able to acquire or develop the same or similar technologies.

Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products.

Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on us entering into collaborations with corporations, academic institutions,

licensors, licensees, and other parties and we may not be successful in establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. Any collaborators may not perform their obligations to our satisfaction, or at all, we may not derive any revenue or profits from such collaborations, and any collaborators may ultimately compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and/or reduced sales of proposed products in such markets.

Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete.

We rely on third-party vendors, scientists and collaborators to provide us with significant data and other information related to our projects, clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, reimbursement practices, or health care reform initiatives, which would harm our business.

The regulations that govern pricing and reimbursement for new medicines vary widely from country to country, and current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Outside the United States, some countries require approval of the sale price of a medicine before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay or might even prevent our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates we may develop, even if any such product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which reimbursement for these product candidates and related treatments will be available from government authorities or health care programs, private health plans, and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary and/or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. At this time, we are unable to determine their cost effectiveness or the likely level or method of reimbursement for our product candidates. Government authorities and third-party payors, such as private health plans, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. health care industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are challenging the prices charged for medical products and requiring that biopharmaceutical companies provide them with predetermined discounts from list prices. Novel medical products, if covered at all, may be subject to enhanced utilization management controls designed to ensure that the products are used only when medically necessary. Such utilization management controls may discourage the prescription or use of a medical product by increasing the administrative burden associated with its prescription or creating coverage uncertainties for prescribers and patients. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, that the level of reimbursement will be adequate. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain therapeutic products that are not usually self-administered (such as most injectable drugs and biologics) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician’s services;
- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining reimbursement for newly approved product candidates, and coverage may be more limited than the purposes for which the product candidate is approved by the FDA or other regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to pay all or part of the costs associated with their prescription medications. Patients are unlikely to use our products unless coverage is provided and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for reimbursement does not imply that any product candidate will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new product candidates, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product candidate and reimbursement in the clinical setting in which it is used may be based on reimbursement levels already set for lower cost therapies or medicines and may be incorporated into existing payments for other services. Net prices for product candidates may be reduced by mandatory discounts or rebates required by government health care programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved product candidates we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of health care and legislative and regulatory proposals to broaden the availability of health care will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory changes in the health care system in the United States and other major health care markets have been proposed and/or adopted in recent years, and such efforts have expanded substantially in recent years.

In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (the “ACA”) was signed into law. This legislation changed the system of health care insurance and benefits and was intended to broaden access to health care coverage, enhance remedies against fraud and abuse, add transparency requirements for the health care and health insurance industries, impose taxes and fees on the health care industry, impose health policy reforms, and control costs. This law also contains provisions that would affect companies in the pharmaceutical industry and other health care related industries by imposing additional costs and changes to business practices. Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA. The uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers, which may in turn negatively impact our product sales. We continue to evaluate the effect that the ACA has or any potential changes to the ACA could have on our business. Additional federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug and biologic pricing and reimbursement. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

If the market opportunities for any of our product candidates are smaller than we believe they are, our potential revenues may be adversely affected, and our business may suffer.

We focus certain research and product development pipelines and our product candidates on lymph node-directed immunotherapies for cancer and infectious diseases. ELI-002 is a KRAS therapeutic vaccine in clinical development for the potential treatment of several cancer types with KRAS mutations. ELI-002 targets six position 12 and one position 13 KRAS mutations, representing approximately 25% of solid tumors.

While we believe that the cancer types to be included in our early-stage clinical trials have a large KRAS mutation positive patient population in the United States, our understanding of both the number of patients who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, is based on estimates. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. By example, because some of the cancer indications that we are targeting are rare, certain estimates are based upon studies with small patient populations. Moreover, because our product candidates, such as ELI-002 target specific positions on a mutation, not all patients with the mutation will be treatment candidates. As a result, the number of patients in the United States may turn out

to be lower than expected, may not be otherwise eligible for treatment with ELI-002, or patients may become increasingly difficult to identify and access for clinical trials, all of which could adversely affect our business, financial condition, results of operations and prospects.

If we or any CMOs and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and any CMOs and suppliers we engage are subject to numerous federal, state, and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment, and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air, and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. Although we believe that the safety procedures utilized by us and such third parties for handling and disposing of these materials and wastes generally comply with the standards prescribed by applicable laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research and product development efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies (which provide for adequate and reasonable amounts of coverage for a company in our industry and at our size and stage) specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws, regulations, and permitting requirements. These current or future laws, regulations, and permitting requirements may impair our research, development, or production efforts. Failure to comply with these laws, regulations, and permitting requirements also may result in substantial fines, penalties, or other sanctions or business disruptions, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Any CMOs and suppliers we engage will also be subject to these and other environmental, health, and safety laws and regulations. Liabilities they incur pursuant to these laws and regulations could result in significant costs or an interruption in operations, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Our technologies are novel, and any product candidates we develop may be complex and difficult to manufacture on a clinical or commercial scale. We could experience delays in satisfying regulatory authorities or production problems that result in delays in our development or commercialization programs, limit the supply of our product candidates we may develop, or otherwise harm our business.

Our AMP platform is novel, and the manufacture of products on the basis of our platform is untested at a large scale. Any current and future product candidates will likely require processing steps that are more complex than those required for most chemical pharmaceuticals. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory, or potentially delay progression of our regulatory filings. Even if we successfully develop product candidates, we may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. If we or our CMOs are unable to scale our manufacturing at the same levels of quality and efficiency, we may not be able to supply the required number of doses for our current or planned clinical trials or for commercial supply, if any of our product candidates receive regulatory approval, and our business could be harmed.

As product candidates proceed through nonclinical studies to clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are tested and then altered along the way in an effort to optimize processes and results. We have updated ELI-002, with two peptides (ELI-002-2P), to a new version of ELI-002, with seven peptides (ELI-002-7P), as part of our product development activities, and, may continue to update ELI-002 in the future if needed and subject to receipt of additional funding. Any such changes could cause any product candidates we may develop to perform differently and affect the results of clinical trials conducted with the materials manufactured using altered processes. Such changes may also require a new IND to be filed, additional testing, FDA notification, and FDA authorization. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. For instance, the FDA may require that we conduct a comparability study that evaluates the potential differences in the product candidate resulting from the change. Delays in designing and completing such a study to the satisfaction of the FDA could delay or preclude our development and commercialization plans, and the regulatory approval of our product candidates. Any of the foregoing could limit our future revenues and growth. Any changes would also require that we devote time and resources to manufacturing development and would also likely require additional testing and regulatory actions on our part, which may delay the development of our product candidates.

In addition, the FDA and other regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances, a regulatory authority may require that we do not distribute a lot until the agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product recalls. Lot failures or product recalls could cause us to delay clinical trials or product launches, which could be costly to us and otherwise harm our business, financial condition, results of operations, and prospects.

We also may encounter problems hiring and retaining the experienced scientific, quality control, and manufacturing personnel needed to manage our manufacturing process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. For example, given the aseptic controls required for the manufacture of our product candidates, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Any such contamination could materially harm our ability to produce product candidates on schedule and could delay our development programs and results of operations and cause reputational damage. We cannot assure that any such issues relating to the manufacture of ELI-002 or any other product candidate will not occur in the future or that significant delays would not occur as a result of any such issue.

ELI-002 drug substances and drug products are supplied by multiple manufacturers at present. Any problems in our manufacturing process or the facilities with which we contract to make, store or ship our product candidates or any problems caused by it, our vendors or other factors not in our control could result in the loss of usable product or prevent or delay the delivery of product candidates to patients in our clinical trials, including the AMPLIFY-201 and the AMPLIFY-7P trials. Any such loss or delay could materially delay our development timelines and harm our business, financial condition and results of operations. Such losses or delays could also make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems with third-party manufacturing processes or facilities also could restrict our ability to ensure sufficient clinical material for any clinical trials we may be conducting or plan to conduct and meet market demand for any product candidates we may develop, obtain regulatory approval for, and commercialize.

Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.

We carry insurance for most categories of risk that our business may encounter; however, we may not have adequate levels of coverage. We currently maintain general liability, property, workers' compensation, products liability and directors' and officers' insurance, along with an umbrella policy. We may not be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Risks Related to Our Intellectual Property

Our success will depend upon intellectual property and proprietary technologies, and we may be unable to protect our intellectual property.

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. If we or our licensors fail to appropriately prosecute and maintain patent protection for our product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

We have sought patent protection in the United States and internationally related to the AMP platform technology as well as the mKRAS and universal adjuvant programs. We have issued patents in Japan, Nigeria, Russia, and Singapore covering clinical product candidates but the patent portfolio owned by us currently largely comprises pending applications. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- pending patent applications may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable, or otherwise may not provide barriers to entry or any competitive advantage;
- because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire, or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent;
- our competitors, many of which have substantially greater resources than us or our partners do, and many of which have made significant investments in competing technologies, may seek, or may already have sought or obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential products;
- others may design around our patent claims to produce competitive technologies, products or uses which fall outside of the scope of our patents or other intellectual property rights;
- others may identify prior art or other bases which could render unpatentable our patent applications or invalidate our patents;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns;
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products; and
- we may be involved in lawsuits to protect or enforce its patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

In addition to patents, we also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or come upon this same or similar information independently. We may become subject to claims that us or consultants, advisors or independent contractors that we may engage to assist us in developing our product candidates have wrongfully or inadvertently disclosed to us or used trade secrets or other proprietary information of their former employers or their other clients.

We may be forced to litigate to enforce or defend our intellectual property rights, and/or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement by competitors, and to protect our trade secrets against unauthorized use. In so doing, we may place our intellectual property at risk of being invalidated, rendered unenforceable, or limited or narrowed in scope such that we may no longer be used to adequately prevent the manufacture and sale of competitive products. Further, an adverse result in any litigation or other proceedings before government agencies such as the United States Patent and Trademark Office (“USPTO”), may place pending applications at risk of non-issuance. Further, interference proceedings, derivation proceedings, entitlement proceedings, ex parte reexamination, *inter partes* reexamination, *inter partes* review, post-grant review, and opposition proceedings provoked by third parties or brought by the USPTO or any foreign patent authority may be used to challenge the inventorship, ownership, claim scope, or validity of our patent applications. Additionally, because of the substantial amount of discovery required in connection with intellectual

property litigation, there is a risk that some of our confidential and proprietary information or trade secrets could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We have rights in some intellectual property that have been discovered through government funded programs and thus are subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry.

We have rights in some intellectual property that have been discovered through government funded programs and thus are subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights, subject us to expenditure of resources with respect to reporting requirements, and limit our ability to contract with non-U.S. manufacturers. Some of the intellectual property rights in-licensed to us have been generated through the use of U.S. government funding and are therefore subject to certain federal regulations. For example, all of the intellectual property rights licensed to us under our license agreement with MIT have been generated using U.S. government funds. As a result, the U.S. government has certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. These U.S. government rights in certain inventions developed under government-funded programs include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if the government determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we fail, or the applicable licensor fails, to disclose the invention to the government, elect title, and file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title to these inventions in any country in which a patent application is not filed within specified time limits. Intellectual property generated under government funded programs is also subject to certain reporting requirements, compliance with which may require us, or the applicable licensor, to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the U.S. This requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible. This preference for U.S. manufacturing may limit our ability to license the applicable patent rights on an exclusive basis under certain circumstances.

If we enter into future arrangements involving government funding, and we make inventions as a result of such funding, our intellectual property rights to such discoveries may be subject to the applicable provisions of the Bayh-Dole Act. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply. Any exercise by the government of certain of its rights could harm our competitive position, business, financial condition, results of operations and prospects.

We are substantially dependent on patents we license from MIT, and if such licensed patent rights lack legal effect or if a dispute arises under such license agreement and our licensed rights are narrowed or this license is terminated, that could cause significant impairment to our ability to develop and commercialize certain of our product candidates.

Our business is substantially dependent upon technology licensed from MIT. Pursuant to our license agreement with MIT, we were granted an exclusive, worldwide license, including the right to sublicense, under patents and patent applications owned by MIT related to the "Amphiphile" technology for the diagnosis, treatment or prevention of diseases. The patent rights licensed from MIT cover products in development by us for all of our current lead programs in tumor indications where mutant KRAS, rearranged anaplastic lymphoma kinase ("ALK"), or expression of human papillomavirus proteins are a driver of disease, as well as programs using CpG as an adjuvant for immune activation. Therefore, our ability to develop and commercialize several of our product candidates, including ELI-002, are substantially dependent on the legal effectiveness of the MIT patent rights licensed under this agreement and continuation of this agreement. MIT has the right to control the preparation, filing and prosecution of

the patent applications, and to maintain the patents, covering the patent rights we licensed from MIT under this license agreement. Therefore, we cannot be certain that these patents and patent applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If MIT fails to maintain such patents, or loses rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and its right to develop and commercialize any of our products that are the subject of such licensed patent rights could be adversely affected, and we may not be able to prevent competitors from making, using or selling competing products. MIT also has the right to control defense of any claims asserting the invalidity of these licensed patent rights and, even if we are permitted to pursue such defense, we cannot ensure the cooperation of MIT. We cannot be certain that MIT will allocate sufficient resources or prioritize their or our enforcement of such patent rights or their defense of such claims to protect our interests in the licensed patent rights. Even if we are not a party to these legal actions, an adverse outcome could harm its business because it might prevent us from continuing to license intellectual property that it may need to operate its business. In addition, although we have the right to control enforcement of the licensed patents, we may be adversely affected or prejudiced by actions or inactions of MIT and their counsel that took place prior to or after us assuming control.

The license agreement with MIT is complex, and certain provisions in this license agreement may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow or eliminate what we believe to be the scope of our rights to the licensed patent rights or increase what we believe to be our financial or other obligations under the license agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we or our partners are sued for infringing on the intellectual property rights of third parties, it could be costly and time-consuming, and an unfavorable outcome in any such litigation could have a material adverse effect on our business.

Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing on the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe upon. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

In addition, third parties may sue us for infringing on their patents. Even if we are successful in defending any claims of infringement, the defense of such claims may be costly and present a time-consuming distraction. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;
- stop using its technologies and methods;
- stop certain research and development efforts;
- develop non-infringing products or methods; and/or
- obtain one or more licenses from third parties.

If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in the development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringed on third-party rights, could be costly, time-consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research endeavors which are similar to those which they were involved in at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of such former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs, be a distraction to management and ultimately have a material adverse effect on us, even if we are successful in defending such claims.

The biotechnology and pharmaceutical industries have experienced substantial litigation and other proceedings concerning intellectual property rights, and third parties may initiate legal proceedings alleging that we are infringing, misappropriating, or otherwise violating their intellectual property rights, the outcome of which could be uncertain and may prevent, delay or otherwise interfere with our product discovery and development efforts.

Our commercial success depends upon our ability and the ability of our collaborators and licensors to develop, manufacture, market, and sell ELI-002 and other Amphiphile immunotherapies. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights as well as administrative proceedings for challenging patents, including interference, derivation, *inter partes* review, post grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be subject to and may in the future become party to, or threatened with, adversarial proceedings or litigation concerning intellectual property rights with respect to our Amphiphile platform and any product candidates we may develop, including interference proceedings, post-grant review, *inter partes* review, and derivation proceedings before the USPTO and similar proceedings in foreign jurisdictions such as oppositions before the European Patent Office ("EPO"). Numerous U.S. and foreign issued patents and pending patent applications that are owned by third parties exist in the fields in which we are developing our product candidates and infringement claims may be asserted against us or our partners based on existing patents or patents that may be granted in the future, regardless of their merit.

As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our AMP platform and product candidates may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of therapies, products or their methods of use or manufacture. As with many technology-based products, there may be third-party patent applications that, if issued, may be construed to cover components of our AMP platform and product candidates. There may also be third-party patents of which we are currently unaware with claims to our technologies, compositions, methods of manufacture or methods of use.

Because of the large number of patents issued and patent applications filed in our fields, third parties may allege they have patent rights encompassing our product candidates, technologies or methods. Third parties may assert that we are employing their proprietary technology without authorization and may file patent infringement claims or lawsuits against us, and if we are found to be infringing on any such third-party patents, we may be required to pay damages, cease commercialization of the infringing technology, or obtain a license from such third party, which may not be available on commercially reasonable terms or at all.

Our ability to commercialize our product candidates in the United States and abroad may be adversely affected if we cannot successfully defend infringement claims, or obtain a license on commercially reasonable terms to relevant third-party patents that cover our product candidates. Even if we believe third-party intellectual property claims are without merit, there can be no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. A court of competent jurisdiction could hold that these third-party patents are valid and enforceable and have been infringed upon, which could materially and adversely affect our ability to commercialize ELI-002 or any other product candidates and any other product candidates or technologies covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claims, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. If we are found to be infringing on a third party's intellectual property rights, and it is unsuccessful in demonstrating that any such patents are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing, and marketing ELI-002 or any other product candidates and its technologies. 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 such a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to it, and it could require us to make substantial licensing and royalty payments. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our AMP platform or product candidates or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing the infringing technology or product candidates. In addition, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed on a patent or other intellectual property right. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations, and prospects.

The defense of third-party claims of infringement, misappropriation, or violation of intellectual property rights often involves substantial litigation expense and could be a substantial diversion of management and employee time and resources from our business. Some third parties may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, financial condition, results of operations and prospects. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications are due to be paid to the USPTO and foreign patent agencies outside of the United States over the lifetime of our owned or licensed patents and applications. For our in-licensed patents and patent applications, we generally rely on our licensors to pay these fees due to U.S. and non-U.S. patent agencies; however, we reimburse MIT for these fees as required by our license agreement with MIT. For our owned patent applications, we rely on our outside patent counsel in the United States and foreign countries to monitor these deadlines and to pay these fees when so instructed.

The USPTO and foreign patent agencies require compliance with several procedural, documentary, fee payment, and other similar provisions, such as the requirement to disclose known prior art, during the patent application process. We depend on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property, and for our owned patent applications, we engage counsel and other professionals to help us comply with these requirements. While certain inadvertent lapses can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in a partial or complete loss of patent rights in the relevant jurisdiction. Were a non-compliance event to occur, our competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on its business, financial condition, results of operations, and prospects.

Changes in patent law in the United States and in non-U.S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our technologies and product candidates.

As is the case with other biotech and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and are therefore costly, time-consuming and inherently uncertain.

Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Under the Leahy-Smith America Invents Act (“AIA”), the United States adopted a “first-inventor-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that filed or files a patent application with the USPTO after March 16, 2013 but before we file an application could therefore have been granted a patent covering an invention of ours even if we had made the invention before it was made by the third party. Since patent applications in the United States and most other countries are confidential at least 18 months after filing, we cannot be certain that we were the first to file any patent application related to our drug or biologic candidates.

The AIA also provides a process known as inter partes review (“IPR”), which has been used by many third parties to challenge and invalidate patents. The IPR process is not limited to patents filed after the AIA was enacted and would therefore be available to a third party seeking to invalidate any of our U.S. patents, even those issued or filed before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures, e.g., an IPR, to invalidate our patent claims that would not have been invalidated if first challenged by the third party in a district court action.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. The terms of individual patents depend upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date in the applicable country. However, the actual protection afforded by a patent varies from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Various extensions including patent term extension ("PTE") and patent term adjustment ("PTA") may be available, but the lives of such extensions, and the protections they afford, are limited. Although we will likely seek patent term extensions in the U.S. and in one or more foreign jurisdictions where available, we cannot provide any assurances that any such patent term extensions will be granted and, if so, for how long. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars and generics. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product candidates might expire before or shortly after we or our partners commercialize those candidates. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

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

In addition to seeking patents for or technologies and product candidates, we also rely on trade secret protection, as well as confidentiality agreements, non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our know-how and other confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable.

It is our policy to require our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors, and other third parties to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements generally provide that all confidential information concerning our business or financial affairs developed by or made known to an individual or entity during the course of that party's relationship with us is to be kept confidential and not disclosed to third parties, except in certain specified circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and that are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In the case of consultants and other third-party service providers, the agreements provide us with certain rights to all inventions arising from the services provided to us by those individuals or entities. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technologies and processes. Additionally, the assignment of intellectual property rights may not be self-executing, or assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against it, to determine the ownership of what we regard as our intellectual property. We may not be able to obtain adequate remedies for any breaches of such agreements. Ultimately, enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information through other appropriate precautions, such as physical and technological security measures. However, trade secrets and know-how can be difficult to protect. These measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and any recourse we might take against this type of misconduct may not provide an adequate remedy to protect our interests fully. In addition, our trade secrets may be independently developed by others in a manner that could prevent us from receiving legal recourse. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any of that information was independently developed by a competitor, our competitive position could be harmed.

In addition, courts inside and outside the United States are sometimes less willing or unwilling to protect trade secrets. If we chose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. Even if we are successful, these types of lawsuits may consume significant amounts of our time and other resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third parties may assert that our employees, consultants, or advisors have wrongfully used or disclosed confidential information or misappropriated trade secrets.

As is common in the biotechnology and pharmaceutical industries, we employ individuals that are currently or were previously employed at universities, research institutions or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and advisors 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 individuals have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. We may then be involved in litigation proceedings to defend against these claims. If we fail in defending against any such claims, in addition to potentially 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 distract

our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, that perception could have a substantial adverse effect on the price of our common stock. Ultimately, any such litigation could substantially increase our operating losses and reduce our resources available for development activities, and we may not have sufficient financial or other resources to adequately engage in such litigation. For example, some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. In any case, uncertainties resulting from the initiation and continuation of intellectual property litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

Any trademarks we may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our product candidates that are approved for marketing from the products of our competitors. However, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversions of resources and could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, any proprietary name we propose to use with any product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of the potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- any of our current and future product candidates, if approved, may eventually become commercially available in generic or biosimilar product forms;
- others may be able to make immunotherapies that are similar to any of our current and future product candidates or utilize lymph node targeting technology but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our licensors or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license or may own in the future, potentially resulting in the invalidation of such patents or refusal of such applications;
- we, or our licensors or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- we, or our licensors or current or future collaborators, may fail to meet our obligations to the U.S. government regarding any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss or unenforceability of patent rights;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing on our owned or licensed intellectual property rights;
- it is possible that our pending, owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents;
- it is possible that there are prior public disclosures that could invalidate our owned or in-licensed patents, or parts of our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates or technology similar to ours;

- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- issued patents that we hold rights to may be held invalid, unenforceable, or narrowed in scope, including as a result of legal challenges by our competitors;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates;
- the laws of foreign countries may not protect our proprietary rights or the proprietary rights of our licensors or current or future collaborators to the same extent as the laws of the United States;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes that design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- our competitors might conduct research and development activities in countries where it does not have patent rights and then use the information learned from such activities to develop competitive products for sale in its major commercial markets;
- we have engaged in scientific collaborations in the past and we intend to continue to do so in the future, and our collaborators may develop adjacent or competing products that are outside the scope of our patents;
- we may not develop additional proprietary technologies that are patentable;
- any product candidates we develop may be covered by third-party patents or other exclusive rights;
- the patents of others may prohibit or otherwise harm our business; or
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Regulatory and Compliance Matters

The FDA regulatory approval process is lengthy, time-consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates.

The research, testing, manufacturing, labeling, approval, selling, import, export, adverse event reporting, record keeping, advertising, promotion, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological product in the United States until we receive a biologics license from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive nonclinical and clinical data and supporting information to establish that the product candidate is safe, pure, potent, and effective for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements.

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies, and submission of safety, efficacy, and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities must comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our CMOs will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing applications, and previous responses

to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control.

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, we will have to comply with requirements including submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP for any clinical trials that we conduct post-approval.

The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs and biologics 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.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or 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; clinical studies 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, restitution, disgorgement of profits or revenues, warning letters or other enforcement-related letters or clinical holds on post-approval clinical trials;
- refusal of the FDA to approve pending BLAs or supplements to approved BLAs, or suspension or revocation of product approvals or suspension of any ongoing clinical trials;
- product seizure or detention, recalls or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal health care programs; or mandated modification of promotional materials and labeling and the issuance of corrective information.

The policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

Additional regulatory burdens and other risks and uncertainties in foreign markets may limit our growth.

Our future growth may depend, in part, on our ability to develop and commercialize product candidates in foreign markets for which we may rely on strategic partnership with third parties. We will not be permitted to market or promote any product candidate before we receive regulatory approval from the applicable regulatory authority in a foreign market, and we may never receive such regulatory approval. To obtain separate regulatory approval in foreign countries, we generally must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of a product candidate, and we cannot predict success in these jurisdictions. In particular, the European Commission issued a proposal in April 2023 for a new Directive and a new Regulation, which will revise and replace the existing general pharmaceutical legislation. If adopted and implemented as currently proposed, these revisions will significantly change several aspects of drug development and approval in the EU. If we obtain approval of any of our potential future product candidates and ultimately commercialize any such product candidate in foreign markets, we would be subject to risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

In addition, obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, but a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional nonclinical studies, or clinical trials as trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Our relationships with health care providers, physicians, and third-party payors will be subject to applicable anti-kickback, fraud and abuse, anti-bribery and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits and future earnings.

Physicians, other health care providers and third-party payors will play a primary role in the recommendation and prescription of ELI-002 or any other product candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product candidates for which we obtain marketing approval. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, including Medicare and Medicaid. Restrictions under applicable domestic and foreign health care laws and regulations include but are not limited to the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase order or recommendation of a good or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- federal civil and criminal false claims laws and civil monetary penalties laws, including the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency requirements, sometimes referred to as the “Sunshine Act,” enacted as part of the Patient Protection and Affordable Care Act (the “ACA”), which requires, among other things, manufacturers of drugs, devices, biologics and medical supplies that are reimbursed under Medicare, Medicaid, or the Children’s Health Insurance Program to report annually to the Centers for Medicare & Medicaid Services (“CMS”) information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain advanced non-physician health care practitioners (such as physician assistants and nurse practitioners) and teaching hospitals, as well as physician ownership and investment interests, including such ownership and investment interests held by a physician’s immediate family members;

- analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non-governmental third-party payors, including private insurers;
- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal health care programs;
- HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and
- state and foreign laws which govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways or conflict with each other and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti-Kickback and criminal health care fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA 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 False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable health care laws and regulations will involve substantial costs. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a health care company may run afoul of one or more of the requirements. If our operations are found to be in violation of any applicable laws or any other government regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, individual imprisonment, disgorgement, contractual damages, reputational harm, exclusion from participation in government health care programs, integrity obligations, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into supply contracts, including government contracts, additional reporting requirements and oversight if subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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.

We intend to develop and implement a comprehensive corporate compliance program prior to the commercialization of our product candidates. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources. Moreover, federal, state or foreign laws or regulations are subject to change, and while we, our collaborators, manufacturers and/or service providers currently may be compliant, that could change due to changes in interpretation, prevailing industry standards or other reasons.

Health care and other reform legislation may increase the difficulty and cost for us and any collaborators we may have to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U.S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially

negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates or any of our potential future product candidates, restrict or regulate post-approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Congress also must reauthorize the FDA's user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 without any substantive policy changes.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way health care is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry.

There remain judicial and Congressional challenges to certain aspects of the ACA, and as a result certain sections of the ACA have not been fully implemented or effectively repealed. However, following several years of litigation in the federal courts, in June 2021, the U.S. Supreme Court upheld the ACA when it dismissed a legal challenge to the law's constitutionality. Further legislative and regulatory changes under the ACA remain possible, although it is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future. We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States.

In addition, the Drug Supply Chain Security Act (the "DSCSA") enacted in 2013 imposed obligations on manufacturers of pharmaceutical products related to product tracking and tracing, and in February 2022, FDA released proposed regulations to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third-party logistics providers; and create a federal system for licensure for use in the absence of a State program, each of which is mandated by the DSCSA. As another example, on December 20, 2019, President Trump signed the Further Consolidated Appropriations Act for 2020 into law (P.L. 116-94) that includes a piece of bipartisan legislation called the CREATES Act. The CREATES Act aims to address the concern articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic and biosimilar product developers access to samples of brand products. The CREATES Act establishes a private cause of action that permits a generic or biosimilar product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Whether and how generic and biosimilar product developments will use this new pathway, as well as the likely outcome of any legal challenges to provisions of the CREATES Act, remain highly uncertain and its potential effects on our future commercial products are unknown. Other legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business.

Additionally, there have been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, state legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area.

The U.S. Federal Trade Commission ("FTC") in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Both the U.S. Congress and state legislatures are increasingly scrutinizing the industry and proposing novel regulatory approaches to address various perceived public policy concerns. Significant efforts to change the PBM industry as it currently exists in the United States may

affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical product developers like us. Further, in September 2023, the FTC issued a policy statement articulating its view that certain "improper" patent listings by drug developers in FDA's Orange Book represent an unfair trade practice and indicated that industry should be prepared for potential enforcement actions based on its analysis. The FTC followed that action in November 2023 by publicly calling out over 100 "improper" patent listings made by ten large pharmaceutical companies and initiating an FDA administrative process with respect to those patents. It remains to be seen whether the FTC, other governmental agencies, pharmaceutical manufacturers, or other stakeholders continue to prioritize the policy issue of "improper" patent listings and whether significant litigation will develop in this area. Accordingly, regulatory and government interest in biopharmaceutical industry business practices continues to expand and pose a risk of uncertainty.

At the federal level, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In addition, the Department of Health and Human Services ("HHS") has solicited feedback on various measures intended to lower drug prices and reduce the out-of-pocket costs of drugs and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

Most recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022 ("IRA"). Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product's price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with pharmaceutical manufacturers to conduct price negotiations in October 2023. However, the IRA's impact on the biopharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Any additional federal or state health care reform measures could limit the amounts that third-party payers will pay for future health care products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability.

Our employees, principal investigators, consultants, and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants, and commercial partners, and, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA or other regulatory authorities, comply with health care fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of significant fines or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain product candidates outside of the United States and require us to develop and implement costly compliance programs.

We will be subject to numerous laws and regulations in each jurisdiction outside the United States in which we operate in the future. The creation, implementation and maintenance of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

The Foreign Corrupt Practices Act ("FCPA") prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the U.S. Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Similarly, the U.K. Bribery Act 2010 has extra-territorial effect for companies and individuals having a connection with the United Kingdom. The U.K. Bribery Act prohibits inducements both to public officials and private individuals and organizations. Compliance with the FCPA and the U.K. Bribery Act is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our business outside of the United States, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violations of the FCPA can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. A conviction under the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices could have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to, and may in the future become subject to, U.S. federal and state, and foreign, stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies and contractual obligations could adversely affect our business.

We and our current and potential collaborators may be subject to federal, state and foreign data protection laws and regulations (*i.e.*, laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws (*e.g.*, HIPAA as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH")), state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (*e.g.*, Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose protected health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. However, determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation.

If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. Furthermore, state attorney generals are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks

associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Many state laws govern the privacy and security of personal information and data in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For example, the California Confidentiality of Medical Information Act ("CMIA") imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. In addition to the CMIA, in 2018, California enacted the California Consumer Privacy Act ("CCPA") which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. In addition, the California Privacy Rights Act ("CPRA") was recently enacted to strengthen elements of the CCPA and became effective on January 1, 2023. A number of other states have considered similar privacy proposals, with states like Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Montana, Oregon, Tennessee, Texas, Utah and Virginia enacting their own privacy laws. These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data.

In the European Union, we may be subject to the General Data Protection Regulation ("GDPR") which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR applies to any company established in the European Economic Area ("EEA") (which includes the European Union Member States plus Iceland, Liechtenstein, and Norway) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for "high risk" processing, limitations on retention of personal data, special provisions affording greater protection to and requiring additional compliance measures for "special categories of personal data" including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), "privacy by design" requirements, and direct obligations on service providers acting as processors. The GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. If we or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR may also impose additional compliance obligations relating to the transfer of data between us and our affiliates, collaborators, or other business partners. For example, on July 16, 2020, the Court of Justice of the European Union ("CJEU"), issued a landmark opinion in the case *Maximilian Schrems vs. Facebook* (Case C-311/18), called *Schrems II*. This decision (a) calls into question commonly relied upon data transfer mechanisms as between the European Union Member States and the United States (such as the Standard Contractual Clauses) and (b) invalidates the European Union-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the European Union to the United States.

On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework (the "Framework"). The Framework provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the *Schrems II* decision. Notably, the new obligations were geared to ensure that data can be accessed by US intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The Commission will continually review developments in the US along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable

jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some patients or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective patients or other business relationships.

Relatedly, following the United Kingdom's withdrawal from the European Union (i.e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the European Union GDPR has been implemented in the United Kingdom (as the "UK GDPR"). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the European Union GDPR into United Kingdom law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £17.5 million or 4% of global turnover.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent our product candidates from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologic products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times, including from December 22, 2018 through January 25, 2019, and congressional impasses periodically threaten to cause future government shutdowns. When a shutdown occurs, certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. Moreover, government shutdowns or slowdowns can increase the time needed for an agency to complete its review or make final approvals or other administrative decisions. If a prolonged government shutdown or slowdown occurs, it could significantly affect the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to Employee and Operations Matters, Managing Growth and Information Technology

Our business, operations and clinical development timelines and plans are subject to risks arising from epidemic or pandemic diseases.

The COVID-19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U.S. and global economies and financial markets. International and U.S. governmental authorities in impacted regions took multiple and diverse actions in an effort to slow the spread of COVID-19 and variants of the virus, including issuing varying forms of "stay-at-home" orders. To date we have not experienced material disruptions in our business operations due to COVID-19. Such measures taken by the governmental authorities to respond to any future epidemic or pandemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for clinical products for use in our clinical trials and research and nonclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, including due to measures taken that may limit social interaction or prevent reopening of high-transmission settings, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our nonclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations. Any future epidemic or pandemic disease outbreak could also potentially further affect the business of the FDA, the European Medical Association (EMA) or other regulatory authorities, which could result in delays in meetings related to our planned clinical trials. Any future epidemic disease outbreak may have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed.

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

We are highly dependent on the principal members of our senior management and scientific teams. Such principal members are employed "at will," meaning we or they may terminate the employment relationship at any time. The

loss of the services of any of these persons could impede the achievement of our research, development, and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing, business development, general and administrative and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these 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 our research and development and commercialization strategy. Our consultants and advisors, including our scientific co-founder, 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 us. In addition, inflation has had, and we expect that it will continue to have, an impact on the costs that it incurs to attract and retain qualified personnel, and may make it more difficult for us to attract and retain such personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants, or advisors, may impede the progress of our research, development, and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations, and prospects.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Over time we will need to hire additional qualified personnel with expertise in drug development, product registration, clinical, preclinical and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. There is currently a shortage of highly qualified personnel in our industry, which is likely to continue. As a result, competition for personnel is intense and the turnover rate can be high. Attracting and retaining qualified personnel will be critical to our success. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for individuals with similar skill sets.

In addition, failure to succeed in development and commercialization of our product candidates may make it more challenging to recruit and retain qualified personnel. The inability to recruit and retain qualified personnel may impede the progress of our research, development and commercialization objectives and would negatively impact our ability to succeed in our product development strategy.

We expect to expand our development, regulatory, and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of December 31, 2023, we had 32 full-time employees and, in connection with the growth and advancement of our pipeline and becoming a public company, we expect to increase the number of our employees and the scope of our operations, particularly in the areas of product development, regulatory affairs, and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expected expansion of our operations or recruit and train additional qualified personnel. Moreover, the expected physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

As a growing biotechnology company, we are actively pursuing new platforms and product candidates in many therapeutic areas and across a wide range of diseases. Successfully developing product candidates for and fully understanding the regulatory and manufacturing pathways to all of these therapeutic areas and disease states requires a significant depth of talent, resources and corporate processes in order to allow simultaneous execution across multiple areas. Due to our limited resources, we may not be able to effectively manage this simultaneous execution and the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, legal or regulatory compliance failures, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively and commercialize our product candidates, if approved, will depend in part on our ability to effectively manage our future development and expansion.

Our internal information technology systems, or those of our vendors, collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents, loss of data, and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information

related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of our business, we collect and store sensitive data, intellectual property, and proprietary business information. This data encompasses a wide variety of business-critical information including research and development information, clinical trial information, personal information, commercial information, and business and financial information. We face risks relative to protecting this critical information, including loss of access, unauthorized access or disclosure, unauthorized modification, and inadequate monitoring of our controls over these risks.

Despite the implementation of security measures, our internal information technology ("IT") systems and those of our current and any future third-party vendors, collaborators and other contractors or consultants are vulnerable to risks and damages from a variety of sources, including, interruption, failure, damage, cybersecurity incidents, or data theft from computer viruses, computer hackers, malicious code, employee theft or misuse, malware, including ransomware, social engineering (including phishing attacks), denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, cyber-attacks, phishing schemes, breaches, interruptions due to employee error or malfeasance, damage from natural disasters, terrorism, war and telecommunication, network, and electrical failures. As use of digital technologies has increased, cybersecurity incidents, including deliberate attacks and attempts to gain unauthorized access to IT systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our IT systems and networks and the confidentiality, availability, and integrity of our data. There can be no assurance that we will be successful in detecting or preventing cybersecurity incidents, or successfully mitigating their effects.

Any such disruption or security incident could cause interruptions in our operations, and result in a disruption of our development programs and our business operations. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If we were to experience a significant cybersecurity incident that impacts our IT systems or data, the costs associated with the investigation, remediation and potential notification of the cybersecurity incident to counterparties, regulatory authorities, and data subjects could be material. In addition, our remediation efforts may not be successful. Cybersecurity incidents could also lead to significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. In addition, our remote workforce could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruption.

To the extent that any disruption or cybersecurity incident were to result in a loss of, or damage to, our or our third-party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential, proprietary, or other critical or sensitive information or data, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory actions or investigations, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients, to the extent we have such information, or our employees, could harm our reputation, require us to comply with federal and/or state data breach notification laws and foreign law equivalents, and potential contractual obligations, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. Despite our implementation of security and other protective measures, sustained or repeated IT system failures that interrupt our ability to generate and maintain data could adversely affect our ability to operate our business. Any of the above could have a material adverse effect on our business, financial condition, reputation, competitive advantage, results of operations or prospects. While we maintain cyber-liability insurance (covering security and privacy matters), such insurance may not be adequate to cover any losses experienced as a result of a cybersecurity incident.

General Risk Factors

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts in the Middle East and between Russia and Ukraine, geopolitical tensions with China, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the ones in the Middle East and in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any

such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce, or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves, or on less favorable terms than we would otherwise choose. In addition, one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our clinical development goals on schedule and on budget.

Uncertainty about global economic conditions could result in increased costs related to the manufacture of our product candidates and, if our product candidates are approved and made available for sale, customers may postpone purchases of our product candidates in response to tighter credit, unemployment, negative financial news and/or declines in income or asset values and other macroeconomic factors, which could have a material adverse effect on demand for our product candidates.

Inflation could adversely affect our business and results of operations.

While inflation in the United States has been relatively low in recent years, during 2021 and 2022, the economy in the United States encountered a material level of inflation. The impact of COVID-19, geopolitical developments such as the Russia-Ukraine and Middle East conflicts, geopolitical tensions with China, and global supply chain disruptions continue to increase uncertainty in the outlook of near-term and long-term economic activity, including whether inflation will continue and how long, and at what rate. Increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding COVID-19, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows.

U.S. federal income tax reform could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, former President Trump signed into law the CARES Act which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses (“NOLs”), interest deductibility limitations and payroll tax matters. Additionally, on December 22, 2017, former President Trump signed into law the Tax Cuts and Jobs Act of 2017 (“TCJA”), which significantly reformed the Internal Revenue Code. The TCJA included significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. Under the TCJA, in general, NOLs generated in taxable years beginning after December 31, 2017 may offset no more than 80 percent of such year’s taxable income and there is no ability for such NOLs to be carried back to a prior taxable year. The CARES Act modifies the TCJA with respect to the TCJA's limitation on the deduction of NOLs and provides that NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021, may be carried back to each of the five taxable years preceding the tax year of such loss, but NOLs arising in taxable years beginning after December 31, 2020 may not be carried back. In addition, the CARES Act eliminates the limitation on the deduction of NOLs to 80 percent of current year taxable income for taxable years beginning before January 1, 2021. As a result of such limitation, we may be required to pay federal income tax in some future year notwithstanding that we had a net loss for all years in the aggregate. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

The market price of our common stock is expected to be volatile, and the market price of our common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology 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, and delays or failures to obtain such approvals;
- failure of any of our product candidates, if approved, to achieve commercial success;

- failure by us to maintain our existing third-party license and supply agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- adverse results, clinical holds, or delays in the clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- introduction of new products, services or technologies by our competitors;
- failure to meet or exceed financial and development projections we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of its common stock by us or our stockholders in the future;
- trading volume of our common stock;
- failure to maintain compliance with the listing requirements of The Nasdaq Global Select Market;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity generally, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with our potential products;
- changes in the structure of health care payment systems;
- disruptions in the financial markets;
- the impact of political instability and military conflict, such as geopolitical tensions between the United States and China, the conflicts in the Middle East, and the conflict in Ukraine, which has resulted in instability in the global financial markets and export control; 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.

Additionally, a decrease in our stock price may cause our common stock to no longer satisfy the continued listing standards of Nasdaq. If we are not able to maintain the requirements for listing on Nasdaq, we could be delisted, which could have a materially adverse effect on our ability to raise additional funds as well as the price and liquidity of our common stock.

We will continue to incur costs and demands upon management as a result of complying with the laws, rules and regulations affecting public companies.

We will continue to incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We will also incur costs associated with corporate governance requirements, including requirements under the laws, rules and regulations of the SEC as well as the Nasdaq rules. These laws, rules and regulations are expected to increase our legal and financial compliance costs and to make some activities more time consuming and costly. For example, some members of our management team have not previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These laws, rules and regulations also may make it difficult and expensive for us to maintain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers, which may adversely affect investor confidence and could cause our business or stock price to suffer.

We may become involved in securities litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

We may be exposed to securities litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources. We may become involved in such litigation, and our stock price may fluctuate for many reasons, including as a result of public announcements regarding the progress of our development efforts or the development efforts of current or future collaboration partners or competitors, the addition or departure of our key personnel, the announcement of the strategic restructuring, variations in our quarterly operating results and changes in market valuations of biopharmaceutical and biotechnology companies. This risk is especially relevant to us because biopharmaceutical and biotechnology companies have experienced significant stock price volatility in recent years. When the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit is without merit, it could result in substantial costs for defending the lawsuit and diversion of the time, attention and resources of our board of directors and management, which could significantly harm our profitability and reputation.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our management.

Provisions in our certificate of incorporation and bylaws may delay or prevent an acquisition or a change in management. In addition, because we will be incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"), which prohibits stockholders owning in excess of 15% of or outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirors to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the board of directors, which is responsible for appointing the members of management.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other employees, and could make it more costly for stockholders to bring a claim against us.

Our amended and restated certificate of incorporation and amended and restated bylaws, provide, among other things, that that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) generally will be the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and the amended and restated bylaws further provide that the federal district courts of the United States of America will be

the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Exchange Act of 1934 (the "Securities Act"). However, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims, and investors cannot waive compliance with the federal laws and rules and regulations thereunder. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there is uncertainty that the provision would be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations, and prospects. This exclusive forum provision may make it more expensive for stockholders to bring a claim than if the stockholders were permitted to select another jurisdiction and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees or stockholders, which may discourage such lawsuits against us and our directors, officers and other employees and stockholders. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation or amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially and adversely affect our business, financial condition and results of operations.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our stockholders' sole source of gain, if any, for the foreseeable future.

An active trading market for our common stock may not develop and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

An active trading market for our shares of common stock may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for our stockholders to sell their shares at an attractive price or at all.

Future sales of a substantial number of shares by existing stockholders, or the perception that such sales could occur, could cause our stock price to decline.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. In addition, shares of our common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plan will be eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts, or the content and opinions included in their reports. The price of our common stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price or trading volume to decline.

We are expected to take advantage of reduced disclosure and governance requirements applicable to smaller reporting companies and emerging growth companies, which could result in our common stock being less attractive to investors.

We have a public float of less than $250 million and therefore qualify as a smaller reporting company under the rules of the SEC. As a smaller reporting company, we are able to take advantage of reduced disclosure

requirements, such as simplified executive compensation disclosures and reduced financial statement disclosure requirements in our SEC filings. Decreased disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of the reporting exemptions applicable to a smaller reporting company until we are no longer a smaller reporting company, which status would end once we have a public float greater than $250 million. In that event, we could still be a smaller reporting company if our annual revenues were below $100 million and we have a public float of less than $700 million.

We are an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012, as amended. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We may remain an EGC or until the earlier of (a) December 31, 2026, (b) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion or more, (c) the date we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (d) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Changes in tax laws may materially adversely affect our business, prospects, financial condition and operating results.

New tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business, prospects, financial condition and operating results. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Tax Act, the CARES Act, and the IRA enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. Such tax law changes could have a material adverse impact on us. In addition, it is uncertain if and to what extent various states will conform to newly enacted federal tax legislation. While it is too early to assess the overall impact of these changes, as these and other tax laws and related regulations are revised, enacted, and implemented, our financial condition, results of operations, and cash flows could be materially adversely impacted.

Our ability to use NOL carryforwards and other tax attributes may be limited.

We have incurred losses during our history, and we do not expect to become profitable in the near future and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire, if at all. As of December 31, 2023, we had U.S. federal NOL carryforwards and state NOL carryforwards of approximately $237.8 million and $170.4 million, respectively. Under current law, U.S. federal NOL carryforwards generated in taxable periods beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal law. In addition, under Sections 382 and 383 of the Code, federal NOL carryforwards and other tax attributes may become subject to an annual limitation in the event of certain cumulative changes in ownership. An "ownership change" pursuant to Section 382 of the Code generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes or other transactions. Similar rules may apply under state tax laws. If we earn taxable income, such limitations could result in increased future income tax liability to us, and our future cash flows could be adversely affected.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

We recognize the critical importance of protecting the confidentiality, integrity and availability of our business operations and systems. With this in mind, we have implemented and maintain an ongoing cybersecurity risk management program, under the oversight of our Board of Directors that is focused on identifying, assessing,

managing, and mitigating cybersecurity risk. Our cybersecurity policies, standards, processes and practices incorporate several standards, specifications, and requirements from the National Institute of Standards and Technology ("NIST") Cybersecurity Framework, and other applicable industry standards. In general, we seek to address cybersecurity risks through a cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents if they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

To identify and assess material risks from cybersecurity threats, we maintain a cybersecurity program to ensure our systems are effective and prepared for information security risks. We consider risks from cybersecurity threats alongside other company risks as part of our overall risk assessment process. We employ a range of tools and services, including regular network and endpoint monitoring to inform our risk identification and assessment, as well as undertaking the following activities:

- monitor emerging data protection laws and implement changes to our processes that are designed to comply with such laws;
- through our policies, practices and contracts (as applicable), require employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employ technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, device encryption, multi-factor authentication, advanced threat protection for emails, anti-virus and anti-malware functionality and access controls, which are evaluated and improved from time to time;
- conduct regular phishing email simulations and cybersecurity training for all employees and contractors with access to our email systems to enhance awareness and responsiveness to possible threats; and
- employ multiple backup systems for our data stored on our servers or other information systems.

As part of the above processes, we regularly engage with third-party cybersecurity vendors to provide a range of services in furtherance of our cybersecurity program, including monitoring our cybersecurity systems and processes to help identify areas for continued focus, improvement and compliance. In addition, we also have a process to assess and review the cybersecurity practices of third-party vendors and service providers, including through the use of contractual security requirements and performing diligence, as appropriate.

We face risks from cybersecurity threats that, if realized, are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. For more information, see the section in our risk factors under the heading "*Our internal information technology systems, or those of our vendors, collaborators or other contractors or consultants, may fail or suffer cybersecurity incidents, loss of data, and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business*." which disclosures are incorporated by reference herein.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for our Board of Directors and management. Our Board of Directors has delegated the oversight of cybersecurity risks to our Audit Committee, which oversees management's implementation of our cybersecurity program.

Our Audit Committee receives periodic updates from management of our cybersecurity program and risks, including, as necessary, any material cybersecurity threat risks or incidents, as well as the steps management has taken to respond to such risks. Members of our Audit Committee are also encouraged to engage in conversations with management on cybersecurity-related news events and discuss any updates to our cybersecurity risk management and strategy programs. The Committee reports to the full Board of Directors regarding its activities and risk management functions, including those related to cybersecurity.

Our cybersecurity program, which is discussed in greater detail above, is led by our Chief Financial Officer with the help of our legal and human resources teams. Such individual has prior work experience in various roles involving managing information security and developing cybersecurity strategy and is responsible for supervising both our internal personnel and our retained third-party cybersecurity vendors. As discussed above, this management team member reports to the Audit Committee of our Board of Directors about cybersecurity related matters, periodically.

Our management team is informed about and monitors the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above. In the last three fiscal years, we have not experienced any material cybersecurity incidents.

Item 2. Properties

In July 2021, we entered into a lease agreement for approximately 13,424 square feet of office and laboratory space in Boston, Massachusetts, which serves as our corporate headquarters. The lease commenced in February 2022. The lease term is for eight years and expires February 28, 2030 and does not contain an option to renew. The initial annual rent was $1,235,008 with a 3% annual increase. We believe substantially all of our property and equipment is in good condition and that we have sufficient capacity to meet our current operational needs. See Note 11 to our consolidated financial statements included in Item 8 of this Annual Report on Form 10-K for additional information.

Item 3. Legal Proceedings

From time to time, we are subject to various legal proceedings, claims and administrative proceedings that arise in the ordinary course of our business activities. Although the results of the litigation and claims cannot be predicted with certainty, as of the date of this report, we do not believe we are party to any claim, proceeding or litigation the outcome of which, if determined adversely to us, would individually or in the aggregate be reasonably expected to have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

Part II

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

Market Information

Our common stock trades under the symbol "ELTX" on the Nasdaq Global Select Market and has been publicly traded under this symbol since June 1, 2023, prior to which it was traded under the symbol "ANGN".

Holders of Record

As of March 26, 2024, there were approximately 245 holders of record of shares of our common stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

Unregistered Sales of Equity Securities

On December 22, 2023, we entered into a Subscription Agreement (the "Subscription Agreement") with GKCC, LLC (the "Purchaser"), an entity controlled by one of our directors, providing for the issuance and sale by us to the Purchaser of an aggregate of 1,213,000 shares of our common stock, par value $0.01 per share, at a purchase price per share of $5.81 (the "Offering"). The gross proceeds were approximately $7.0 million.

The issuance of these shares was pursuant to a private placement exemption from registration afforded by Section 4(a)(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D thereunder and similar exemptions under applicable state laws. We plan to use the proceeds of the Offering for the advancement of our development pipeline, as well as for working capital and general corporate purposes.

Repurchases of Equity Securities

None.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination related to dividend policy will be made at the discretion of our board of directors after considering our financial condition, results of operations, capital requirements, business prospects and other factors the board of directors deems relevant, and subject to the restrictions contained in any future financing instruments.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to the historical financial information, this discussion contains forward-looking statements that involve risk, assumptions and uncertainties, such as statements of our plans, objectives, expectations, intentions, forecasts and projections. Our actual results and the timing of selected events could differ materially from those discussed in these forward-looking statements as a result of several factors, including those set forth under the section of this Annual Report on Form 10-K titled "Risk Factors," which you should read carefully to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section titled "Forward-Looking Statements" at the beginning of this report.

Overview

We are a clinical-stage biotechnology company pioneering the development of immunotherapies for patients with limited treatment options and poor outcomes suffering from cancer and infectious disease. Our proprietary Amphiphile ("AMP") technology is designed to mobilize the body's immune response by preferentially targeting our product candidates to the lymph nodes with the goal of generating a robust T cell response. Recent advances have identified T cell responses as a key component of effective cancer immunotherapy and we believe our AMP technology can generate a robust T cell response that can potentially provide meaningful clinical benefit.

We believe the therapeutic utility of currently approved and development stage immunotherapies are limited in many cases due to their inability to sufficiently localize to lymph nodes and adequately engage with the critical immune cells responsible for stimulating adaptive immunity. Our AMP technology is specifically intended to localize

payloads to lymph nodes leading to the generation of a robust T cell response that we believe is critical to generate an anticancer immune response.

We have developed our cancer vaccine product candidates to target biologically validated tumor mutation drivers using known neoantigens. This strategy results in an "off-the-shelf" therapeutic option allowing patients to receive treatment without delay due to manufacturing timelines and costs associated with personalized vaccine approaches.

Our clinical and preclinical pipeline includes the lymph node targeted therapeutic cancer vaccines ELI-002, currently being evaluated in a Phase 2 clinical program, designed to stimulate an immune response against mutant KRAS cancers, ELI-007, currently being evaluated in a preclinical study for the treatment of mutant v-raf murine sarcoma viral oncogene homolog B1 ("BRAF")-driven cancers, and ELI-008, currently being evaluated in a preclinical study for use in the treatment of mutated tumor protein p53 ("TP53") expressing cancers. We believe that each of our cancer vaccine product candidates, if approved, have the potential to improve the lives of patients suffering from solid tumors arising due to specific oncogenic driver mutations.

Our operations to date have been financed primarily by aggregate net proceeds of $106.6 million from the issuance of common stock, convertible preferred stock, convertible notes, and the exercise of stock options and common stock warrants and proceeds from the Merger. Since inception, we have had significant annual operating losses. Our net loss was $35.2 million and $28.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $142.2 million and $12.9 million in cash and cash equivalents.

Elicio Operating Company, Inc. ("Former Elicio") was incorporated in Delaware as Vedantra Pharmaceuticals Inc. in August 2011. In December 2018, Former Elicio formed a wholly owned subsidiary, Elicio Securities Corporation, a Massachusetts corporation.

On January 17, 2023, Former Elicio entered into a definitive merger agreement (the "Merger Agreement") with Angion Biomedica Corp ("Angion"), a clinical-stage biotechnology company, and Arkham Merger Sub, Inc., a wholly owned subsidiary of Angion ("Merger Sub"), pursuant to which Merger Sub merged with and into Former Elicio, with Former Elicio surviving the merger as a wholly owned subsidiary of Angion (the "Merger").

On June 1, 2023, the Merger was completed in accordance with the terms and conditions of the Merger Agreement and Angion changed its name from "Angion Biomedica Corp." to "Elicio Therapeutics, Inc." Immediately following the consummation of the Merger, there were approximately 9.7 million shares of our common stock outstanding on a fully-diluted basis, with Former Elicio equity holders collectively owning approximately 65.2% of the Company and Angion equity holders collectively owning approximately 34.8% of the Company, in each case on a fully diluted basis. The Merger was accounted for as a reverse recapitalization, with Former Elicio being treated as the acquirer for accounting purposes. As a result of the Merger, the net assets of Angion were recorded at their acquisition-date fair value, which approximated book value due to the short-term nature of the instruments, in the financial statements of Former Elicio and the reported operating results prior to the Merger were those of Former Elicio.

We are currently facing substantial doubt about our ability to continue as a going concern, given our cash position and cash runway. We believe that our cash on hand will enable us to fund our operations into the third quarter of 2024 based on our current plan. This period could be shortened if there are any significant increases in planned or actual spending on development programs or more rapid progress of development programs than anticipated. There is no assurance that financing will be available when needed to allow us to continue as a going concern. Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations for at least twelve months following the issuance of the consolidated financial statements, raise substantial doubt about our ability to continue as a going concern. We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates and will require additional financing to continue this development. We plan to address this condition through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including licensing arrangements, partnerships and collaborations with other companies or other strategic transactions, but there is no assurance these plans will be completed successfully or at all. If we are unable to obtain additional capital when and as needed to continue as a going concern, we might have to further reduce or scale back our operations and/or liquidate our assets, and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

Our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. Our consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, attorneys and accountants, and incur other increased costs associated with being a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase significantly in connection with our ongoing activities, as we:

- advance our lead product candidate, ELI-002, to late stage clinical trials;
- advance our preclinical programs to clinical trials;
- expand our pipeline of product candidates;
- seek regulatory approval for our investigational medicines;
- maintain, expand, protect and defend our intellectual property portfolio;
- acquire or in-license technology;
- expand our clinical, scientific, management and administrative teams; and
- operate as a public company.

We believe that our cash on hand will enable us to fund our operations into the third quarter of 2024 based on our current plan. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured. Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations for at least twelve months following the issuance of the consolidated financial statements, raise substantial doubt about our ability to continue as a going concern.

We have not had any products approved for sale. We do not expect to generate any product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any 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, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

Components of Results of Operations

The following discussion summarizes the key factors our management believes are necessary for an understanding of our financial statements.

Operating Expenses

Our operating expenses since inception have consisted primarily of research and development expenses and general and administrative costs.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred for the development of our product candidates and our drug discovery efforts, which include:

- personnel costs, which include salaries, benefits and equity-based compensation expense;
- expenses incurred under agreements with consultants and contract organizations that conduct research and development activities on our behalf;
- costs related to sponsored research service agreements;

- costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical studies and planned clinical trials; and
- laboratory supplies and equipment used for internal research and development activities.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and service providers.

Our research and development expenses are not currently tracked on a program-by-program basis. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Substantially all our research and development costs are incurred on the development of ELI-002 and ELI-004, an AMP adjuvant that is a significant component of ELI-002, and our preclinical candidates.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in conducting clinical trials, manufacturing and otherwise advancing our programs. The process of conducting the clinical research necessary to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and costs of the efforts that will be needed to complete the development of, or the period, if any, in which material net cash inflows may commence from ELI-002 or any of our preclinical candidates. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- clinical trials and early-stage results;
- the terms and timing of regulatory approvals; and
- the ability to market, commercialize and achieve market acceptance for ELI-002, or any of our preclinical candidates that we or our future collaboration partners may develop in the future.

Any of these variables with respect to the development of ELI-002, or any other of our preclinical candidates that we may develop could result in a significant change in the costs and timing associated with the development of such candidates. For example, if the FDA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, including equity-based compensation, and other expenses for outside professional services, including marketing, legal, audit and accounting, facility-related costs not otherwise included in research and development expenses, and recruiting. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of expanding our operations and operating as a public company. These increases will likely include increases related to the hiring of additional personnel and legal, regulatory and other fees and services associated with maintaining compliance with Nasdaq Stock Market LLC (“Nasdaq”), Marketplace Rules, or the Nasdaq Listing Rules and Securities and Exchange Commission (“SEC”) requirements, accounting and audit fees, director and officer insurance costs and investor relations costs associated with being a public company.

Other Income (Expense)

For the years ended December 31, 2023 and 2022, other income and expense consisted primarily of interest income, foreign exchange transaction losses, loss on sale of equipment, interest expense, changes in fair value of the embedded derivative, gain on extinguishment of promissory notes, and gains and losses related to the re-measurement of our warrant liabilities.

Results of Operations

Comparison for the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the periods indicated:

	Year Ended December 31,			
	2023	2022	$ Change	% Change
	(In thousands, except percentages)			
Operating expenses:				
Research and development	$ 23,849	$ 18,103	$ 5,746	31.7 %
General and administrative	11,896	5,630	6,266	111.3 %
Total operating expenses	35,745	23,733	12,012	50.6 %
Loss from operations	(35,745)	(23,733)	(12,012)	50.6 %
Other income (expense), net	550	(4,475)	5,025	(112.3)%
Net loss	**$ (35,195)**	**$ (28,208)**	**$ (6,987)**	24.8 %

Research and Development Expenses

Research and development expenses increased by $5.7 million, or 31.7%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The net increase in research and development expenses was primarily due to an increase in external costs associated with ELI-002 manufacturing and clinical trials.

General and Administrative Expenses

General and administrative expenses increased by $6.3 million, or 111.3%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was primarily due to higher personnel-related costs in support of organizational growth and higher professional fees incurred in connection with the Merger and operating as a public company.

Other Income (Expense), Net

Other income (expense), increased by $5.0 million for the year ended December 31, 2023 compared to the year ended December 31, 2022. The increase was primarily due to reduced interest expense associated with the promissory notes.

Liquidity and Capital Resources

Sources and Uses of Liquidity

Our operations through December 31, 2023 have been financed primarily by aggregate net proceeds of $106.6 million from the issuance of common stock, convertible preferred stock, convertible notes, the exercise of stock options and common stock warrants and proceeds from the Merger. Since inception, we have had significant operating losses. Our net loss was $35.2 million and $28.2 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $142.2 million and $12.9 million in cash and cash equivalents. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

Our losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations for at least twelve months following the issuance of the consolidated financial statements, raise substantial doubt about our ability to continue as a going concern. We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates and will require additional financing to continue this development. The consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. We plan to address this condition through the sale of common stock in public

offerings and/or private placements, debt financings, or through other capital sources, including licensing arrangements, partnerships and collaborations with other companies or other strategic transactions. However, there is no assurance that we will be successful in raising additional capital or that such additional funds will be available on acceptable terms, if at all. Should we be unable to raise this amount of capital our operating plans will be limited to the amount of capital that we can access. We may also consider steps to reduce our operating expenses. There can be no assurances that we will be successful in any of the foregoing.

Summary Statement of Cash Flows

The following table sets forth a summary of our net cash flow activity for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash provided by (used in)		
Operating activities	$ (32,694)	$ (22,179)
Investing activities	(32)	(654)
Financing activities	38,613	21,202
Effect of foreign currency on cash	—	—
Net (decrease) increase in cash	$ 5,887	$ (1,631)

Operating activities

For the year ended December 31, 2023, net cash used in operating activities was $32.7 million, which primarily consisted of a net loss of $35.2 million and the change in net operating assets and liabilities of $0.1 million partially offset by the net non-cash charges of $2.6 million. The change in net operating assets and liabilities of $0.1 million was the result of a $0.7 million decrease in the deferred research obligation, $0.8 million decrease in prepaid assets, and $0.8 million decrease in the operating lease liability offset by an increase in accounts payable and accrued expenses of $2.2 million. The $2.6 million of net non-cash charges were related to $1.1 million of interest expense related to the accretion of promissory notes payable, $1.2 million of stock-based compensation, $0.8 million related to the amortization of the right-of-use asset, $0.4 million of depreciation, $0.1 million loss on disposal of property and equipment partially offset by $0.4 million increase in the fair value of the embedded derivative associated with the promissory notes payable and $0.6 million of gain on the extinguishment of the promissory notes payable.

For the year ended December 31, 2022, net cash used in operating activities was $22.2 million, which primarily consisted of a net loss of $28.2 million and a change in net operating assets and liabilities of $0.2 million, partially offset by net non-cash charges of $6.2 million. The change in net operating assets and liabilities of $0.2 million was the result of a $1.8 million decrease in prepaid assets and a $0.5 million decrease in the operating lease liability offset by an increase in accounts payable and accrued expenses of $0.8 million, and an increase of the deferred research obligation of $1.4 million. The net non-cash charges of $6.2 million were primarily related to $3.6 million of non-cash interest expense, $0.9 million of non-cash change in the fair value of the embedded derivative, $0.4 million of depreciation expense, $0.7 million related to amortization of the right-of-use asset associated with our operating leases and $0.6 million of stock-based compensation expense.

Investing activities

For the year ended December 31, 2023, an immaterial amount of cash was provided or used in investing activities, and for the year ended December 31, 2022, net cash used in investing activities was $0.7 million, primarily used to purchase capital equipment.

Financing activities

For the year ended December 31, 2023, net cash provided by financing activities was $38.6 million, comprised of $31.6 million of net proceeds from the Merger and $7.0 million of proceeds from the sale of common stock. For the year ended December 31, 2022, net cash provided by financing activities was $21.2 million, comprised of $21.1 million of net proceeds from the issuance of Series C preferred stock and $0.1 million of proceeds from the exercise of common stock options.

Future Cash Needs and Funding Requirements

Based on our current operating plan, we believe our cash and cash equivalents will be sufficient to fund our planned operations into the third quarter of 2024. However, we have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all our available capital resources

sooner than we expect. We are unable to estimate the exact amount of our operating capital requirements. The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching and developing product candidates, and conducting preclinical studies and clinical trials;
- the outcome of any future clinical trials, for any existing or future product candidates;
- whether we are able to take advantage of any FDA expedited development and approval programs for any of our product candidates;
- the outcome, costs and timing of seeking and obtaining and maintaining FDA and any foreign regulatory approvals;
- the costs associated with any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of our product candidates;
- the number and characteristics of product candidates we pursue, including product candidates in preclinical development;
- the ability of our product candidates to progress through clinical development successfully;
- our need to expand our research and development activities, including to conduct additional clinical trials;
- market acceptance of our product candidates, including physician adoption, market access, pricing and reimbursement;
- the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments potentially required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional personnel, including management, clinical development, medical and commercial personnel;
- the effect of competing technological, market developments and government policy;
- the costs associated with being a public company, including our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the costs associated with securing and establishing commercialization and manufacturing capabilities, as well as those associated with packaging, warehousing and distribution;
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future and timing and amount of payments thereunder; and
- the timing, receipt and amount of sales and general commercial success of any future approved products, if any.

Until such time as we can generate significant revenue from sales of product candidates, if ever, we expect to finance our operations through the sale of common stock in public offerings and/or private placements, debt financings, or through other capital sources, including licensing arrangements, partnerships and collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. To the extent we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, or 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 grant licenses on terms that may not be favorable to and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Going Concern

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities one year from the date our audited consolidated financial statements are issued. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of pharmaceutical products is inherently subject to uncertainty.

Research and Development Costs

We will incur substantial expenses associated with manufacturing and clinical trials. Accounting for clinical trials relating to activities performed by contract research organizations ("CROs") and other external vendors requires management to exercise significant estimates in regard to the timing and accounting for these expenses. We estimate costs of research and development activities conducted by service providers, which include the conduct of sponsored research, preclinical studies and contract manufacturing activities. The diverse nature of services being provided under CROs and other arrangements, the different compensation arrangements that exist for each type of service and the lack of timely information related to certain clinical activities complicates the estimation of accruals for services rendered by CROs and other vendors in connection with clinical trials. We record the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced and include these costs in the accrued expenses or prepaid expenses on the balance sheets and within research and development expense on the consolidated statements of operations and comprehensive loss. In estimating the duration of a clinical study, we evaluate the start-up, treatment and wrap-up periods, compensation arrangements and services rendered attributable to each clinical trial and fluctuations are regularly tested against payment plans and trial completion assumptions.

We estimate these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities and prepaid expense balances in each reporting period. As actual costs become known, we adjust our accrued liabilities or prepaid expenses. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

Our expenses related to clinical trials will be based on estimates of patient enrollment and related expenses at clinical investigator sites as well as estimates for the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that may be used to conduct and manage clinical trials on our behalf. We will accrue expenses related to clinical trials based on contracted amounts applied to the level of patient enrollment and activity. If timelines or contracts are modified based upon changes in the clinical trial protocol or scope of work to be performed, we will modify our estimates of accrued expenses accordingly on a prospective basis.

Leases

ASU No. 2016-02, Leases (ASC 842) establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of operations and comprehensive loss as well as the reduction of the right of use asset.

At the inception of an arrangement, we determine whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and our control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, we will utilize the incremental borrowing rate, which is the

rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

We have elected to combine lease and non-lease components as a single component. Operating leases are recognized on the consolidated balance sheet as ROU lease assets, current lease liabilities and non-current lease liabilities. Fixed rents are included in the calculation of the lease balances, while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

Stock-based Compensation

Prior to the Merger, we issued equity-based compensation awards through the granting of options, which generally vest over four years. We account for equity-based compensation in accordance with Accounting Standards Codification 718, *Compensation - Stock Compensation* ("ASC 718"). In accordance with ASC 718, compensation cost is measured at estimated fair value at grant date and is included as compensation expense over the vesting period during which service is provided in exchange for the award. Compensation cost of awards that contain a performance condition are recognized when success is considered probable during the performance period.

We use the Black-Scholes option pricing model ("Black-Scholes") to determine fair value of our options. Black-Scholes includes various assumptions, including the fair value of common shares, expected life of incentive shares, the expected volatility, expected dividend yield, and the expected risk-free interest rate. These assumptions reflect our best estimates, but they involve inherent uncertainties based on market conditions generally outside our control. As a result, if other assumptions had been used, equity-based compensation cost could have been materially impacted. Furthermore, if we use different assumptions for future grants, equity-based compensation cost could be materially impacted in future periods.

The risk-free interest rate is estimated using the weighted average rate of return on U.S. Treasury notes with a life that approximates the expected life of the option. The expected term of options granted to employees was calculated using the simplified method, which represents the average of the contractual term of the option and the weighted-average vesting period of the option. We use the simplified method because we do not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term. The contractual life of the option was used for the expected life of options granted to non-employees. Expected volatility is based on the weighted average of the historical volatility of a peer group of publicly traded companies. The assumed dividend yield is based upon our expectation of not paying dividends in the foreseeable future.

We will continue to use judgment in evaluating the assumptions utilized for our equity-based compensation expense calculations on a prospective basis. In addition to the assumptions used in the Black-Scholes model, the amount of equity-based compensation expense we recognize in our consolidated financial statements includes incentive share forfeitures as they occurred.

Subsequent to the effective date of the Merger, we determine the fair value of our common stock based on the closing price of our common stock as reported by Nasdaq on the date of grant.

Derivative Financial Instruments

The convertible notes include an embedded derivative requiring bifurcation in accordance with Accounting Standards Codification ("ASC") 815, Derivatives and Hedging. The valuation of this instrument is determined using widely accepted valuation technique including the probability weighted expected return model. The fair value was determined using a model with the assumptions for equity value proceeds, probability of occurrence of various liquidation scenarios, timeline to liquidity and risk-free interest rate. The fair value of this derivative instrument is measured at each reporting period with changes in fair value reported in earnings. On October 18, 2022, in conjunction with the shares of Series C preferred stock issued on this same date, the convertible notes payable totaling $14.5 million and the related accrued interest totaling $1.1 million automatically converted into 1,370,187 shares of Series C preferred stock at an 80% discount to the Series C preferred stock issuance price per share of $14.23, or $11.39 per share. Just prior to settlement, the fair value of the embedded derivative was marked to market a final time to the aggregate value of $3.9 million. We recorded an immaterial gain on extinguishment related to the difference in the total of convertible notes payable, total accrued interest and the final fair value of the embedded derivative versus the value of the Series C preferred stock shares issued based on the original issuance price of $14.23 per share.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2023:

(in thousands)	Payments due by period				
	Total	Less than one year	One to two years	Three to four years	Five and more years
Leases	$ 8,817	$ 1,427	$ 1,350	$ 2,808	$ 3,232

We enter into contracts in the normal course of business with third-party service providers for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. We have not included our payment obligations under these contracts in the table as these contracts generally provide for termination upon notice, and therefore, we believe that our non-cancelable obligations under these agreements are not material and we cannot reasonably estimate the timing of if and when they will occur. We could also enter into additional research, manufacturing, supplier and other agreements in the future, which may require up-front payments and even long-term commitments of cash.

In January 2016, we licensed certain intellectual property from MIT on terms that have been amended from time to time. The license term extends until terminated by either party under certain provisions. We are required to pay certain contractual maintenance and milestone payments related to clinical trials and royalties on product sales over the term of the contract, with minimum annual royalty payments commencing in the calendar year after commercialization.

Recent Accounting Pronouncements

See Note 2, “Summary of Significant Accounting Policies” in the Notes to the Consolidated Financial Statements set forth in Item 8 of this Annual Report on Form 10-K for a full description of recent accounting standards.

Emerging Growth Company and Smaller Reporting Company Status

We are a smaller reporting company and an emerging growth company, as defined under the JOBS Act. Under the JOBS Act, emerging growth companies can delay the adoption of new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Sarbanes-Oxley Act of 2002, as amended (“Sarbanes-Oxley”) an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting standards as of public company effective dates.

We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the last day of our first fiscal year in which we have total annual gross revenue of $1.235 billion or more, (iii) the date on which we are deemed to be a "large accelerated filer," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), which means the market value of equity securities that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter and (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" and/or “non-accelerated filer” which may allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply for a period of time with the auditor attestation requirements of Section 404 of Sarbanes-Oxley, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements of Elicio Therapeutics, Inc., listed below are set forth in Item 8 of this Annual Report for the years ended December 31, 2023 and 2022:

ELICIO THERAPEUTICS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Elicio Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Elicio Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered losses and negative cash flow from operations, and has an accumulated deficit as of December 31, 2023, that raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 to 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.

/s/ Baker Tilly US, LLP

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

Tewksbury, Massachusetts
March 29, 2024

ELICIO THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 12,894	$ 6,156
Restricted cash, current	722	1,641
Prepaid expenses and other current assets	2,732	2,920
Total current assets	16,348	10,717
Property and equipment, net	717	1,147
Operating lease, right-of-use assets	6,563	7,350
Restricted cash, noncurrent	685	617
Other long-term prepaid assets	2,833	2,833
Total assets	**$ 27,146**	**$ 22,664**
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 4,369	$ 2,805
Accrued expenses	3,757	1,935
Deferred research obligation	694	1,436
Operating lease liability, current	910	692
Unvested option exercise liability, current	25	—
Warrant liability	11	—
Total current liabilities	9,766	6,868
Operating lease liability, noncurrent	6,007	6,789
Unvested option exercise liability, noncurrent	—	92
Total liabilities	15,773	13,749
Commitments and contingencies—Note 10		
Convertible preferred stock:		
Series A convertible preferred stock, $0.06 par value: no shares and 132,387 shares authorized, issued and outstanding at December 31, 2023 and 2022, respectively	—	7,495
Series B convertible preferred stock, $0.06 par value: no shares and 1,927,375 shares authorized, issued and outstanding at December 31, 2023 and 2022, respectively	—	62,944
Series C convertible preferred stock, $0.06 par value: no shares and 4,888,798 shares authorized at December 31, 2023 and 2022, respectively; no shares and 2,938,158 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	40,621
Total convertible preferred stock	—	111,060
Stockholders' equity (deficit):		
Common stock, $0.01 par value; 300,000,000 shares authorized at December 31, 2023 and 2022, respectively; 9,618,178 and 320,281 shares issued at December 31, 2023 and 2022, respectively; 9,603,723 and 320,281 shares outstanding as of December 31, 2023 and 2022, respectively	96	3
Treasury stock, at cost, 14,455 and no shares outstanding as of December 31, 2023 and 2022, respectively	(150)	—
Additional paid-in capital	153,827	4,860
Accumulated other comprehensive loss	(197)	—
Accumulated deficit	(142,203)	(107,008)
Total stockholders' equity (deficit)	11,373	(102,145)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	**$ 27,146**	**$ 22,664**

The accompanying notes are an integral part of these consolidated financial statements.

ELICIO THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 23,849	$ 18,103
General and administrative	11,896	5,630
Total operating expenses	35,745	23,733
Loss from operations	**(35,745)**	**(23,733)**
Other income (expense)		
Change in fair value of warrant liability	(2)	—
Change in fair value of embedded derivatives	429	(945)
Gain on extinguishment of promissory notes payable	605	2
Foreign exchange transaction gain	204	—
Interest income	373	65
Interest expense	(1,059)	(3,597)
Total other income (expense)	550	(4,475)
Net loss	**(35,195)**	**(28,208)**
Other comprehensive loss:		
Foreign currency translation adjustment	(197)	—
Comprehensive loss	**$ (35,392)**	**$ (28,208)**
Net loss per common share, basic and diluted	$ (6.96)	$ (89.27)
Weighted average common shares outstanding, basic and diluted	5,056,225	315,998

The accompanying notes are an integral part of these consolidated financial statements.

ELICIO THERAPEUTICS, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Total Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value	Shares	Amount				
Balance as of December 31, 2022	**4,997,920**	**$ 111,060**	**320,281**	**$ 3**	**—**	**$ —**	**$ 4,860**	**$ —**	**$ (107,008)**	**$ (102,145)**
Exercise of stock options	—	**—**	16,349	1	—	—	126	—	—	**127**
Vesting of restricted common stock	—	**—**	5,310	—	—	—	67	—	—	**67**
Conversion of preferred stock	(4,997,920)	(111,060)	4,997,920	50	—	—	111,010	—	—	**111,060**
Issuance of common stock to Angion stockholders as a result of Merger and reset to par of $0.01, net of transaction costs of $2.4 million	—	**—**	3,012,854	30	—	—	19,496	—	—	**19,526**
Settlement of promissory notes in connection with Merger	—	**—**	—	—	—	—	10,027	—	—	**10,027**
Issuance of common stock upon accelerated vesting of restricted stock units due to Merger, net of treasury stock	—	**—**	26,550	—	—	—	—	—	—	**—**
Return of common stock to pay withholding taxes on restricted stock	—	**—**	—	—	(14,455)	(150)	—	—	—	**(150)**
Issuance of common stock related to stock purchase agreement	—	**—**	1,213,000	12	—	—	6,987	—	—	**6,999**
Issuance of common stock related to service agreement	—	**—**	11,459	—	—	—	75	—	—	**75**
Stock-based compensation	—	**—**	—	—	—	—	1,179	—	—	**1,179**
Foreign currency translation adjustment	—	**—**	—	—	—	—	—	(197)	—	**(197)**
Net loss	—	**—**	—	—	—	—	—	—	(35,195)	**(35,195)**
Balance as of December 31, 2023	**—**	**$ —**	**9,603,723**	**$ 96**	**(14,455)**	**$ (150)**	**$ 153,827**	**$ (197)**	**$ (142,203)**	**$ 11,373**

The accompanying notes are an integral part of these consolidated financial statements.

ELICIO THERAPEUTICS, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands, except share amounts)

	Total Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value	Shares	Amount				
Balance as of December 31, 2021	**1,408,100**	**$ 70,439**	**310,200**	**$ 3**	**—**	**$ —**	**$ 4,261**	**$ —**	**$ (78,800)**	**$ (74,536)**
Stock-based compensation	—	—	—	—	—	—	579	—	—	**579**
Issuance of common stock upon exercise of options	—	—	593	—	—	—	7	—	—	**7**
Vesting of restricted common stock	—	—	9,488	—	—	—	13	—	—	**13**
Issuance of Series C convertible preferred stock, net of issuance costs of $1.2 million	2,219,633	21,120	—	—	—	—	—	—	—	**—**
Issuance of Series C convertible preferred stock upon extinguishment of convertible notes payable	1,370,187	19,501	—	—	—	—	—	—	—	**—**
Net loss	—	—	—	—	—	—	—	—	(28,208)	**(28,208)**
Balance as of December 31, 2022	**4,997,920**	**$ 111,060**	**320,281**	**$ 3**	**—**	**$ —**	**$ 4,860**	**$ —**	**$ (107,008)**	**$ (102,145)**

The accompanying notes are an integral part of these consolidated financial statements.

ELICIO THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (35,195)	$ (28,208)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	382	390
Amortization of right-of-use assets, operating leases	788	667
Non-cash interest expense	1,061	3,596
Change in fair value of embedded derivative	(429)	945
Change in fair value of warrant liability	2	—
Stock-based compensation	1,179	579
Non-cash professional services expense	75	—
Gain on extinguishment of promissory notes	(605)	(2)
Loss on disposal of property and equipment	105	4
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(729)	(1,985)
Other long-term prepaid assets	—	114
Accounts payable	23	1,125
Accrued expenses and other current liabilities	2,216	(305)
Deferred research obligation	(742)	1,436
Operating lease liability	(825)	(535)
Net cash used in operating activities	(32,694)	(22,179)
Cash flows from investing activities		
Purchases of property and equipment	(66)	(654)
Proceeds from sale of property and equipment	34	—
Net cash used in investing activities	(32)	(654)
Cash flows from financing activities		
Cash acquired in connection with the reverse merger	24,001	—
Merger transaction costs	(2,364)	—
Proceeds from issuance of promissory notes payable	10,000	—
Proceeds from issuance of Series C convertible preferred stock, net of issuance costs	—	21,120
Proceeds from issuance of common stock per purchase agreement	6,999	
Payment for purchase of treasury stock	(150)	—
Proceeds from exercise of stock options	127	82
Net cash provided by financing activities	38,613	21,202
Effect of foreign currency on cash	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	5,887	(1,631)
Cash, cash equivalents and restricted cash at the beginning of the year	8,414	10,045
Cash, cash equivalents and restricted cash at the end of the year	**$ 14,301**	**$ 8,414**
Components of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	**$ 12,894**	**$ 6,156**
Restricted cash	**1,407**	**2,258**
Total cash, cash equivalents and restricted cash	**$ 14,301**	**$ 8,414**
Supplemental disclosure of noncash investing and financing activities:		
Loss on disposal of property and equipment	$ 105	$ 4
Non-cash issuance of Series C convertible preferred stock	$ —	$ 19,501
Settlement of promissory notes payable	$ 10,027	$ —
Accretion of promissory note discount from embedded derivative	$ 130	$ —
Accretion of promissory note to face value	$ 897	$ —
Non-cash vesting of restricted common stock	$ 67	$ 13
Non-cash issuance of common stock from conversion of preferred stock	$ 111,060	$ —

Non-cash issuance of common stock to Angion stockholders	$	19,526	$	—
Non-cash issuance of common stock related to service agreement	$	75	$	—
Accretion of convertible note discount from embedded derivative	$	—	$	2,344
Accretion of convertible note discount from issuance costs	$	—	$	328
Interest expense from convertible notes payable	$	—	$	923

The accompanying notes are an integral part of these consolidated financial statements.

ELICIO THERAPEUTICS, INC.
Notes to Consolidated Financial Statements

Note 1—Description of the Business and Financial Condition

Elicio Therapeutics, Inc. ("Elicio" or the "Company") was incorporated in Delaware as Vedantra Pharmaceuticals Inc., in August 2011. Elicio is a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer. In December 2018, Elicio formed a wholly-owned subsidiary, Elicio Securities Corporation ("ESC"), a Massachusetts corporation. ESC is an investment company. Elicio and ESC are collectively referred to as "Elicio" throughout these consolidated financial statements.

Reverse Merger Transaction

On January 17, 2023, the Company entered into a definitive merger agreement (the "Merger Agreement") with Angion Biomedica Corp. ("Angion"), a clinical-stage biotechnology company, Arkham Merger Sub, Inc., a wholly owned subsidiary of Angion ("Merger Sub"), and Elicio Operating Company, Inc. ("Former Elicio"), pursuant to which Merger Sub merged with and into Former Elicio, with Former Elicio surviving the merger as a wholly owned subsidiary of Angion (the "Merger").

On June 1, 2023, the Company completed the Merger in accordance with the terms and conditions of the Merger Agreement and Angion changed its name from "Angion Biomedica Corp." to "Elicio Therapeutics, Inc." Immediately following the consummation of the Merger, there were approximately 9.7 million shares of the Company's common stock outstanding on a fully-diluted basis, with Former Elicio equity holders collectively owning approximately 65.2% of the Company and Angion equity holders collectively owning approximately 34.8% of the Company, in each case on a fully diluted basis.

The Merger was accounted for as a reverse recapitalization, with Former Elicio being treated as the acquirer for accounting purposes. See discussions of the transactions in connection with the Merger at Note 3 - Merger and Related Transactions.

Liquidity and Going Concern

The Company has experienced net losses and negative cash flows from operating activities since inception. As of December 31, 2023, the Company had an accumulated deficit of $142.2 million. The Company expects that its operating losses and negative operating cash flows will continue for the foreseeable future as the Company continues to develop its product candidates.

As of December 31, 2023, the Company had $ 12.9 million in cash and cash equivalents. The Company's losses from operations, negative operating cash flows and accumulated deficit, as well as the additional capital needed to fund operations for at least twelve months following the issuance of the consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. The Company expects to incur substantial expenditures in the foreseeable future for the development of its product candidates and will require additional financing to continue this development. The Company plans to address this condition through the sale of Company common stock in public offerings and/or private placements, debt financings, or through other capital sources, including licensing arrangements, partnerships and collaborations with other companies or other strategic transactions, but there is no assurance these plans will be completed successfully or at all. If the Company is unable to obtain additional capital when and as needed to continue as a going concern, it might have to further reduce or scale back its operations and/or liquidate its assets, and the values it receives for its assets in liquidation or dissolution could be significantly lower than the values reflected in its financial statements.

The accompanying consolidated financial statements have been prepared on a basis that assumes that the Company will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Note 2—Summary of Significant Accounting Policies

Basis of Presentation

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The consolidated financial statements include the accounts of the Company, its wholly owned subsidiary, Elicio Australia Pty Ltd. ("Elicio Pty"), which was established on August 22, 2019, and its wholly-owned subsidiary, ESC, which was established in Massachusetts in December 2018. The Company established Elicio Australia Pty, an Australian subsidiary, for the purpose of qualifying for research credits for studies conducted in Australia and ESC is an investment company. All significant intercompany balances and transactions have been eliminated in consolidation.

Since Former Elicio was determined to be the accounting acquirer in connection with the Merger, for periods prior to the Merger, the consolidated financial statements were prepared on a stand-alone basis for Former Elicio and did not include the combined entities activity or financial position. Subsequent to the Merger, the consolidated financial statements as of and for the year ended December 31, 2023 include the acquired business from June 2, 2023 through December 31, 2023, and assets and liabilities at their acquisition date fair value. Historical share and per share figures of Former Elicio have been retroactively restated to reflect the impact of a reverse stock split completed in connection with and prior to the effective time of the Merger, based on the exchange ratio of 0.0181.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business as one operating segment. The Company has determined that the chief executive officer is the CODM.

Use of Estimates

The Company's management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates. Significant estimates reflected in these consolidated financial statements include but are not limited to, the accrual of research and development expenses, the valuation of stock-based awards, the operating right of use assets and operating lease liability, and going concern.

Foreign Currency Translation and Transactions

The Australian Dollar ("AUD") is the functional currency for Elicio Pty. Accordingly, nonmonetary assets and liabilities originally acquired or assumed in other currencies are recorded in AUD at the date they were acquired or assumed. As part of the consolidation process, the Elicio Pty results are translated from AUD into the reporting currency of USD using average rates for profit and loss transactions and applicable spot rates for period-end balances. The effect of translating our functional currency into our reporting currency is reported separately in Accumulated Other Comprehensive Loss.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially subject the Company to concentration of credit risk consist primarily of cash, cash equivalents, and restricted cash. At times, cash balances deposited at major financial banking institutions exceed the federally insured limit. The Company regularly monitors the financial condition of the institutions in which it has depository accounts and believes the risk of loss is minimal. The Company has not experienced any losses in such accounts.

Cash and Cash Equivalents

Cash and cash equivalents are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. As of December 31, 2023 and 2022, the Company's cash equivalents were held in institutions in the United States and include deposits in a money market fund which were unrestricted as to withdrawal or use.

Restricted Cash

Restricted cash consists of cash securing a collateral letter of credit issued in connection with the Company's facility operating lease and a research grant. See Notes 6 and 11 for further discussion.

Fair Value Measurement

The Company follows the guidance prescribed by ASC Topic 820, *Fair Value Measurements*, which establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The standard provides a consistent definition of fair value that focuses on an exit price which is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the

measurement date. The standard establishes a three-level hierarchy for fair value measurements based on the nature of inputs used in the valuation of an asset or liability as of the measurement date.

Level 1: Observable inputs such as unadjusted quoted prices in active markets for identical assets or liabilities at measurement.

Level 2: Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

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.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The carrying amounts of financial instruments reflected in the consolidated balance sheets for cash and cash equivalents, current and non-current restricted cash, accounts payable, and accrued expenses approximate their respective fair values because of the short-term maturity of those financial instruments.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful life of the asset. Upon sale or retirement, the cost and accumulated depreciation are eliminated from their respective accounts, and the resulting gain or loss is recorded in the consolidated statement of operations and comprehensive loss. Repair and maintenance expenditures are expensed as incurred. Construction in process is not depreciated until the asset is placed into service.

Asset Classification	Estimated Useful Life
Equipment	5 years
Furniture and fixtures	3 years
Leasehold improvements	Shorter of useful life or lease term

Impairment of Long-Lived Assets

Periodically, the Company evaluates its long-lived assets, which consist primarily of property and equipment, and right of use asset, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. During the years ended December 31, 2023 and 2022, no impairments have occurred.

Derivative Financial Instruments

The convertible and promissory notes included embedded derivatives requiring bifurcation in accordance with ASC 815, *Derivatives and Hedging*. The valuation of the instruments was determined using widely accepted valuation techniques including the probability weighted expected return model. The fair value was determined using a model with the assumptions for equity value proceeds, probability of occurrence of various liquidation scenarios, timeline to liquidity and risk-free interest rate. The fair value of the derivative instruments was measured at each reporting period prior to settlement on October 18, 2022, with changes in fair value reported in earnings (loss).

Convertible Preferred Stock

Former Elicio had classified convertible preferred stock, par value $ 0.06 per share, (the "Preferred Stock") as temporary equity in the accompanying consolidated balance sheets due to certain changes in control events that were outside of the Former Elicio's control, including sale or transfer of control of Former Elicio, as holders of the Preferred Stock could cause redemption of the shares in these situations. Former Elicio did not accrete the carrying values of the Preferred Stock to the redemption values since a liquidation event was not considered probable as of December 31, 2022. Subsequent adjustments of the carrying values to the ultimate redemption values would be made only if it becomes probable that such a liquidation event will occur. During the year ended December 31, 2023 an immaterial error was discovered in Former Elicio's 2022 audited financial statements whereas the amount of

Series A and Series B Preferred Stock did not include 41,887 and 609,755 shares, respectively, that were deemed to be issued due to the antidilutive protection triggered by the Series C shares issued in October 2022 at a price below $1.00. As a result of the Merger, all Former Elicio preferred stock were converted into Company common stock on June 1, 2023. See Note 7.

Income Taxes

The Company provides for income taxes in accordance with ASC Topic 740, *Income Taxes*. Deferred tax assets and liabilities are determined based on the difference between the financial reporting and tax bases of assets and liabilities using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. A valuation allowance is provided if, based upon the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions when the Company management determines that it is probable that a loss will be incurred related to these matters and the amount of the loss is reasonably determinable. The Company has not identified any significant uncertain tax positions as of December 31, 2023.

Research and Development

Research and development costs are charged to expense as incurred and consist of expenses incurred in performing research and development activities, including salaries and benefits, materials and supplies, preclinical expenses, stock-based compensation expense, depreciation of equipment, contract services, and other outside expenses. The Company accrues for costs incurred by external service providers, based on estimates of services performed and costs. These estimates include the level of services performed by the third parties, and other indicators of the services completed. Based on the timing of payments to service providers, the Company may also record prepaid expenses for those service providers that will be recognized as expenses in future periods as the related services are rendered. Research and development costs may be offset by research and development refundable tax rebates received by the Company's wholly-owned Australian subsidiary.

Leases

ASU No. 2016-02, *Leases* ("ASC 842") establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and corresponding lease liability on the balance sheet for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the consolidated statements of operations as well as the reduction of the ROU asset.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company will utilize the incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

The Company has elected to combine lease and non-lease components as a single component. Operating leases are recognized on the consolidated balance sheet as ROU lease assets, current lease liabilities and non-current lease liabilities. Fixed rents are included in the calculation of the lease balances, while variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected term on a straight-line basis.

Research Grant

The Company analogizes to the guidance provided by International Accounting Standards 20, *Accounting for Government Grants and Disclosure of Government Assistance* ("IAS 20") for funds received from grants from entities that are not customers nor government agencies. The Company recognizes the amount of grant income based on the activity in allowable expenses covered under the grant and has elected to recognize the funds earned as an offset to the related research expenses recorded in operations. Advances from the grant that have yet to be recognized are recorded as restricted cash if the grant requires the funds to be isolated from general cash and cash equivalents. The Company records a liability for any research activity that is required under the grant but has not yet been performed. The liability is recorded as deferred research obligation on the consolidated balance sheets.

Stock-Based Compensation

The Company issues stock-based awards to employees and non-employees, generally in the form of stock options. The Company accounts for stock-based awards in accordance with ASC 718, *Compensation—Stock Compensation*, which requires all stock-based payments, to be recognized in the consolidated statements of operations based on their fair values. The expense is recognized on a straight line basis over the requisite service period, which is generally the vesting period. The Company has elected to account for option forfeitures as they occur.

The Company uses the Black-Scholes option-pricing model ("Black-Scholes") to determine the weighted-average fair value of options granted, which uses as inputs the fair value of the Company common stock, assumptions the Company makes for the volatility of its Company common stock, the expected term of its stock options, the risk-free interest rate for a period that approximates the expected term of its stock options and its expected dividend yield.

Compensation cost of awards that contain a performance condition are recognized when success is considered probable during the performance period.

Prior to the Merger, there was no public market for Former Elicio's common stock. The estimated fair value of the Company's common stock underlying Former Elicio's stock-based awards was determined by Former Elicio's board of directors as of the grant date of each option grant. To determine the fair value of Former Elicio's common stock underlying option grants, Former Elicio's board of directors considered, among other things, input from management and valuations of Former Elicio's common stock prepared by third-party valuation firms performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Following the Merger, the fair value of Company's common stock is based on the closing stock price on the date of grant as reported on the Nasdaq Global Select Market.

Net Loss Per Share

Basic net loss per share of Company common stock is computed by dividing net loss attributable to Company common stockholders by the weighted average number of shares of Company common stock outstanding for the period. Diluted net loss per share excludes the potential impact of Company common stock options, warrants and unvested shares of restricted stock because their effect would be anti-dilutive due to the Company's net loss. Since the Company had net losses for the years ended December 31, 2023 and 2022, basic and diluted net loss per common share are the same.

Comprehensive Loss

Comprehensive loss is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments* ("ASU No. 2016-13"), which requires an entity to utilize a new impairment model known as the current expected credit loss ("CECL") model to estimate its lifetime "expected credit loss" and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to, available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The Company adopted ASU No. 2016-13 on January 1, 2023 and the adoption of the standard had no material impact on its consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, *Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) - Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU No. 2020-16"), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. The Company adopted ASU No. 2020-06 on January 1, 2023 and the adoption of the standard had no material impact on its consolidated financial statements.

Recently Issued Accounting Standards Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Except as noted below, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its consolidated financial statements and disclosures.

In November 2023, the FASB issued No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.* This ASU broadens the disclosure requirements by requiring disclosures of significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss. The standard also requires entities to disclose, on an interim and annual basis, the amount and description, including the nature and type, of the other segment items. Additionally, entities are required to disclose the title and position of the individual identified as the CODM and an explanation of how the CODM uses the reported measures of a segment's profit or loss in assessing segment performance and deciding how to allocate resources. These enhanced disclosure obligations apply to entities that operate with one reportable segment as well. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. Early adoption is permitted. We are currently assessing the impact that this new accounting standard will have on our consolidated financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* This ASU requires disaggregated information about a reporting entity's effective tax rate reconciliation as well as additional information on income taxes paid. The standard requires entities to disclose federal, state, and foreign income taxes in their rate reconciliation tables and elaborate on reconciling items that exceed a quantitative threshold. Additionally, it requires an annual disclosure of income taxes paid, net of refunds, categorized by jurisdiction based on a quantitative threshold. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024. Early adoption is permitted. This ASU will result in the required additional disclosures being included in our consolidated financial statements, once adopted.

Note 3—Merger and Related Transactions

As described in Note 1, Former Elicio merged with a wholly owned subsidiary of Angion on June 1, 2023. The Merger was accounted for as a reverse recapitalization under U.S. GAAP. Former Elicio was considered the accounting acquirer for financial reporting purposes. This determination was based on the facts that, immediately following the Merger: (i) Former Elicio stockholders own a substantial majority of the voting rights; (ii) Former Elicio designated a majority (six of nine) of the initial members of the Company's board of directors of the combined company; (iii) Former Elicio's executive management team became the management team of the combined company; and (iv) the Company was named Elicio Therapeutics, Inc. and is headquartered in Boston, Massachusetts. Accordingly, for accounting purposes, the Merger was treated as the equivalent of Former Elicio issuing stock to acquire the net assets of Angion. As a result of the Merger, the net assets of Angion were recorded at their acquisition-date fair value, which approximated book value due to the short-term nature of the instruments, in the financial statements of Former Elicio and the reported operating results prior to the Merger were those of Former Elicio. Historical common share amounts of Former Elicio have been retroactively restated based on the exchange ratio of 0.0181 (the "Exchange Ratio"). It was concluded that any in-process research and development assets that remained as of the Merger would be *de minimis* when compared to the cash and investments obtained through the Merger.

Prior to the effective time of the Merger, on June 1, 2023, in connection with the transactions contemplated by the Merger Agreement, the Company effected a reverse stock split of Angion's common stock, par value $0.01 per share ("Angion common stock"), at a ratio of 10:1 (the "Reverse Stock Split"). At the effective time of the Merger, each outstanding share of Former Elicio capital stock (after giving effect to the automatic conversion of all shares of Former Elicio preferred stock into shares of Former Elicio common stock and excluding any shares held as treasury stock by Former Elicio or held or owned by Angion or any subsidiary of Angion or Former Elicio and any dissenting shares) was converted into the right to receive 0.0181 shares of Angion common stock, which resulted in the issuance by Angion of an aggregate of 5,375,751 shares of Angion common stock to the stockholders of Former Elicio (the "Exchange Shares"), and a total of 8,387,025 shares of the Company common stock being issued and outstanding immediately following the effective time of the Merger. In addition, Angion assumed the Elicio 2022 Equity Incentive Plan and the Elicio 2012 Equity Incentive Plan (the "Elicio Plans") and each outstanding and unexercised option to purchase Former Elicio common stock and each outstanding and unexercised warrant to purchase Former Elicio capital stock were adjusted with such stock options and warrants henceforth representing the right to purchase a number of shares of the Company's common stock equal to the Exchange Ratio multiplied by the number of shares of Former Elicio common stock previously represented by such options, and warrants at an exercise price equal to the exercise price of Former Elicio capital stock divided by the Exchange Ratio.

In connection with execution of the Merger Agreement, Angion made a bridge loan to Former Elicio pursuant to a note purchase agreement and promissory notes up to an aggregate principal amount of $12.5 million, issued with a 20% original issue discount, with an initial closing held substantially concurrently with the execution of the Merger Agreement for a principal amount of $6.25 million on account of a $5.0 million loan and an additional closing for a

principal amount of $6.25 million on account of a $5.0 million loan upon delivery by Former Elicio to Angion of Former Elicio's audited financial statements for the year ended December 31, 2022.

As part of the recapitalization, the Company obtained the assets and liabilities listed below (in thousands):

Cash and cash equivalents	$	24,001
Other current assets		540
Promissory notes		10,027
Accrued liabilities		(2,438)
Net assets acquired	$	32,130

Per the terms of the Merger Agreement, upon completion of the Merger, all obligations owed by Former Elicio related to the promissory notes were automatically forgiven and the amount advanced by Angion, along with any accrued and unpaid interest, was credited towards the net cash balance used to calculate the assets and liabilities listed above. Upon settlement of the promissory notes, the Company recognized a gain of $0.6 million related to extinguishment of the promissory notes.

The Company recognized the net assets acquired, excluding the promissory notes and transaction costs of $ 2.9 million, as an increase to additional paid-in capital in the consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the year ended December 31, 2023.

Note 4—Fair Value Measurements

The following tables present the Company's financial assets and liabilities measured at fair value on a recurring basis and their assigned levels within the fair value hierarchy (in thousands):

	Fair Value Measured at December 31, 2023			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Money market funds [1]	$ 5,973	$ —	$ —	$ 5,973
Total assets	$ 5,973	$ —	$ —	$ 5,973
Warrant liabilities	$ —	$ —	$ 11	$ 11
Total Liabilities	$ —	$ —	$ 11	$ 11

	Fair Value Measured at December 31, 2022			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Money market funds [1]	$ 5,340	$ —	$ —	$ 5,340
Total assets	$ 5,340	$ —	$ —	$ 5,340

(1) Included in cash and cash equivalents on the consolidated balance sheets. This balance includes cash requirements settled on a nightly basis.

Cash equivalents at December 31, 2023 and 2022 were held in U.S. Treasury Securities.

There were no transfers made among the three levels in the fair value hierarchy during periods presented.

As part of the Merger transaction, Former Elicio adopted Angion's warrant liabilities. The following table presents a summary of changes in Level 3 in the fair value of the Company's common stock warrant liability (in thousands):

	As of December 31, 2023	As of December 31, 2022
Balance, beginning of year	$ —	$ —
Existing Angion Warrant Liability	9	—
Change in fair value	2	—
Balance, end of year	$ 11	$ —

Both observable and unobservable inputs were used to determine the fair value of positions that the Company has classified within the Level 3 category. Unrealized gains and losses associated with assets and liabilities within the Level 3 category include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

The fair value of the warrants issued by the Company has been estimated using a variant of Black-Scholes. The underlying equity included in Black-Scholes was valued based on the equity value implied from sales of preferred and common stock at each measurement date. The fair value of the warrants was impacted by the model selected as well as assumptions surrounding unobservable inputs including the underlying equity value, expected volatility of the underlying equity, risk free interest rate, and the expected term.

The Company records the change in the fair value of common stock warrants in change in fair value of warrant liability in the consolidated statements of operations.

The fair value of the common stock warrant liability was estimated using the following assumptions:

	December 31, 2023	June 1, 2023
Strike price	$ 76.00	$ 76.00
Contractual term (years)	4.7	5.2
Volatility (annual)	94.0 %	100.0 %
Risk-free rate	3.9 %	3.9 %
Dividend yield (per share)	0.0 %	0.0 %

Note 5—Balance Sheet Components

Prepaid and Other Current Assets

Prepaid and other current assets were comprised of the following (in thousands):

	December 31,	
	2023	2022
Prepaid research and development contract services	$ 1,883	$ 2,132
Advanced professional fees	300	648
Prepaid insurance	376	104
Other prepaid expenses and other current assets	173	36
Total prepaid and other current assets	$ 2,732	$ 2,920

Property and Equipment, Net

The Company's property and equipment, net was comprised of the following (in thousands):

	December 31,	
	2023	2022
Equipment	$ 1,574	$ 1,787
Furniture and fixtures	242	359
Leasehold improvements	132	124
Total property and equipment	1,948	2,270
Less: accumulated depreciation	(1,231)	(1,123)
Property and equipment, net	$ 717	$ 1,147

Depreciation expense for the years ended December 31, 2023 and 2022 was $ 0.4 million and $0.4 million, respectively.

Other Long-term Prepaid Assets

Other long-term prepaid assets consisted of the advanced payments for clinical trial services, totaling $ 2.8 million for the years ended December 31, 2023 and 2022.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued professional fees	$ 945	$ 180
Accrued compensation and benefits	1,849	1,491
Accrued research and development	912	260
Other accrued expenses	51	4
Total accrued expenses	$ 3,757	$ 1,935

Note 6—Research Grant

In September 2022, Former Elicio entered into a grant agreement with the Gastro-Intestinal (“GI”) Research Foundation, a not-for-profit organization focused on supporting research to treat, cure and prevent digestive diseases. Of the $2.8 million award, $2.3 million was received in September 2022 and the remaining $0.5 million was received in June 2023 with the completion of the development efforts as defined in the agreement. The final $ 0.5 million payment was applied as a credit to the second grant agreement described below. For the years ended December 31, 2023 and 2022, the Company incurred $1.9 million and $0.9 million in research and development expenses related to this project.

In September 2023, the Company entered into a second grant agreement with the GI Research Foundation for $ 3.1 million, with such amount received net of a $0.5 million credit. The grant funds available as of December 31, 2023 are $ 0.7 million, which are reflected in restricted cash and the deferred research obligation in the accompanying consolidated balance sheets. For the year ended December 31, 2023, the Company incurred $1.9 million in research and development expenses related to this project.

The award money for both agreements was earned and recognized as a contra research and development expense as the expenses were incurred.

Note 7—Convertible Preferred Stock, Common Stock and Stockholders' Equity

Authorized Shares

The Company's current Amended and Restated Certificate of Incorporation, as amended, authorizes 300,000,000 shares of common stock, par value $0.01 per share, and 10,000,000 shares of preferred stock, par value $ 0.01 per share.

Convertible Preferred Stock of Former Elicio

Former Elicio's convertible preferred stock consisted of Series A preferred stock ("Series A Preferred Shares"), Series B preferred stock ("Series B Preferred Shares") and Series C preferred stock ("Series C Preferred Shares").

Series C Convertible Preferred Stock

In May 2022, Former Elicio authorized the sale and issuance of up to 760,200 shares of $0.06 par value Series C Preferred Shares at an original issuance price of $66.30 per share and up to 325,800 shares of Series C Preferred for the settlement of the convertible notes payable. The Series C Preferred Shares financing was structured to be issued in rolling closes in 2022.

In October 2022, Elicio increased the authorized number of Series C Preferred Shares to 3,513,198 shares at an issuance price of $14.23 per share and 1,375,600 shares of Series C Preferred for the settlement of the Convertible Notes Payable.

From the period May through December 2022, Former Elicio issued 3,589,820 shares of Series C Preferred Shares for gross proceeds of approximately $41.8 million inclusive of the conversion of the outstanding amount of the Convertible Notes (as described in Note 12). Former Elicio incurred cash issuance costs of approximately $1.2 million in connection with these shares.

Conversion of Convertible Preferred Stock

On June 1, 2023, Former Elicio completed the Merger with Angion in accordance with the Merger Agreement. Under the terms of the Merger Agreement, immediately prior to the effective time of the Merger, each share of Former Elicio's preferred stock was converted into a share of Former Elicio's common stock. At the closing of the Merger, the Company issued an aggregate of 5,375,751 shares of its common stock to Former Elicio stockholders, based on an exchange ratio of 0.0181 shares of the Company's common stock for each share of Former Elicio's common stock outstanding immediately prior to the Merger, including those shares of common stock issued upon conversion of the Former Elicio preferred stock. No shares and 3,589,820 shares of convertible preferred stock were issued during the years ended December 31, 2023 and 2022, respectively.

The authorized, issued and outstanding shares of the convertible preferred stock and liquidation preferences of Former Elicio as of December 31, 2022 were as follows (in thousands, except share and per share amounts):

	Authorized Shares	Shares Issued and Outstanding	Aggregate Liquidation Amount	Proceeds Net of Liquidation Costs
Series A Convertible Preferred Shares	132,387	132,387	$7,495	$7,495
Series B Convertible Preferred Shares	1,927,375	1,927,375	$72,803	$62,944
Series C Convertible Preferred Shares	4,888,798	2,938,158	$41,816	$40,621
Total Preferred Shares	6,948,560	4,997,920		

The Series A and Series B Preferred Shares were deemed changed as of October 18, 2022 into 132,387 and 1,927,375 preferred shares (retroactively restated for the reverse recapitalization as described in Note 3) due to the antidilutive protection triggered by the Series C Preferred Shares issued in October 2022 at a price below $1.00.

As a result of the Merger, the aggregate amount of 4,997,920 shares of Former Elicio preferred stock (retroactively restated for the reverse recapitalization as described in Note 3) were converted into 4,997,920 shares of Former Elicio's common stock to be exchanged for the same number of shares of the Company's common stock.

At-The-Market Equity Program

In May 2022, the Company filed an automatically effective registration statement on Form S-3 (the "Registration St atement") with the SEC that registers the offering, issuance, and sale of an amount of common stock, preferred stock, debt securities, and warrants to purchase common stock, preferred stock and/or debt securities, not to exceed an aggregate initial offering price of $100 million. Simultaneously, the Company entered into an At-the-Market Equity Offering Sales Agreement with Stifel, Nicolaus & Company, Incorporated and Virtu Americas LLC, as sales agents, pursuant to which the Company may offer, issue or sell shares of its common stock having an aggregate offering price of up to $21 million from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement (the "ATM Program"). No sales were made under the ATM Program for the years ended December 31, 2023 and 2022.

Private Placement

In December 2023, the Company entered into a Subscription Agreement (the "Subscription Agreement") with GKCC, LLC (the "Purchaser"), an entity controlled by a director of the Company, providing for the issuance and sale by the Company to the Purchaser of an aggregate of 1,213,000 shares of the Company's common stock, par value $0.01 per share, at a purchase price per share of $ 5.81 (the "Offering"). See Note 16 - Related Party Transactions for a discussion of the Offering.

Note 8—Stock-Based Compensation

2012 Plan and 2022 Plan

Pursuant to the Merger Agreement, the Company assumed the Former Elicio 2022 Equity Incentive Plan and the Former Elicio 2012 Equity Incentive Plan (the "Former Elicio Plans") and all stock options issued and outstanding under the Former Elicio Plans. Each outstanding and unexercised option to purchase Former Elicio common stock was adjusted with such Company stock options henceforth representing the right to purchase a number of shares of the Company's common stock based on an exchange ratio of 0.0181. Any restriction on the exercise of any Former Elicio stock options assumed by the Company continued in full force and effect and the term, exercisability, vesting schedule, accelerated vesting provisions, and any other provisions of such Former Elicio stock option otherwise remained unchanged; provided, however, that the Compensation Committee of the Company's board of directors assumed the responsibility and the authority of Former Elicio's board of directors or any committee thereof with respect to each Former Elicio stock option assumed by the Company.

2015 Plan

In June 2019, Angion approved an Amended and Restated 2015 Equity Incentive Plan (the "2015 Plan") permitting the granting of incentive stock options, non-statutory stock options, restricted stock and other stock-based awards. Following the effectiveness of the 2021 Incentive Award Plan ("2021 Plan"), Angion ceased making grants under the 2015 Plan. However, the 2015 Plan continues to govern the terms and conditions of the outstanding awards granted under it. Shares of common stock subject to awards granted under the 2015 Plan that cease to be subject to such awards by forfeiture or otherwise after the termination of the 2015 Plan will be available for issuance under the 2021 Plan.

2021 Plan and Amendment to 2021 Plan

On January 25, 2021, Angion's board of directors approved the 2021 Plan which permits the granting of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards to employees, directors, officers and consultants. The 2021 Plan provides that the number of shares reserved and available for issuance will automatically increase each January 1 by the lesser of 5% of the Company's common stock outstanding on the immediately preceding December 31, or such lesser number of shares as determined by the Company's board of directors. On March 17, 2023, Angion's board of directors approved an amendment to the 2021 Plan to increase the cumulative number of shares of common stock reserved for issuance thereunder by 30,113 shares.

As of December 31, 2023, 540,171 shares and 153,243 shares remain available for future grants under the 2021 Plan and Former Elicio 2022 Equity Incentive Plan, respectively.

Stock Options

The following table summarizes information and activity related to the Company's stock options:

	Number of Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Total Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	854,076	$ 5.24	7.72	
Options granted	219,672	9.68		
Existing Angion options outstanding	351,656	61.99		
Options exercised	(16,349)	7.74		
Forfeited (unvested)	(103,131)	5.83		
Outstanding as of December 31, 2023	1,305,924	$ 21.27	7.43	$ 2,510,341
Options vested and exercisable	871,564	$ 41.91	5.25	$ 860,479

The aggregate intrinsic value in the above table is calculated as the difference between the estimated fair value of the Company's common stock price and the exercise price of the stock options. 219,672 stock options were granted in the year ended December 31, 2023. The weighted average grant date fair value per share for the stock option grants during the year ended December 31, 2023 was $9.68. As of December 31, 2023, the total unrecognized compensation related to unvested stock option awards granted was $2.4 million, which the Company expects to recognize over a weighted-average period of approximately 1.8 years years.

The following table summarizes total stock-based compensation expense recorded in the consolidated statements of operations (in thousands):

	For the Year Ended December 31,	
	2023	2022
Research and development	$ 552	$ 291
General and administrative	627	288
Total	$ 1,179	$ 579

The fair value of each option is estimated on the date of grant using Black-Scholes with the assumptions noted in the table below. The fair value of an award with only a service condition is amortized as compensation cost on a straight-line basis over the requisite service period of the awards, which is generally the vesting period. Compensation cost of awards that contain a performance condition are recognized when success is considered probable during the performance period. The Company has elected to account for forfeitures as they occur, rather than estimating the number of awards that are expected to vest. The risk-free interest rate is estimated using the weighted average rate of return on U.S. Treasury notes with a life that approximates the expected life of the option. The expected term of options granted to employees was calculated using the simplified method, which represents the average of the contractual term of the option and the weighted-average vesting period of the option. The Company uses the simplified method because it does not have sufficient historical option exercise data to provide a reasonable basis upon which to estimate expected term. The contractual life of the option was used for the expected life of options granted to non-employees. Expected volatility is based on the weighted average of the historical volatility of a peer group of publicly traded companies. The assumed dividend yield is based upon the Company's expectation of not paying dividends in the foreseeable future.

The fair value of each employee and non-employee stock option grant was estimated on the date of grant using Black-Scholes based on the following assumptions.

Options	December 31,	
	2023	2022
Risk-free interest rate	3.68 - 4.49%	1.64 - 3.88%
Expected dividend yield	0.0%	0.0%
Expected volatility	71.70 - 75.50%	60.30 - 73.20%
Expected term in years (employees)	5.5 - 6.1	5.5 - 10

In March 2021 and June 2022, certain employees of the Company early exercised options to purchase shares of the Company's common stock. The shares had not fully vested at the time of exercise and were recorded as an unvested option exercise liability. As the shares vest, the Company recognizes the shares and related expense as issuance of common stock upon settlement of restricted stock on the consolidated statements of convertible preferred stock and stockholders' equity (deficit) for the years ended December 31, 2023 and 2022.

Employee Stock Purchase Plan

In January 2021, the board of directors of Angion approved the Employee Stock Purchase Plan (the "ESPP"). The ESPP was effective on the date immediately prior to the effectiveness of the Angion's registration statement relating to the IPO. The offering period and purchase period was determined by Angion's board of directors. No offering periods or purchasing periods were active as of December 31, 2023. As of December 31, 2023, 68,958 shares under the ESPP remain available for purchase and no offerings have been authorized.

Restricted Stock Units

In March 2021, Former Elicio granted restricted stock units ("RSUs") with service and performance vesting conditions to an employee. The completion of the Merger satisfied the performance vesting criteria and triggered accelerated vesting for all unvested RSUs. As a result, the employee received 41,005 shares on June 1, 2023. To pay for the tax withholdings that were due upon vesting of the RSUs, the employee sold 14,455 shares to the Company, which are held in treasury stock as of December 31, 2023. As of December 31, 2023, there are no RSUs outstanding.

Note 9—Warrants

In accordance with ASC 815, the warrants classified as liabilities are recorded at fair value at the issuance date, with changes in the fair value recognized in the consolidated statements of operations at the end of each reporting period. Refer to Note 4 for changes in the fair value recognized during the periods reported.

In accordance with ASC 815, the warrants classified as equity do not meet the definition of a derivative and are classified in stockholders' equity in the consolidated balance sheets.

There was no warrant activity during the year ended December 31, 2023, other than the assumption of the previously issued Angion warrants by the Company.

The following table summarizes information regarding common stock warrants outstanding at December 31, 2023:

	Warrants	Weighted Average Exercise Price	Weighted Average Life (years)
Outstanding at December 31, 2022	144,814	$ 53.59	6.5
Angion warrants assumed	3,950	76.00	4.7
Outstanding at December 31, 2023	148,764	$ 54.19	5.5

Note 10—Commitments and Contingencies

Legal Proceedings

From time to time, the Company may be involved in legal proceedings, as well as demands, claims and threatened litigation, which arise in the normal course of its business or otherwise.

The outcome of any future litigation is uncertain. Such litigation, if not resolved, could result in substantial costs to the Company, including any costs associated with the indemnification of directors and officers.

The Company may be exposed to litigation in connection with its products under development and operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses. The Company is not aware of any material legal matters.

License Agreements

In July 2012 and January 2016, Former Elicio licensed certain intellectual property from a university, of which the January 2016 agreement has been amended from time to time. The Company is required to pay certain contractual maintenance and milestone payments related to clinical trials and royalties on product sales over the term of the contract, with minimum annual royalty payments commencing in the calendar year after commercialization. In January 2019, Former Elicio licensed additional intellectual property and terminated a license obtained in July 2012 from the university. The license term for January 2016 license extends until terminated by either party under certain provisions. No commercialization royalties have been achieved.

Future minimum annual maintenance payments are $0.1 million for the year ended December 31, 2023 and for each year thereafter. Future minimum annual payments are due until the termination of the agreement.

Note 11—Leases

Operating Leases

In July 2021, the Company signed an operating lease for office and laboratory space in Boston, Massachusetts (the "Boston Lease"). The Boston Lease commenced in February 2022 with the term set to expire in February 2030. The Boston Lease has rent payments escalating annually, which total $11.1 million in the aggregate. As a result, at the commencement of the Boston Lease, the Company recognized a right-of-use lease asset of $ 8.0 million with a corresponding lease liability of $8.0 million based on the present value of the minimum rental payments. In addition, the Company will make payments for operating expenses and real estate taxes. In June 2023, the Company secured a letter of credit for the deposit on the Boston Lease and has a deposit in the amount of $0.7 million, which was reported as Restricted Cash on the consolidated balance sheets as of December 31, 2023.

As part of the Merger Agreement, the Company also assumed a lease for clinical and regulatory space in Newton, Massachusetts (the "Newton lease"), comprising approximately 6,157 square feet for approximately $0.2 million per year, under a non-cancelable operating lease through June 30, 2024.

Lease expense for all leases for the years ended December 31, 2023 and 2022 was $ 1.5 million and $1.2 million, respectively. All expenses are included in operating expenses in the accompanying consolidated statements of operations.

The following table summarizes quantitative information about the Company's operating leases (dollars in thousands):

	For the year ended December 31,	
	2023	2022
Operating cash flows from operating leases	$ 1,380	$ 1,106
Right-of-use assets exchanged for operating lease liabilities	$ —	$ 8,017
Weighted-average remaining lease term—operating leases (in years)	5.6	7.2
Weighted-average discount rate—operating leases	7.5 %	8.0 %

As of December 31, 2023, maturities of lease liabilities were as follows (in thousands):

Year Ended December 31,	Amounts
2024	$ 1,427
2025	1,350
2026	1,383
2027	1,425
2028	1,467
Thereafter	1,765
Total	8,817
Less present value discount	(1,900)
Operating lease liabilities	6,917
Less: operating lease liability, current portion	910
Operating lease liability, noncurrent portion	$ 6,007

Note 12—Convertible Notes Payable

In October and November 2021, Former Elicio entered into convertible promissory note agreements for an aggregate amount of $ 14.5 million (the "Convertible Notes"). The Convertible Notes accrue interest at 8% per annum and are payable upon demand at any time on or after October 4, 2022 (the "Demand date"). Interest expense for the year ended December 31, 2022 was $0.9 million.

There were $0.4 million of issuance costs incurred in 2021 and was initially recorded as a discount to the carrying value of the convertible note. Former Elicio recorded interest expense for the year ended December 31, 2022 related to the accretion of the discount to the Convertible Notes due to issuance costs of $0.3 million.

The Convertible Notes included multiple conversion features. Former Elicio evaluated all the conversion features included within the Convertible Note agreements, noting that none of the features was considered to be predominant. Former Elicio also evaluated all conversion features under FASB ASC Topic 815, *Derivatives and Hedging*, and determined conversion features associated with the qualified and non-qualified financings met the definition of a derivative and require bifurcation from the Convertible Notes. The bifurcated embedded derivative of $2.9 million was recorded as a liability at fair value at the date of issuance based on the probability of occurrence of a triggering event taking place during the term of the Convertible Notes and was recorded as a discount to the carrying value of the Convertible Note. Former Elicio recorded interest expense for the year ended December 31, 2022 related to the accretion of the discount to the Convertible Notes due to the bifurcated embedded derivative of $2.3 million.

During the year ended December 31, 2022, the increase in the fair value of the embedded derivative was determined to be $ 0.9 million and was recorded as interest expense in the accompanying consolidated statements of operations.

On October 18, 2022, in conjunction with the Series C Preferred Shares issued on this same date, the Convertible Notes Payable totaling $ 14.5 million and the related accrued interest totaling $1.1 million automatically converted into 1,370,187 Series C Preferred Shares at an 80% discount to the Series C Preferred Share issuance price per share of $14.23, or $11.39 per share. Just prior to settlement, the fair value of the embedded derivative was marked to market a final time to the aggregate value of $3.9 million. Former Elicio recorded an immaterial gain on extinguishment related to the difference in the total of Convertible Notes Payable, total accrued interest and the final fair value of the embedded derivative versus the value of the Series C Preferred Shares issued based on the original issuance price of $14.23 per share.

Note 13—Income Taxes

The components of the Company's provision for income taxes for the years ended December 31, 2023 and 2022 consists of the following (in thousands):

ELICIO THERAPEUTICS, INC.
Notes to Consolidated Financial Statements (Continued)

	December 31,	
	2023	2022
Current:		
Federal	$ —	$ —
United States	—	—
Foreign	—	—
Total Current	—	—
Deferred		
Federal	7,743	5,162
State	3,116	2,102
Foreign	—	—
Change in valuation allowance	(10,859)	(7,264)
Total Deferred	—	—
Total tax provision	$ —	$ —

The reconciliations between the federal statutory income tax rate and the Company's effective income tax rate were as follows:

	Year Ended December 31,	
	2023	2022
Statutory federal income tax rate	21.0 %	21.0 %
State tax, net of federal benefits	6.2 %	5.1 %
Permanent differences	(0.3)%	(4.6)%
Federal research and development credits	3.1 %	2.6 %
State research and development credits	0.8 %	0.9 %
Other differences	0.1 %	0.9 %
Change in valuation allowance	(30.9)%	(25.9)%
Effective income tax rate	0.0 %	0.0 %

The principal components of the Company's net deferred tax asset at December 31, 2023 and 2022 were as follows (in thousands):

	December 31,	
	2023	2022
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 60,696	$ 19,146
Research and development tax credit carryovers	12,940	3,820
Capitalized research and development	13,686	4,304
Lease liability	1,897	1,949
Other	2,732	611
ROU Asset	(1,800)	(1,915)
Property and equipment	(33)	(37)
Total deferred tax assets	90,118	27,878
Less: Deferred tax asset valuation allowance	(90,118)	(27,878)
Net deferred tax asset	$ —	$ —

Net operating losses (“NOL”) generated before December 31, 2017 can be carried forward 20 years and carried back two years under the Internal Revenue Code (“IRC”). NOLs arising in tax years ended after December 31, 2017 are limited to 80% of taxable income, only carried forward and carried forward indefinitely. The Company

has no income tax expense due to operating losses incurred for the years ended December 31, 2023 and 2022. The Company has provided a valuation allowance for the full amount of the net deferred tax assets as, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. The increase in the net deferred tax assets and valuation allowance is primarily due to the reverse merger transaction with Angion in June 2023 (as described in Note 3). For federal income tax purposes the transaction qualified as a tax-free reverse subsidiary merger pursuant to IRC Section 368 (a)(2)(E) and therefore the historical tax basis in the assets acquired and liabilities assumed was carried over upon acquisition. Net deferred tax assets acquired of $50.1 million with an offsetting valuation allowance of $ 50.1 million are primarily related to pre-merger net operating loss and research and development credits carryovers. At December 31, 2023, Elicio has federal NOLs of $237.8 million, of which $19.1 million was generated before the tax year ended December 31, 2017, and state NOLs of $ 170.4 million. If not utilized, certain NOLs for federal and state tax purposes will start to expire beginning in 2032. At December 31, 2023, Elicio has $11.1 million and $2.2 million of federal and state research and development credit carryforwards, respectively, that start to expire in 2027.

As the Company has not yet achieved profitable operations, management believes the tax benefits as of December 31, 2023 did not satisfy the realization criteria set forth in ASC Topic 740, Income Taxes and, therefore, has recorded a full valuation allowance for the entire deferred tax asset. The valuation allowance increased in 2023 by $62.2 million due to the increase in the deferred tax assets by the same amount, primarily due to NOL carryforwards. The Company's effective income tax rate differed from the federal statutory rate primarily due to state taxes and the Company's full valuation allowance, the latter of which reduced the Company's effective federal income tax rate to zero.

Ownership changes, as defined in the IRC, may limit the amount of net operating loss carryforwards that can be utilized annually to offset future taxable income pursuant to IRC Section 382 or similar provisions. Subsequent ownership changes could further affect the limitation in future years. The Company has not completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and because there could be additional changes in control in the future. As a result, the Company is not able to estimate the effect of the change in control, if any, on the Company's ability to utilize net operating loss and research and development credit carryforwards in the future.

The Company files tax returns in the United States, Australia, California, Connecticut, Delaware, Florida, Iowa, Massachusetts, Missouri, New Hampshire, New Jersey, and Tennessee. All tax years from 2020 to 2023 remain open to examination by the major taxing jurisdictions to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service ("IRS") or other authorities if they have or will be used in a future period. To its knowledge, the Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

As of December 31, 2023, the Company had $ 4.1 million of uncertain tax positions related to prior research tax credits that may not be substantiated upon audit. The Company does not anticipate that uncertain tax positions will decrease within the next 12 months. The Company has elected to recognize interest and penalties related to income tax matters as a component of income tax expense, of which no interest or penalties were recorded for the years ended December 31, 2023 and 2022.

Note 14—Employee Benefit Plan

Employee Benefit Plan

The Company provides a retirement savings plan through the Vendantra Pharmacueticals Inc. 401(k) Plan (the "Elicio Retirement Plan"), subject to certain limitations. As allowed under Section 401(k) of the IRC, the Elicio Retirement Plan allows tax deferred salary deductions for eligible employees. An employee's interest in his or her salary deferral contributions is 100% vested when contributed.

Pursuant to the Merger Agreement, the Company assumed the retirement savings plan sponsored by Angion (the "Angion Retirement Plan"). The Angion Retirement Plan is intended to qualify for favorable tax treatment under Section 401(a) of the IRC, and contains a cash or deferred feature that is intended to meet the requirements of Section 401(k) of the IRC. Currently, no employees are contributing under the Angion Retirement Plan.

Note 15—Net Loss Per Share

The Company has reported losses since inception and has computed basic net loss per share attributable to common stockholders by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potentially dilutive securities. The Company computes diluted net loss per share of common stock after giving consideration to all potentially dilutive

shares of common stock, including options to purchase common stock and preferred stock outstanding during the period determined using the treasury-stock and if-converted methods, except where the effect of including such securities would be antidilutive. Because the Company has reported net losses since inception, these potential shares of common stock and preferred stock have been anti-dilutive and basic and diluted loss per share were the same for all periods presented.

Basic and diluted net loss per share attributable to common stockholders was calculated at December 31, 2023 and 2022 as follows (in thousands, except share and per share data):

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (35,195)	$ (28,208)
Denominator:		
Weighted-average shares used in computing net loss per share, basic and diluted	5,056,225	315,998
Net loss per share, basic and diluted	$ (6.96)	$ (89.27)

The table below provides potentially dilutive securities not included in the calculation of the diluted net loss per share because to do so would be anti-dilutive:

	December 31,	
	2023	2022
Convertible preferred stock	—	4,997,920
Shares issuable upon exercise of stock options	1,305,924	854,076
Shares issuable upon the exercise of warrants	148,764	144,814
Unvested Common Stock	1,933	7,240
Total	1,456,621	6,004,050

Note 16—Related Party Transactions

Consulting Agreement

The Company paid $0.7 million and $0.4 million for the years ended December 31, 2023 and 2022, respectively, for consulting services provided by an entity affiliated with the Company's former interim chief financial officer and former board member.

Subscription Agreement

In December 2023, the Company entered into a subscription agreement (the "December Subscription Agreement") with GKCC, LLC (the "Purchaser"), an entity which is controlled by a director of the Company, providing for the issuance and sale by the Company to the Purchaser of an aggregate of 1,213,000 shares of the Company's common stock, par value $ 0.01 per share, at a purchase price per share of $ 5.81 (the "December Offering"). The gross proceeds to the Company from the December Offering was approximately $7.0 million. The closing of the December Offering occurred in December 2023. Upon closing of the December Offering, the Purchaser became a greater than 10% holder of the Company's shares outstanding.

Pursuant to the December Subscription Agreement, the Company is obligated, among other things, to file a registration statement with the SEC by March 31, 2024 for purposes of registering the shares for resale by the Purchaser, and use its commercially reasonable efforts to have the registration statement declared effective no later than 30 days after filing such registration statement with the SEC, or in the event the SEC reviews and has written comments to the registration statement, within 90 days following the receipt of such written comments. The December Subscription Agreement contains customary terms and conditions for a transaction of this type, including certain customary indemnification rights and certain customary cash penalties on the Company for its failure to satisfy specified filing and effectiveness time periods.

Note 17—Subsequent Events

The Company has completed an evaluation of all subsequent events after the audited consolidated balance sheet date as of December 31, 2023 through the date these consolidated financial statements were issued to ensure that these consolidated financial statements include appropriate disclosure of events both recognized in the consolidated financial statements as of December 31, 2023, and events which occurred subsequently but were not recognized in the consolidated financial statements. Non-recognizable subsequent events are summarized below.

ATM Program

Subsequent to December 31, 2023, the Company issued and sold a total of 615,363 shares of common stock under the ATM Program for aggregate net sale proceeds of approximately $5.1 million after deducting sales commissions.

Subscription Agreement

In March 2024, the Company entered into a subscription agreement (the "March Subscription Agreement") with the Purchaser, an entity controlled by a member of the board of directors of the Company and which owns greater than 10% of the Company's shares outstanding, providing for the issuance and sale by the Company to the Purchaser of pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 1,032,702 shares of the Company's common stock, at a purchase price per Pre-Funded Warrant of $5.81 (the "March Offering"). The March Offering closed on March 19, 2024 (the "March Offering Closing Date"). Each Pre-Funded Warrant is exercisable at any time on or after the March Offering Closing Date at an exercise price equal to $0.01 per share, subject to adjustments as provided under the terms of the Pre-Funded Warrant, subject to a post-exercise beneficial ownership limitation of 19.99%, unless Stockholder Approval (defined below) is obtained. The gross proceeds to the Company from the March Offering was approximately $6.0 million.

Pursuant to the March Subscription Agreement, the Company is obligated, among other things, to file a registration statement with the SEC by June 30, 2024 for purposes of registering the shares of the Company's common stock issuable upon exercise of the Pre-Funded Warrants (the "Pre-Funded Warrant Shares") for resale by the Purchaser, and to use its commercially reasonable efforts to have the registration statement declared effective no later than 30 days after filing such registration statement with the SEC, or in the event the SEC reviews and has written comments to the registration statement, within 90 days following the receipt of such written comments. The March Subscription Agreement contains customary terms and conditions for a transaction of this type, including certain customary indemnification rights and certain customary cash penalties on the Company for its failure to satisfy specified filing and effectiveness time periods.

In addition, pursuant to the March Subscription Agreement, no later than six months following the March Offering Closing Date, the Company has agreed to use commercially reasonable efforts to obtain such approval as may be required by the applicable rules and regulations of The Nasdaq Stock Market (or any successor entity) from the stockholders of the Company with respect to a change of control of the Company pursuant to Section 5635(b) of the Listing Rules of The Nasdaq Stock Market resulting from beneficial ownership in excess of 19.99% of the outstanding common stock of the Company upon the issuance of the Pre-Funded Warrant Shares ("Stockholder Approval").

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

None.

Item 9A. Controls and Procedures

Definition and Limitations of Disclosure Controls

Our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, such as this Annual Report on Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to ensure that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management evaluates these controls and procedures on an ongoing basis.

There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. These limitations include the possibility of human error, the circumvention or overriding of the controls and procedures and reasonable resource constraints. In addition, because we have designed our system of controls based on certain assumptions, which we believe are reasonable, about the likelihood of future events, our system of controls may not achieve its desired purpose under all possible future conditions. Accordingly, our disclosure controls and procedures provide reasonable assurance, but not absolute assurance, of achieving their objectives.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and our Chief Financial Officer, our principal executive officer and principal accounting and financial officer, respectively, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2023.

Based on the evaluation of our disclosure controls and procedures, our President and Chief Executive Officer and our Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2023 as a result of our material weaknesses in our internal control over financial reporting.

However, our management, including our Chief Executive Officer and our Chief Financial Officer, has concluded that, notwithstanding the identified material weaknesses in our internal control over financial reporting, the financial statements in this Annual Report on Form 10-K fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f)) under the Exchange Act) that occurred during the year ended December 31, 2023, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except as follows:

Material Weakness Remediation Plan

As previously reported, in connection with the preparation of our consolidated financial statements, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified in our internal control over financial reporting related to (i) insufficient resources with knowledge and expertise in U.S. GAAP to properly evaluate certain complex transactions, including debt instruments and equity instruments; (ii) insufficient financial reporting and close controls to ensure that incurred expenses are accrued at period end and deliverables from third party contractors are reviewed for accuracy; and (iii) insufficient resources to ensure that calculations used in financial reporting are properly reviewed, including EPS and WASO calculations.

We initiated several steps to remediate these material weaknesses, including:

- engaging SEC compliance and technical accounting consultants to assist in evaluating transactions for conformity with U.S. GAAP;

- hiring additional finance and accounting personnel to augment accounting staff and to provide more resources for complex accounting matters and financial reporting; and

- strengthening our financial reporting and close relating to incurred expenses by ensuring our data capture procedures are clearly defined and that responsible personnel, including supervisory personnel, have adequate training regarding the process and expectation.

Although we have initiated efforts to remediate these material weaknesses, the material weaknesses have not been fully remediated as of December 31, 2023. Our remediation efforts are intended to address the identified material weaknesses. Management is committed to continuous improvement of our internal control over financial reporting and will continue to diligently review our internal control over financial reporting. However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

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 Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed by, or under the supervision of, the Company's principal executive and principal accounting and financial officers and effected by the Company's board of directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013 framework). Based on our assessment, management concluded our internal control over financial reporting was not effective as of December 31, 2023, based on the COSO criteria.

Inherent Limitation on the Effectiveness Over Financial Reporting

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but there can be no assurance that such improvements will be sufficient to provide us with effective internal control over financial reporting.

Item 9B. Other Information

During the three months ended December 31, 2023, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Item 12. Security ownership of certain beneficial owners and management and related stockholder matters.

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

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

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Item 14. Principal Accountant Fees

The information required by this Item is incorporated herein by reference to the information that will be contained in our proxy statement related to the 2024 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K pursuant to General Instruction G(3) of Form 10-K.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) Financial Statements: See "Index to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K

(b) Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
2.1	Agreement and Plan of Merger and Reorganization, dated January 17, 2023, by and among Angion Biomedica Corp., Arkham Merger Sub, Inc. and Elicio Therapeutics, Inc.	8-K	1/17/2023	2.1	
3.1	Amended and Restated Certificate of Incorporation	8-K	2/9/2021	3.1	
3.2	Certificate of Amendment (Reverse Stock Split) to the Amended and Restated Certificate of Incorporation, dated June 1, 2023..	8-K	6/2/2023	3.3	
3.3	Certificate of Amendment (Officer Exculpation) to the Amended and Restated Certificate, dated June 1, 2023.	8-K	6/2/2023	3.4	
3.4	Certificate of Amendment (Name Change) to the Amended and Restated Certificate of Incorporation, dated June 1, 2023.	8-K	6/2/2023	3.5	
3.5	Amended and Restated Bylaws	8-K	2/9/2021	3.2	
4.1	Reference is made to exhibits 3.1 through 3.5.				
4.2	Form of Common Stock Certificate.	S-1/A	2/1/2021	4.2	
4.3	Form of Warrant to Purchase Common Stock.	S-1	1/15/2021	4.3	
4.4	Amended and Restated Registration Rights Agreement, dated as of March 31, 2020, by and among Angion Biomedica Corp. and the investors party thereto.	S-1	1/15/2021	4.6	
4.5	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	3/30/2022	4.5	
10.1	Lease Between Elicio Therapeutics, Inc. and RREF II 451D, LLC dated July 21, 2021.	S-4/A	3/29/2023	10.34	
10.2#	Offer Letter between Elicio Therapeutics, Inc. and Brian Piekos, dated May 9, 2023.	8-K	6/2/2023	10.2+	
10.3	Form of Indemnification Agreement between Elicio Therapeutics, Inc. and each of its directors and officers.	8-K	6/2/2023	10.8	
10.4	Information Rights Letter, dated May 30, 2023, by and between Clal Biotechnology Industries Ltd. and Elicio Therapeutics, Inc.	8-K	6/2/2023	10.13	
10.5#	Employment Agreement between Elicio Therapeutics, Inc. and Robert Connelly, dated as of November 15, 2018.	S-4/A	3/29/2023	10.29+	
10.6#	Offer Letter between Elicio Therapeutics, Inc. and Dr. Christopher Haqq, dated as of September 29, 2019.	S-4/A	3/29/2023	10.30+	
10.7#	Separation and Release Agreement, dated as of October 19, 2023, by and between the Company and Annette Matthies, Ph.D.				
10.8#	Employment Letter, by and between Elicio Therapeutics, Inc. and Peter DeMuth, dated as of April 13, 2022.	S-4/A	3/29/2023	10.32+	
10.9	Subscription Agreement, dated as of December 22, 2023, by and between the Company and GKCC, LLC.	8-K	12/22/2023	10.1	
10.10#	Elicio Therapeutics, Inc. 2012 Equity Incentive Plan, as amended.	S-4/A	3/29/2023	10.27+	
10.11#	Elicio Therapeutics, Inc. 2022 Equity Incentive Plan, as amended.	S-4/A	3/29/2023	10.28+	
10.12†	Exclusive Patent License Agreement, dated January 22, 2016, by and between Elicio Therapeutics, Inc. and the Massachusetts Institute of Technology, as amended.	S-4/A	3/29/2023	10.25+	
10.13	Note Purchase Agreement, dated January 17, 2023, by and between Elicio Therapeutics and Angion Biomedica Corp., and Form of Promissory Note.	8-K	1/17/2023	10.1	
10.14#	Amended and Restated Non-Employee Director Compensation Policy.				X
10.15#	Executive Severance Plan.	8-K	2/2/2024	10.1	
10.16(a)#	Second Amended and Restated 2015 Equity Incentive Plan.	S-1	1/15/2021	10.5(a)	

10.16(b)#	Form of Incentive Stock Option Grant under 2015 Equity Incentive Plan.	S-1	1/15/2021	10.5(b)	
10.16(c)#	Form of Non-Qualified Stock Option Grant under 2015 Equity Incentive Plan.	S-1	1/15/2021	10.5(c)	
10.16(d)#	Form of Stock Option Exercise under 2015 Equity Incentive Plan.	S-1	1/15/2021	10.5(d)	
10.17(a)#	2021 Incentive Award Plan.	S-1/A	2/1/2021	10.6(a)	
10.17(b)#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2021 Incentive Award Plan.	S-1/A	2/1/2021	10.6(b)	
10.17(c)#	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2021 Incentive Award Plan.	S-1/A	2/1/2021	10.6(c)	
10.17(d)#	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2021 Incentive Award Plan.	S-1/A	2/1/2021	10.6(d)	
10.18#	2021 Employee Stock Purchase Plan.	S-1/A	2/1/2021	10.7	
10.19#	Elicio Therapeutics, Inc. 2024 Inducement Incentive Award Plan.				X
10.20#	Form of Stock Option Grant Notice and Stock Option Agreement under the 2024 Inducement Incentive Award Plan.				X
10.21#	Form of Inducement Stock Option Grant Notice and Agreement.				X
21.1	Subsidiaries of the registrant.	S-1	1/15/2021	21.1	
23.1	Consent of independent registered public accounting firm.				X
24.1	Power of Attorney (reference is made to the signature page hereto).				X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of Principal Financial Officer and Principal Accounting 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.				X
32.1^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
97.1	Elicio Therapeutics, Inc. Clawback Policy (effective October 31, 2023).				
101.INS	Inline XBRL Instance Document				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document				X
104	Cover Page Interactive Data File				X

† Portions of this exhibit have been omitted in accordance with Item 601(b)(10) of Regulation S-K.

# Indicates management contract or compensatory plan.

^ The certification that accompanies the Annual Report on Form 10-K pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is not deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 29, 2024

ELICIO THERAPEUTICS, INC.

By: /s/ Robert Connelly
Robert Connelly
Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Robert Connelly and Brian Piekos, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Robert Connelly Robert Connelly	Chief Executive Officer, President and Director (Principal Executive Officer)	March 29, 2024
/s/ Brian Piekos Brian Piekos	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2024
/s/ Jay Venkatesan, M.D. Jay Venkatesan, M.D.	Director	March 29, 2024
/s/ Julian Adams, Ph.D. Julian Adams, Ph.D.	Director	March 29, 2024
/s/ Carol Ashe Carol Ashe	Director	March 29, 2024

/s/ Yekaterina (Katie) Chudnovsky Yekaterina (Katie) Chudnovsky	Director	March 29, 2024
/s/ Robert R. Ruffolo, Jr., Ph.D. Robert R. Ruffolo, Jr., Ph.D.	Director	March 29, 2024
/s/ Karen Wilson Karen Wilson	Director	March 29, 2024
/s/ Allen Nissenson, M.D. Allen Nissenson, M.D.	Director	March 29, 2024

ELICIO THERAPEUTICS, INC.

AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

Non-employee members of the board of directors (the "***Board***") of Elicio Therapeutics, Inc. (the "***Company***") shall be eligible to receive the compensation as set forth in this Non-Employee Director Compensation Policy (this "***Policy***"), which was first adopted pursuant to the Board's action on June 9, 2022, and further amended as of December 28, 2023 (the "***Effective Date***"). The compensation described in this Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who may be eligible to receive such compensation, unless such Non-Employee Director declines the receipt of such compensation by written notice to the Company; provided, however, that Non-Employee Directors shall not be eligible to receive cash or equity compensation under the Policy (but shall be entitle to receive reimbursement pursuant to Section 3 below) if and while they are receiving other compensation (including severance compensation) from the Company resulting from their former employment with the Company. This Policy shall remain in effect until it is revised or rescinded by further action of the Board. This Policy may be amended, modified or terminated by the Board at any time, without advance notice, in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors, including pursuant to this Policy as in effect prior to the Effective Date.

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $40,000 for service on the Board.

(b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:

(i) Non-Executive Chairman of the Board. A Non-Employee Director serving as the Non-Executive Chairman of the Board shall receive an additional annual retainer of $35,000 for such service.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall receive an additional annual retainer of $7,500 for such service.

(iv) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of $5,000 for such service.

(v) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of $8,000 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive an additional annual retainer of $5,000 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than the fifteenth (15th) day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2021 Equity Incentive Award Plan, as amended from time to time, or any other applicable Company equity incentive plan then-maintained by the Company (in any case, the "***Equity Plan***") and shall be evidenced by the execution and delivery of award agreements in substantially the forms approved by the Board from time to time. All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan.

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall automatically be granted, on the date of such initial election or appointment, an option (an "***Initial Award***") to purchase 8,200 shares of the Company's common stock ("***Shares***"). No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board immediately prior to any annual meeting of the Company's stockholders on or after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an option (a "***Subsequent Award***") to purchase 4,100 Shares.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(d) Terms of Awards Granted to Non-Employee Directors

(i) Purchase Price. The per Share exercise price of each option granted to a Non-Employee Director shall equal the Fair Market Value (as defined in the Equity Plan) of a Share on the date the option is granted.

(ii) Vesting. Subject to Section 2(d)(iii) below, each Initial Award shall vest and become exercisable in thirty-six (36) substantially equal installments on each monthly anniversary of the date of grant, subject to the Non-Employee Director continuing to provide services to the Company through each such vesting date. Subject to Section 2(d)(iii) below, each Subsequent Award shall vest and become exercisable in full on the earlier of the one-year anniversary of the date of grant and the next annual meeting of the Company's stockholders after the grant date, subject to the Non-Employee Director continuing to provide services to the Company through such vesting date.

(iii) Accelerated Vesting.

(A) Termination Due to Death or Disability. In the event that any Non-Employee Director incurs a Termination of Service (as defined in the Equity Plan) due to such Non-Employee Director's death or Disability (as defined the Equity Plan), each of such Non-Employee Director's Initial Award and Subsequent Award(s), along with any other stock options or other equity-based awards held by such Non-Employee Director, shall vest and, if applicable, become exercisable with respect to one hundred percent (100%) of the Shares subject thereto upon such Termination of Service.

(B) Change in Control. In the event that a Change in Control (as defined in the Equity Plan) occurs, each Initial Award and Subsequent Award, along with any other stock options or other equity-based awards held by any Non-Employee Director, shall vest and, if applicable, become exercisable with respect to one hundred percent (100%) of the Shares subject thereto as of immediately prior to such Change in Control.

(iv) Term. The term of each stock option granted to a Non-Employee Director shall be ten (10) years from the date the option is granted.

3. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

* * * * *

ELICIO THERAPEUTICS, INC.
EXECUTIVE SEVERANCE PLAN

PLAN DOCUMENT AND SUMMARY PLAN DESCRIPTION

Effective as of February 1, 2024

1. Establishment of Plan. Elicio Therapeutics, Inc. (the "Company"), hereby establishes an unfunded severance benefits plan (this "Plan") that is intended to be a welfare benefit plan within the meaning of Section 3(1) of ERISA. This Plan, adopted on February 1, 2024, is in effect for Participants who experience certain terminations of employment occurring after the Effective Date and before the termination of this Plan. This Plan supersedes any and all (i) severance plans and separation policies applying to Participants that may have been in effect before the Effective Date with respect to any termination that would, under the terms of this Plan, constitute a termination by the Company without Cause or by Participant for Good Reason, and (ii) the provisions of any agreements between any Participant and the Company that provide for severance payments and benefits.

2. Purpose. The purpose of this Plan is to establish the conditions under which Participants will receive the severance payments and benefits described herein if their employment with the Company (or its successor in a Change in Control (as defined below)) terminates under the circumstances specified herein. The severance payments and benefits paid under this Plan are intended to assist employees in making a transition to new employment and are not intended to be a reward for prior service with the Company.

3. Definitions. For purposes of this Plan:

(a) "Base Salary" shall mean, for any Participant, such Participant's base salary as in effect immediately before a Participant's termination of employment (or immediately prior to the effective date of a Change in Control, if greater) and exclusive of any bonuses, "adders," any other form of premium pay, or other forms of compensation.

(b) "Board" shall mean the Board of Directors of the Company.

(c) "Cause" shall mean Participant's: (i) willful misconduct or gross negligence in the performance of Participant's duties; (ii) refusal to follow the lawful directions of the Board (in the case of the CEO), the Chief Executive Officer (in the case of the Executive Officers), or the Company employee to whom the Participant reports (in the case of other Eligible Employees); (iii) breach of a fiduciary duty owed to the Company; (iv) fraud, embezzlement or other material dishonesty with respect to the Company; (v) violation of applicable federal, state or local law or regulation governing the Company's business; (vi) commission, conviction, plea of nolo contendere, guilty plea, or confession to a crime based upon an act of fraud, embezzlement or dishonesty or to a felony; (vii) habitual abuse of alcohol or any controlled substance or reporting to work under the influence of alcohol or any controlled substance (other than a controlled substance that Participant is properly taking under a current prescription); (viii) misappropriation (or attempted misappropriation) by Participant any material assets or business opportunities of the Company or any of its Subsidiaries or affiliates; (ix) a material failure to comply with the Company's written policies or rules, as they may be in effect from time to time during Participant's employment, including policies and rules prohibiting discrimination or harassment; or (x) a material breach of Participant's employment agreement or offer letter, the Employee Confidentiality, Assignment and Non-Solicitation Agreement or any Non-competition Agreement (the "Restrictive Covenants Agreement") or any other written agreement between the Company or one of its Subsidiaries and Participant, provided that Participant will have 30 days

after notice from the Board, the Chief Executive Officer or the employee to whom the Participant reports, as appropriate, to cure a failure or a breach under (ii), (ix) or (x), if curable.

(d) "Change in Control" shall mean the occurrence of any of the following events:

(i) A transaction or series of transactions (other than an offering of the Company's common stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the U.S. Securities Exchange Act of 1934, as amended ("Exchange Act")) directly or indirectly acquires beneficial ownership (within the meaning of Rules 13d-3 and 13d-5 under the Exchange Act) of the Company's securities possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; provided, however, that the following acquisitions shall not constitute a Change in Control: (i) any acquisition by the Company or any of its Subsidiaries; (ii) any acquisition by an employee benefit plan maintained by the Company or any of its Subsidiaries, (iii) any acquisition which complies with Sections 3(d)(iii)(A), 3(d)(iii)(B) and 3(d)(iii)(C); or (iv) in respect of payments or benefits to a particular Participant, any acquisition by the Participant or any group of persons including the Participant (or any entity controlled by the Participant or any group of persons including the Participant); or

(ii) The Incumbent Directors cease for any reason to constitute a majority of the Board, with "Incumbent Directors" meaning, for any period of 12 consecutive months, individuals who, at the beginning of such period, constitute the Board together with any new director(s) (other than a director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 3(d)(i) or 3(d)(iii)) whose election or nomination for election to the Board was approved by a vote of at least a majority (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for director without objection to such nomination) of the directors then still in office who either were directors at the beginning of the 12-month period or whose election or nomination for election was previously so approved. No individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any person other than the Board shall be an Incumbent Director; or

(iii) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination, (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction: (A) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction; (B) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be

treated for purposes of this Section 3(d)(iii)(B) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; and (C) after which at least a majority of the members of the board of directors (or the analogous governing body) of the Successor Entity were Board members at the time of the Board's approval of the execution of the initial agreement providing for such transaction; or

(iv) The completion of a liquidation or dissolution of the Company;

provided that notwithstanding the foregoing, if a Change in Control constitutes a payment event that provides for the deferral of compensation that is subject to Section 409A of the Code and the guidance issued thereunder ("Section 409A"), to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (i), (ii), (iii) or (iv) above with respect to such payment shall only constitute a Change in Control for purposes of the payment timing of such payment if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Plan Administrator shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

(e) "Change in Control Period" means: period beginning three (3) months prior to the date of a Change in Control and ending twelve (12) months following the date of a Change in Control.

(f) "COBRA" shall mean the Consolidated Omnibus Budget Reconciliation Act.

(g) "Code" shall mean the Internal Revenue Code of 1986, as amended.

(h) "Company" shall mean Elicio Therapeutics, Inc. or, following a Change in Control, any successor thereto.

(i) "Effective Date" shall mean February 1, 2024.

(j) "Eligible Employee" shall mean: (i) the Chief Executive Officer; (ii) all executive officers as determined by the Board other than the CEO ("Executive Officers"), and (iii) all other executives having the title of Vice President.

(k) "ERISA" shall mean the Employee Retirement Income Security Act of 1974, as amended.

(l) "Executive Officers" shall have the meaning set forth in Section 3(j).

(m) "Good Reason" shall mean the occurrence of any of the following events without Participant's consent: (i) a material reduction of Participant's Base Salary as in effect immediately prior to the reduction; (ii) a material reduction in Participant's authority, duties or responsibilities, provided however, following a Change in Control, a change in job title or reporting relationship without a reduction in Participant's Base Salary will not constitute Good Reason; (iii) relocation of the offices at which Participant

is required to work to a location that would increase Participant's one-way commute by more than 50 miles; provided that, within 30 days of the first occurrence of the event that Participant believes constitutes Good Reason, Participant notifies the Company in a writing of the event, the Company fails to correct the act or omission within 30 days after receiving Participant's written notice and Participant actually terminates his or her employment within 60 days after the date the Company receives Participant's notice.

(n) "Participant" shall mean the Eligible Employees employed by the Company from time to time.

(o) "Plan Administrator" shall have the meaning set forth in Section 14 hereof.

(p) "Subsidiary" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

4. Severance Not in Connection with a Change in Control. If the Company terminates Participant's employment without Cause at any time other than during a Change in Control Period, subject to the provisions of Section 6 and 7, Participant shall be eligible to receive the following payments and benefits (collectively, the "Severance Package"):

(a) Participant shall be entitled to receive an amount equal to the product of (the "Normal Severance"): (i) the Normal Multiplier, as determined under Exhibit A based on Participant's title or role with the Company; and (ii) the Participant's then-current Base Salary. The Normal Severance shall be payable in the form of salary continuation in accordance with the Company's regular payroll schedule over the Severance Period, commencing on such date determined in accordance with Section 6 or as a lump sum at the Company's sole discretion. The "Severance Period" will equal the period of months equal to the product of (A) Participant's Normal Multiplier and (B) 12; provided in the event the Participant is entitled to any payments pursuant to a Restrictive Covenants Agreement, the Normal Severance received in any calendar year will be reduced by the amount the Participant is paid in the same such calendar year pursuant to the Restrictive Covenants Agreement (the "Restrictive Covenants Agreement Setoff").

(b) In the case of the Chief Executive Officer, the portion of any outstanding unvested time-based equity award held by Participant scheduled to vest during the twelve (12) months following the Participant's termination date will become fully vested as of the date the termination of Participant's employment becomes effective.

(c) Participant shall be entitled to continue participating in the Company's health benefits for the Severance Period (the "Severance Benefits"), as follows: (i) such continued benefits shall be subject to Participant's timely election of continuation coverage under COBRA; (ii) the Company will pay the company contribution and Participant shall be required to pay the employee contribution directly or as a reimbursement to Participant at the at the Company's sole discretion, (iii) Participant's right to receive further Severance Benefits shall terminate if and when Participant secures alternative health benefits from a new employer, of which Participant shall promptly notify the Company, or if and when Participant otherwise becomes ineligible for further coverage under COBRA; and (iv) the Company shall be required to provide the Severance Benefits only to the extent that the Company continues offering an employee health benefits

plan and to extent that the Company is not required to provide and pay for such post-termination coverage to other employees to avoid a violation of applicable nondiscrimination requirements.

(d) The payments and benefits described in this Section 4 shall be in lieu of any other benefits or payments under any severance or similar plan, policy or arrangement of the Company.

5. Severance in Connection with a Change in Control. If during the Change in Control Period, the Company terminates Participant's employment without Cause or Participant resigns Participant's employment with Good Reason, subject to the provisions of Section 6 and 7, Participant shall be eligible to receive the following payments and benefits (collectively, the "CIC Severance Package"):

(a) Participant shall be entitled to receive an amount equal to the product of (the "CIC Severance"): (A) the CIC Multiplier, as determined under Exhibit A based on Participant's title or role with the Company; and (B) the sum of Participant's then-current Base Salary and then-current target annual bonus opportunity. The CIC Severance shall be payable in a single lump sum, on such date in determined accordance with Section 6; provided the CIC Severance shall be reduced by the amount of any Restrictive Covenants Agreement Setoff, if applicable, paid or to be paid in the same calendar year.

(b) Participant shall be entitled to continue participating in the Company's health benefits for the CIC Severance Period (the "CIC Severance Benefits"), as follows: (i) such continued benefits shall be subject to Participant's timely election of continuation coverage under COBRA; (ii) the Company will pay the company contribution directly or as a reimbursement to Participant at the Company's sole discretion and Participant shall be required to pay the employee contribution; (iii) Participant's right to receive further CIC Severance Benefits shall terminate if and when Participant secures alternative health benefits from a new employer, of which Participant shall promptly notify the Company, or if and when Participant otherwise becomes ineligible for further coverage under COBRA; and (iv) the Company shall be required to provide the CIC Severance Benefits only to the extent that the Company continues offering an employee health benefits plan and to extent that the Company is not required to provide and pay for such post-termination coverage to other employees to avoid a violation of applicable nondiscrimination requirements. The "CIC Severance Period" will equal the period of months equal to the product of (A) Participant's CIC Multiplier and (B) 12.

(c) Any outstanding unvested equity awards held by Participant under the Company's then-current outstanding equity incentive plan(s) will become fully vested as of the date the termination of Participant's employment becomes effective.

(d) The payments and benefits described in this Section 5 shall be in lieu of any other benefits or payments under any severance or similar plan, policy or arrangement of the Company, and shall be in lieu of any benefits set forth in Section 5 of this Agreement.

6. Release. A Participant's rights to the Severance Package or the CIC Severance Package, as applicable, is conditioned upon Participant executing and not revoking a valid separation and general release agreement in a form provided by the Company (the "Release"), and provided such release becomes effective and irrevocable within 60 days following termination or such shorter time period set forth therein, releasing the Company, its Subsidiaries, other affiliates and shareholders from any and all liability. Any payments or benefits due for the period after termination and before the Release becomes effective shall be paid with the first payment after the Release becomes effective. Notwithstanding any other provision herein, if the period during which Participant has discretion to execute or revoke the Release straddles two calendar

years, the Company shall make payments conditioned on the Release no earlier than January 1st of the second calendar year, regardless of which year the Release becomes effective.

7. Restrictive Covenants. A Participant's rights to the Severance Package or the CIC Severance Package, as applicable, is conditioned on Participant's compliance with Participant's obligations under, as applicable: (a) Participant's Restrictive Covenants Agreement; and (b) any other applicable confidentiality, invention, work product, non-disparagement, non-competition, non-solicitation, non-interference, and/or other restrictive covenant obligations contained in any written agreement between the Participant and the Company. In the event that Participant fails to comply with any of these obligations, the Participant's right to receive any additional Severance Package or CIC Severance Package payments or benefits shall cease immediately and Participant shall promptly refund any such payments or benefits previously paid by the Company. The Company's rights under this Section 7 shall be full recourse. The Company shall have the right to offset Participant's obligations under this Section 7 against any amounts otherwise owed to Participant from the Company or its affiliates.

8. Accrued Obligations. Notwithstanding anything to the contrary contained herein, a Participant shall be entitled to all Accrued Obligations as of his or her termination of employment, regardless of whether he or she is eligible for severance payments or benefits under this Plan. "Accrued Obligations" shall mean, for any Participant: (i) the portion of such Participant's Base Salary that has accrued prior to any termination of such Participant's employment with the Company and has not yet been paid; (ii) the portion of such Participant's prior-year annual bonus that has been earned prior to any termination of such Participant's employment with the Company and has not yet been paid; (iii) the amount of any expenses properly incurred by such Participant on behalf of the Company in accordance with Company policy prior to any such termination and not yet reimbursed; and (iv) the amount of such Participant's vacation time that has accrued prior to any such termination that has not yet been used. A Participant's entitlement to any other compensation or benefit under any plan of Company shall be governed by and determined in accordance with the terms of such plans, except as otherwise specified in this Plan.

9. Non-Duplication of Benefits. Nothing in this Plan will entitle any Participant to receive duplicate benefits in connection with any voluntary or involuntary termination of employment. A Participant's right to receive any payments under this Plan will be expressly conditioned upon such Participant not receiving severance payments or benefits under any other agreement, program or arrangement.

10. Death. If a Participant dies after the date Participant commences receiving benefits and payments under the Severance Package or the CIC Severance Package, as applicable, but before all such payments or benefits have been paid or provided, payments will be made to any beneficiary designated by Participant prior to or in connection with such Participant's termination or, if no such beneficiary has been designated, to Participant's estate.

11. Withholding. The Company may withhold from any payment or benefit under this Plan: (a) any federal, state, or local income or payroll taxes required by law to be withheld with respect to such payment; (b) such sum as the Company may reasonably estimate is necessary to cover any taxes for which the Company may be liable and which may be assessed with regard to such payment; and (c) such other amounts as appropriately may be withheld under the Company's payroll policies and procedures from time to time in effect.

12. Section 409A. It is expected that the payments and benefits provided under this Plan will be exempt from the application of Section 409A. This Plan shall be interpreted consistent with this intent to the maximum extent permitted and generally, with the provisions of Section 409A. A termination of

employment shall not be deemed to have occurred for purposes of any provision of this Plan providing for the payment of any amounts or benefits upon or following a termination of employment (which amounts or benefits constitute nonqualified deferred compensation within the meaning of Section 409A) unless such termination is also a "separation from service" within the meaning of Section 409A and, for purposes of any such provision of this Plan, references to a "termination," "termination of employment" or like terms shall mean "separation from service". Neither Participant nor the Company shall have the right to accelerate or defer the delivery of any payment or benefit except to the extent specifically permitted or required by Section 409A. Notwithstanding the foregoing, to the extent the severance payments or benefits under this Plan are subject to Section 409A, the following rules shall apply with respect to distribution of the payments and benefits, if any, to be provided to Participants under this Plan:

(a) Each installment of the payments and benefits provided under this Plan will be treated as a separate "payment" for purposes of Section 409A. Whenever a payment under this Plan specifies a payment period with reference to a number of days (e.g., "payment shall be made within 10 days following the date of termination"), the actual date of payment within the specified period shall be in the Company's sole discretion. Notwithstanding any other provision of this Plan to the contrary, in no event shall any payment under this Plan that constitutes "non-qualified deferred compensation" for purposes of Section 409A be subject to transfer, offset, counterclaim or recoupment by any other amount unless otherwise permitted by Section 409A.

(b) Notwithstanding any other payment provision herein to the contrary, if the Company or appropriately-related affiliates is publicly-traded and a Participant is deemed on the date of termination to be a "specified employee" within the meaning of that term under Code Section 409A(a)(2)(B) with respect to such entity, then each of the following shall apply:

(i) With regard to any payment that is considered "non-qualified deferred compensation" under Section 409A payable on account of a "separation from service," such payment shall be made on the date which is the earlier of (A) the day following the expiration of the six month period measured from the date of such "separation from service" of Participant, and (B) the date of Participant's death (the "Delay Period") to the extent required under Section 409A. Upon the expiration of the Delay Period, all payments delayed pursuant to this provision (whether otherwise payable in a single sum or in installments in the absence of such delay) shall be paid to or for Participant in a lump sum, and all remaining payments due under this Plan shall be paid or provided for in accordance with the normal payment dates specified herein; and

(ii) To the extent that any benefits to be provided during the Delay Period are considered "non-qualified deferred compensation" under Section 409A payable on account of a "separation from service," and such benefits are not otherwise exempt from Section 409A, Participant shall pay the cost of such benefits during the Delay Period, and the Company shall reimburse Participant, to the extent that such costs would otherwise have been paid by the Company or to the extent that such benefits would otherwise have been provided by the Company at no cost to Participant, the Company's share of the cost of such benefits upon expiration of the Delay Period. Any remaining benefits shall be reimbursed or provided by the Company in accordance with the procedures specified in this Plan.

(c) The Company makes no representations or warranties and shall have no liability to any Participant or any other person, other than with respect to payments made by the Company in violation of the provisions of this Plan, if any provisions of or payments under this Plan are determined to constitute deferred compensation subject to Section 409A of the Code but not to satisfy the conditions of that section.

13. Modified 280G Cutback.

(a) To the extent that any payment, benefit or distribution of any type to or for a Participant's benefit by the Company or any of its affiliates, whether paid or payable, provided or to be provided, or distributed or distributable pursuant to the terms of this Plan or otherwise (including, without limitation, any accelerated vesting of stock options or other equity-based awards) (collectively, the "Total Payments") would be subject to the excise tax imposed under Section 4999 of the Code, then the Total Payments shall be reduced (but not below zero) so that the maximum amount of the Total Payments (after reduction) shall be one dollar ($1.00) less than the amount which would cause the Total Payments to be subject to the excise tax imposed by Section 4999 of the Code, but only if the Total Payments so reduced result in Participant receiving a net after tax amount that exceeds the net after tax amount Participant would receive if the Total Payments were not reduced and were instead subject to the excise tax imposed on excess parachute payments by Section 4999 of the Code. Unless Participant shall have given prior written notice to the Company to effectuate a reduction in the Total Payments if such a reduction is required, any such notice consistent with the requirements of Section 409A to avoid the imputation of any tax, penalty or interest thereunder, the Company shall reduce or eliminate the Total Payments by first reducing or eliminating any cash severance benefits (with the payments to be made furthest in the future being reduced first), then by reducing or eliminating any accelerated vesting of stock options or similar awards, then by reducing or eliminating any accelerated vesting of restricted stock or similar awards, then by reducing or eliminating any other remaining Total Payments. The preceding provisions of this Section shall take precedence over the provisions of any other plan, arrangement or agreement governing Participant's rights and entitlements to any benefits or compensation.

(b) If the Total Payments to a Participant are reduced in accordance with Section 14(a), as a result of the uncertainty in the application of Section 4999 of the Code at the time of the initial reduction under Section 14(a), it is possible that Total Payments to a Participant which will not have been made by the Company should have been made ("Underpayment") or that Total Payments to a Participant which were made should not have been made ("Overpayment"). If an Underpayment has occurred, the amount of any such Underpayment shall be promptly paid by the Company to or for the benefit of such Participant. In the event of an Overpayment, then Participant shall promptly repay to the Company the amount of any such Overpayment together with interest on such amount (at the same rate as is applied to determine the present value of payments under Section 280G of the Code or any successor thereto), from the date the reimbursable payment was received by such Participant to the date the same is repaid to the Company

14. Plan Administration.

(a) Plan Administrator. The Plan Administrator shall be the Board or a committee thereof designated by the Board (the "Committee"); provided, however, that the Board or such Committee (as constituted prior to the closing of a Change in Control) may in its sole discretion appoint a new Plan Administrator to administer this Plan following a Change in Control, which such Plan Administrator shall not be removed or modified following a Change in Control other than at its own initiative. If such Plan Administrator designated by the Board or Committee prior to a Change in Control ceases to serve as Plan Administrator at any point after a Change in Control but prior to the later to occur of the first (1st) anniversary of the Change in Control or the final payment of benefits under this Plan to any Participant, then until the later to occur of the first (1st) anniversary of the Change in Control or the final payment of benefits under this Plan to any Participant, any such successor Plan Administrator appointed by the Board or the Committee shall be a qualified independent third party, such as a retired judge selected by the head of the American Arbitration Association in Manhattan, an independent compensation consultant or a law firm. The Plan Administrator shall also serve as the Named Fiduciary of this Plan under ERISA. The Plan Administrator shall be the "administrator" within the meaning of Section 3(16) of ERISA and shall have all the responsibilities and duties contained therein. Notwithstanding any provision of this Plan to the contrary, any employee(s) appointed to serve as Plan Administrator (whether individually or as members of a committee)

shall serve as such only for so long as he or she is an employee of the Company and shall be deemed to resign his or her position effective as of his or her termination of employment (whether voluntary or involuntary). The Plan Administrator can be contacted at the following address:

Elicio Therapeutics, Inc.
451 D Street, 5th Floor
Boston, Massachusetts 02110
Attention: Head of Human Resources
Phone: (857) 209-0050

(b) Decisions, Powers and Duties. The general administration of this Plan and the responsibility for carrying out its provisions shall be vested in the Plan Administrator. The Plan Administrator shall have such powers and authority as are necessary to discharge such duties and responsibilities which also include, but are not limited to, interpretation and construction of this Plan, the determination of all questions of fact, including, without limit, eligibility, participation and benefits, the resolution of any ambiguities and all other related or incidental matters, and such duties and powers of the plan administration which are not assumed from time to time by any other appropriate entity, individual or institution. The Plan Administrator may determine from time to time, in its discretion, whether an employee of the Company who is not an Eligible Employee shall become a Participant in this Plan, provided the Plan Administrator delivers written notice to such employee that the employee will be a Participant in the Plan. The Plan Administrator may adopt rules and regulations of uniform applicability in its interpretation and implementation of this Plan. The Plan Administrator may delegate any of its duties hereunder to such person or persons from time to time as it may designate.

(c) The Plan Administrator shall discharge its duties and responsibilities and exercise its powers and authority in its sole discretion and in accordance with the terms of the controlling legal documents and applicable law, and its actions and decisions that are not arbitrary and capricious shall be binding on any employee, and employee's spouse or other dependent or beneficiary and any other interested parties whether or not in being or under a disability. The Plan Administrator is empowered, on behalf of this Plan, to engage accountants, legal counsel and such other personnel as it deems necessary or advisable to assist it in the performance of its duties under this Plan. The functions of any such persons engaged by the Plan Administrator shall be limited to the specified services and duties for which they are engaged, and such persons shall have no other duties, obligations or responsibilities under this Plan. Such persons shall exercise no discretionary authority or discretionary control respecting the management of this Plan.

(d) The Company shall promptly reimburse the Plan Administrator or the Committee for any expenses incurred in good faith in the course of carrying out its obligations under this Plan, including, but not limited to, attorney's fees, claims, fines, judgments, taxes, causes of action or liability and amounts paid in settlement, actually and reasonably incurred by such Committee or Plan Administrator, unless such expense, claim, fine, judgment, taxes, cause of action, liability or amount arose from his or her negligence, fraud or willful breach of his or her fiduciary responsibilities under ERISA.

15. Claims, Inquiries and Appeals.

(a) Applications for Benefits and Inquiries. Any application for benefits under or inquiries about this Plan or inquiries about present or future rights under this Plan must be submitted to the Plan Administrator in writing, as follows:

Plan Administrator
Elicio Therapeutics, Inc.
451 D Street, 5th Floor
Boston, Massachusetts 02110

(b) Denial of Claims. In the event that any application for benefits is denied in whole or in part, the Plan Administrator must notify the applicant, in writing, of the denial of the application, and of the applicant's right to review the denial. The written notice of denial will be set forth in a manner designed to be understood by the applicant, and will include specific reasons for the denial, specific references to this Plan provision upon which the denial is based, a description of any information or material that the Plan Administrator needs to complete the review and an explanation of this Plan's review procedure. This written notice will be given to the applicant within 15 days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional 15 days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial 15-day period. This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render his or her decision on the application. If written notice of denial of the application for benefits is not furnished within the specified time, the application shall be deemed to be denied. The applicant will then be permitted to appeal the denial in accordance with the review procedure described below.

(c) Request for a Review. Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within 30 days after the application is denied (or deemed denied). The Plan Administrator will give the applicant (or his or her representative) an opportunity to review pertinent documents in preparing a request for a review and submit written comments, documents, records and other information relating to the claim. A request for a review shall be in writing and shall be addressed to:

Plan Administrator
Elicio Therapeutics, Inc.
451 D Street, 5th Floor
Boston, Massachusetts 02110

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The Plan Administrator may require the applicant to submit additional facts, documents or other material as he or she may find necessary or appropriate in making his or her review.

(d) Decision on Review. The Plan Administrator will act on each request for review within 15 days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional 15 days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial 15-day period. The Plan Administrator will give prompt, written notice of his or her decision to the applicant. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will outline, in a manner calculated to be understood by the applicant, the specific Plan provisions upon which the decision is based.

(e) Rules and Procedures. The Plan Administrator may establish rules and procedures, consistent with this Plan and with ERISA, as necessary and appropriate in carrying out his or her

responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial (or deemed denial) of benefits to do so at the applicant's own expense.

(f) Exhaustion of Remedies. No legal action for benefits under this Plan may be brought until the claimant (i) has submitted a written application for benefits in accordance with the procedures described by Section 15(a) above, (ii) has been notified by the Plan Administrator that the application is denied (or the application is deemed denied due to the Plan Administrator's failure to act on it within the established time period), (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 15(c) above and (iv) has been notified in writing that the Plan Administrator has denied the appeal (or the appeal is deemed to be denied due to the Plan Administrator's failure to take any action on the claim within the time prescribed by Section 15(d) above).

16. Indemnification. To the extent permitted by law, the Plan Administrator and all employees, officers, directors, agents and representatives of the Company shall be indemnified by the Company and held harmless against any claims and all associated expenses of defending against such claims, resulting from any action or conduct relating to the administration of this Plan, whether as a member of the Committee or otherwise, except to the extent that such claims arise from gross negligence, willful neglect, or willful misconduct. The Company shall advance all expenses for which a party is indemnified under this Section 16 to such indemnified party or shall arrange for direct payment of any such expenses by the Company.

17. Plan Not an Employment Contract. This Plan is not a contract between the Company and any employee, nor is it a condition of employment of any employee. Nothing contained in this Plan gives, or is intended to give, any employee the right to be retained in the service of the Company, or to interfere with the right of the Company to discharge or terminate the employment of any employee at any time and for any reason. No employee shall have the right or claim to benefits beyond those expressly provided in this Plan, if any. All rights and claims are limited as set forth in this Plan.

18. Severability. In case any one or more of the provisions of this Plan (or part thereof) shall be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions hereof, and this Plan shall be construed as if such invalid, illegal or unenforceable provisions (or part thereof) never had been contained herein.

19. Non Assignability. No right or interest of any Participant in this Plan shall be assignable or transferable in whole or in part either directly or by operation of law or otherwise, including, but not limited to, execution, levy, garnishment, attachment, pledge or bankruptcy.

20. Integration With Other Pay or Benefits Requirements. The severance payments and benefits provided for in this Plan are the maximum benefits that the Company will pay to Participants on a termination of employment, except to the extent otherwise required by applicable law. To the extent that any federal, state or local law, including, without limitation, so called "plant closing" laws, requires the Company to give advance notice or make a payment of any kind to an employee because of that employee's involuntary termination due to a layoff, reduction in force, plant or facility closing, sale of business, or similar event, the benefits provided under this Plan or the other arrangement shall either be reduced or eliminated to avoid any duplication of payment. The Company intends for the benefits provided under this Plan to partially or fully satisfy any and all statutory obligations that may arise out of an employee's involuntary termination for the foregoing reasons and the Company shall so construe and implement the terms of this Plan.

21. Amendment or Termination. The Board may amend, modify, or terminate this Plan at any time in its sole discretion; provided, however, that: (a) any such amendment, modification or termination made prior to a Change in Control that adversely affects the rights of any Participant shall be approved by the Company's Board of Directors; (b) no such amendment, modification or termination may adversely affect the rights of a Participant then receiving payments or benefits under this Plan without the consent of such person; and (c) no such amendment, modification or termination made after a Change in Control shall be effective until after the later to occur of the first (1st) anniversary of the Change in Control or the final payment of benefits under this Plan to any Participant. The Board intends to review this Plan at least annually.

22. Source of Benefit. The Company will pay benefits under the Plan from its general assets to the extent available. The benefits is not funded through a trust fund or insurance contracts. No employee shall have any right to, or interest in, any assets of the Company upon termination of employment or otherwise.

23. Statement of ERISA Rights. Participants are entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). ERISA provides that Participants are entitled to the following rights:

(a) Receive Information About the Plan and Benefits. A Participant may examine, without charge, at the Plan Administrator's office all documents governing the Plan and, if applicable, a copy of the latest annual report (Form 5500) filed with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration. A Participant may also obtain copies of these documents upon written request to the Plan Administrator. There may be a reasonable charge for the cost of copying. A Participant is also entitled to receive a summary of the Plan's annual financial report. The Plan Administrator is required by law to furnish each Participant with a copy of this summary annual report.

(b) Prudent Actions by Plan Fiduciaries. In addition to creating rights for Plan participants, ERISA imposes duties upon the people who are responsible for the operation of the Plan. The people who operate the Plan, called "fiduciaries," have a duty to do so prudently and in the interest of the Plan's Participants and their beneficiaries. No one, including the Company, may fire you or otherwise discriminate against a Participant in any way to prevent the Participant from obtaining a welfare benefit or exercising the Participant's rights under ERISA.

(c) Enforce Participant Rights. If a Participant' claim for a welfare benefit is denied or ignored, in whole or in part, the Participant has the right to know the reason and to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain timeframes as set forth in this Plan. Under ERISA, there are steps a Participant can take to enforce the above rights. For instance, if a Participant requests a copy of Plan documents, or the latest annual report from the Plan and the Participant does not receive them within 30 days, the Participant may file suit in a federal court. In such a case, the court may require the Plan Administrator to provide the materials to the Participant and pay the Participant up to $110 per day until the Participant receives the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator. If the Participant has a claim for benefits that is denied or ignored, in whole or in part, the Participant may file suit in federal or state court, provided the Participant has exhausted the Plan's administrative remedies (i.e. claims procedures). If it should happen that the Plan fiduciaries misuse the Plan's money, or if a Participant is discriminated against for asserting the Participant's rights under this Plan or under ERISA, the Participant may seek assistance from the U.S. Department of Labor, or may file suit in federal court. The court will decide who should pay court costs and legal fees. If a Participant is successful, the court may order the person that the Participant sued to pay these

costs and fees. If a Participant loses, the court may order the Participant to pay these costs and fees if it finds the Participant's claim is frivolous.

(d) Assistance With Questions. If a Participant has any questions about the Plan, the Participant should contact the Plan Administrator. If a Participant has questions about this statement or about the Participant's rights under ERISA, the Participant should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Participant Assistance and Communications, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210. The Participant may obtain publications about the Participant's rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration. A Participant may also access the Employee Benefits Security Administration's website at www.dol.gov/ebsa.

24. **Type of Plan**. This Plan is a severance pay Plan.

25. **Plan Sponsor**. The sponsor of this Plan is Elicio Therapeutics, Inc. (referred to in this Plan as the "Company"). The Plan sponsor's address is:

Elicio Therapeutics, Inc.
451 D Street, 5th Floor
Boston, Massachusetts 02110
Attention: Head of Human Resources
Phone: (857) 209-0050

26. **Agent for Legal Process**. A Participant or beneficiary may serve legal process on the Plan Administrator, c/o:

Elicio Therapeutics, Inc.
451 D Street, 5th Floor
Boston, Massachusetts 02110
Attention: Head of Human Resources

27. **Plan Year**. The Plan Year is the calendar year.

28. **Identification Number**. The Plan's number for purposes of discussion with a federal government agency is 501. The Company's Employer Identification Number is 11-3430072.

29. **Summary Plan Description**. This Plan constitutes both the governing document and the summary plan description for the Plan.

30. **Governing Law.** This Plan and the rights of all persons under this Plan shall be construed in accordance with and under applicable provisions of ERISA, and the regulations thereunder, and the laws of the State of Delaware (without regard to conflict of law provisions) to the extent not preempted by federal law.

EXHIBIT A
MULTIPLIERS

Title/Role of Participant	Normal Multiplier	CIC Multiplier
Chief Executive Officer	1	1.5
Executive Officer	.75	1
Senior Vice President	.75	1
Vice President	.5	.75

ELICIO THERAPEUTICS, INC.
2024 INDUCEMENT INCENTIVE AWARD PLAN

ARTICLE I.
PURPOSE

The Plan's purpose is advance the interests of the Company's stockholders by enhancing the Company's ability to attract new Employees who are expected to make important contributions to the Company and by providing these individuals with equity ownership opportunities that are intended to better align the interests of such persons with those of the Company's stockholders. The Company intends that the Plan be reserved for persons whom the Company may issue securities without stockholder approval as an inducement pursuant to Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market.

ARTICLE II.
DEFINITIONS

As used in the Plan, the following words and phrases have the meanings specified below, unless the context clearly indicates otherwise:

2.1 "***Administrator***" means the Board or a Committee to the extent that the Board's powers or authority under the Plan have been delegated to such Committee.

2.2 "***Applicable Law***" means any applicable law, including without limitation: (a) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (b) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (c) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

2.3 "***Award***" means an Option, Stock Appreciation Right, Restricted Stock award, Restricted Stock Unit award, Performance Bonus Award, Performance Stock Unit award, Dividend Equivalents award or Other Stock or Cash Based Award granted to a Participant under the Plan.

2.4 "***Award Agreement***" means an agreement evidencing an Award, which may be written or electronic, that contains such terms and conditions as the Administrator determines, consistent with and subject to the terms and conditions of the Plan.

2.5 "***Board***" means the Board of Directors of the Company.

2.6 "***Change in Control***" means any of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) directly or indirectly acquires beneficial ownership (within the meaning of Rules 13d-3 and 13d-5 under the Exchange Act) of the Company's securities possessing more than 50% of the total combined voting power of the

Company's securities outstanding immediately after such acquisition; provided, however, that the following acquisitions shall not constitute a Change in Control: (i) any acquisition by the Company or any of its Subsidiaries; (ii) any acquisition by an employee benefit plan maintained by the Company or any of its Subsidiaries, (iii) any acquisition which complies with Sections 2.6(c)(i), 2.6(c)(ii) and 2.6(c)(iii); or (iv) in respect of an Award held by a particular Participant, any acquisition by the Participant or any group of persons including the Participant (or any entity controlled by the Participant or any group of persons including the Participant);

(b) The Incumbent Directors cease for any reason to constitute a majority of the Board;

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination, (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "***Successor Entity***")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction;

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 2.6(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; and

(iii) after which at least a majority of the members of the board of directors (or the analogous governing body) of the Successor Entity were Board members at the time of the Board's approval of the execution of the initial agreement providing for such transaction; or

(d) The completion of a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to any Award (or any portion of an Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b), (c) or (d) of this Section 2.6 with respect to such Award (or portion thereof) shall only constitute a Change in

Control for purposes of the payment timing of such Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

2.7 "***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and all regulations, guidance, compliance programs and other interpretative authority issued thereunder.

2.8 "***Committee***" means the Company's compensation committee (as constituted in compliance with Rule 5605(d)(2) of the Nasdaq Listing Rules) in order to comply with the exemption from the stockholder approval requirement for "inducement grants" provided under Rule 5635(c)(4) of the Nasdaq Listing Rules.

2.9 "***Common Stock***" means the common stock of the Company.

2.10 "***Company***" means Elicio Therapeutics, Inc., a Delaware corporation, or any successor.

2.11 "***Designated Beneficiary***" means the beneficiary or beneficiaries the Participant designates, in a manner the Company determines, to receive amounts due or exercise the Participant's rights if the Participant dies. Without a Participant's effective designation, "Designated Beneficiary" will mean the Participant's estate.

2.12 "***Director***" means a Board member.

2.13 "***Disability***" means a permanent and total disability under Section 22(e)(3) of the Code.

2.14 "***Dividend Equivalents***" means a right granted to a Participant to receive the equivalent value (in cash or Shares) of dividends paid on a specified number of Shares. Such Dividend Equivalent shall be converted to cash or additional Shares, or a combination of cash and Shares, by such formula and at such time and subject to such limitations as may be determined by the Administrator.

2.15 "***DRO***" means a "domestic relations order" as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended, or the rules thereunder.

2.16 "***Effective Date***" has the meaning set forth in Section 11.3.

2.17 "***Employee***" means any employee of the Company or any of its Subsidiaries.

2.18 "***Equity Restructuring***" means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split (including a reverse stock split), spin-

off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Awards.

2.19 "***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended, and all regulations, guidance and other interpretative authority issued thereunder.

2.20 "***Fair Market Value***" means, as of any date, the value of a Share determined as follows: (i) if the Common Stock is listed on any established stock exchange, the value of a Share will be the closing sales price for a Share as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (ii) if the Common Stock is not listed on an established stock exchange but is quoted on a national market or other quotation system, the value of a Share will be the closing sales price for a Share on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; or (iii) if the Common Stock is not listed on any established stock exchange or quoted on a national market or other quotation system, the value established by the Administrator in its sole discretion.

2.21 "***Incentive Stock Option***" means an Option that meets the requirements to qualify as an "incentive stock option" as defined in Section 422 of the Code.

2.22 "***Incumbent Directors"*** means, for any period of 12 consecutive months, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 2.6(a) or 2.6(c)) whose election or nomination for election to the Board was approved by a vote of at least a majority (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for Director without objection to such nomination) of the Directors then still in office who either were Directors at the beginning of the 12-month period or whose election or nomination for election was previously so approved. No individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to Directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any person other than the Board shall be an Incumbent Director.

2.23 "***Nonqualified Stock Option***" means an Option that is not an Incentive Stock Option.

2.24 "***Option***" means a right granted under Article VI to purchase a specified number of Shares at a specified price per Share during a specified time period. Options granted under the Plan shall be Nonqualified Stock Options.

2.25 "***Other Stock or Cash Based Awards***" means cash awards, awards of Shares, and other awards valued wholly or partially by referring to, or are otherwise based on, Shares or other property.

2.26 "***Overall Share Limit***" means 500,000 Shares.

2.27 "***Participant***" means an Employee who has been granted an Award.

2.28 "***Performance Bonus Award***" has the meaning set forth in Section 8.3.

2.29 "***Performance Stock Unit***" means a right granted to a Participant pursuant to Section 8.1 and subject to Section 8.2, to receive Shares, the payment of which is contingent upon achieving certain performance goals or other performance-based targets established by the Administrator.

2.30 "***Permitted Transferee***" means, with respect to a Participant, any "family member" of the Participant, as defined in the General Instructions to Form S-8 Registration Statement under the Securities Act (or any successor form thereto), or any other transferee specifically approved by the Administrator after taking into account Applicable Law.

2.31 "***Plan***" means this 2024 Inducement Incentive Award Plan.

2.32 "***Restricted Stock***" means Shares awarded to a Participant under Article VII, subject to certain vesting conditions and other restrictions.

2.33 "***Restricted Stock Unit***" means an unfunded, unsecured right to receive, on the applicable settlement date, one Share or an amount in cash or other consideration determined by the Administrator to be of equal value as of such settlement date, subject to certain vesting conditions and other restrictions.

2.34 "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act.

2.35 "***Section 409A***" means Section 409A of the Code.

2.36 "***Securities Act***" means the Securities Act of 1933, as amended, and all regulations, guidance and other interpretative authority issued thereunder.

2.37 "***Shares***" means shares of Common Stock.

2.38 "***Stock Appreciation Right***" or "***SAR***" means a right granted under Article VI to receive a payment equal to the excess of the Fair Market Value of a specified number of Shares on the date the right is exercised over the exercise price set forth in the applicable Award Agreement.

2.39 "***Subsidiary***" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

2.40 "***Termination of Service***" means the time when the employee-employer relationship between a Participant and the Company or any Subsidiary is terminated for any

reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where the Participant simultaneously commences or remains in employment or service with the Company or any Subsidiary. The Company, in its sole discretion, shall determine the effect of all matters and questions relating to any Termination of Service, including, without limitation, whether a Termination of Service has occurred, whether a Termination of Service resulted from a discharge for "cause" and all questions of whether particular leaves of absence constitute a Termination of Service. For purposes of the Plan, a Participant's employee-employer relationship shall be deemed to be terminated in the event that the Subsidiary employing such Participant ceases to remain a Subsidiary following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off), even though the Participant may subsequently continue to perform services for that entity.

ARTICLE III.
ELIGIBILITY

Employees are eligible to be granted Awards under the Plan as an inducement pursuant to Listing Rule 5635(c)(4) of the corporate governance rules of the Nasdaq Stock Market, subject to the limitations described herein. No Employee shall have any right to be granted an Award pursuant to the Plan and neither the Company nor the Administrator is obligated to treat Employees, Participants or any other persons uniformly.

ARTICLE IV.
ADMINISTRATION AND DELEGATION

4.1 Administration.

(a) The Plan is administered by the Administrator. The Administrator has authority to determine which Employees receive Awards, grant Awards and set Award terms and conditions, subject to the conditions and limitations in the Plan. The Administrator also has the authority to take all actions and make all determinations under the Plan, to interpret the Plan and Award Agreements and to adopt, amend and repeal Plan administrative rules, guidelines and practices as it deems advisable. The Administrator may correct defects and ambiguities, supply omissions, reconcile inconsistencies in the Plan or any Award and make all other determinations that it deems necessary or appropriate to administer the Plan and any Awards. The Administrator (and each member thereof) is entitled to, in good faith, rely or act upon any report or other information furnished to it, him or her by any officer or other employee of the Company or any Subsidiary, the Company's independent certified public accountants, or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan. The Administrator's determinations under the Plan are in its sole discretion and will be final, binding and conclusive on all persons having or claiming any interest in the Plan or any Award.

(b) Without limiting the foregoing, the Administrator has the exclusive power, authority and sole discretion to: (i) designate Participants; (ii) determine the type or types of Awards to be granted to each Participant; (iii) determine the number of Awards to be granted and the number of Shares to which an Award will relate; (iv) subject to the limitations in the Plan,

determine the terms and conditions of any Award and related Award Agreement, including, but not limited to, the exercise price, grant price, purchase price, any performance criteria, any restrictions or limitations on the Award, any schedule for vesting, lapse of forfeiture restrictions or restrictions on the exercisability of an Award, and accelerations, waivers or amendments thereof; (v) determine whether, to what extent, and under what circumstances an Award may be settled in, or the exercise price of an Award may be paid in cash, Shares, or other property, or an Award may be canceled, forfeited, or surrendered; and (vi) make all other decisions and determinations that may be required pursuant to the Plan or as the Administrator deems necessary or advisable to administer the Plan. Notwithstanding the foregoing, any grants of Awards under the Plan made by the Board must be approved by the majority of the Company's independent directors (as defined in Rule 5605(a)(2) of the Nasdaq Listing Rules) in order to comply with Nasdaq Listing Rule 5635(c)

4.2 Delegation of Authority. Any delegation hereunder shall be subject to the restrictions and limits that the Board specifies at the time of such delegation or that are otherwise included in the applicable organizational documents, and the Board may at any time rescind the authority so delegated. Further, regardless of any delegation, the Board may, in its discretion, exercise any and all rights and duties as the Administrator under the Plan delegated thereby, except with respect to Awards that are required to be determined in the sole discretion of the Committee under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

ARTICLE V.
STOCK AVAILABLE FOR AWARDS

5.1 Number of Shares. Subject to adjustment under Article IX and the terms of this Article V, Awards may be made under the Plan covering up to the Overall Share Limit.

5.2 Share Recycling.

(a) If all or any part of an Award expires, lapses or is terminated, converted into an award in respect of shares of another entity in connection with a spin-off or other similar event, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, in any case, in a manner that results in the Company acquiring Shares covered by the Award at a price not greater than the price (as adjusted to reflect any Equity Restructuring) paid by the Participant for such Shares or not issuing any Shares covered by the Award, the unused Shares covered by the Award will, as applicable, become or again be available for Awards under the Plan. The payment of Dividend Equivalents in cash in conjunction with any outstanding Awards shall not count against the Overall Share Limit.

(b) In addition, Shares subject to a Stock Appreciation Right that are not issued in connection with the stock settlement of the Stock Appreciation Right on exercise thereof shall be available for future grants of Awards.

ARTICLE VI.
STOCK OPTIONS AND STOCK APPRECIATION RIGHTS

6.1 General. The Administrator may grant Options or Stock Appreciation Rights to one or more Employees, subject to such terms and conditions not inconsistent with the Plan as the Administrator shall determine. The Administrator will determine the number of Shares covered by each Option and Stock Appreciation Right, the exercise price of each Option and Stock Appreciation Right and the conditions and limitations applicable to the exercise of each Option and Stock Appreciation Right. A Stock Appreciation Right will entitle the Participant (or other person entitled to exercise the Stock Appreciation Right) to receive from the Company upon exercise of the exercisable portion of the Stock Appreciation Right an amount determined by multiplying the excess, if any, of the Fair Market Value of one Share on the date of exercise over the exercise price per Share of the Stock Appreciation Right by the number of Shares with respect to which the Stock Appreciation Right is exercised, subject to any limitations of the Plan or that the Administrator may impose and payable in cash, Shares valued at Fair Market Value on the date of exercise or a combination of the two as the Administrator may determine or provide in the Award Agreement.

6.2 Exercise Price. The Administrator will establish each Option's and Stock Appreciation Right's exercise price and specify the exercise price in the Award Agreement. Subject to Section 6.6, the exercise price will not be less than 100% of the Fair Market Value on the grant date of the Option or Stock Appreciation Right.

6.3 Duration of Options. Subject to Section 6.6, each Option or Stock Appreciation Right will be exercisable at such times and as specified in the Award Agreement, provided that the term of an Option or Stock Appreciation Right will not exceed ten years; provided, further, that, unless otherwise determined by the Administrator, (a) no portion of an Option or Stock Appreciation Right which is unexercisable at a Participant's Termination of Service shall thereafter become exercisable and (b) the portion of an Option or Stock Appreciation Right that is unexercisable at a Participant's Termination of Service shall automatically expire on the date of such Termination of Service. Notwithstanding the foregoing, if the Participant, prior to the end of the term of an Option or Stock Appreciation Right, commits an act of "cause" (as determined by the Administrator), or violates any non-competition, non-solicitation or confidentiality provisions of any employment contract, confidentiality and nondisclosure agreement or other agreement between the Participant and the Company or any of its Subsidiaries, the right to exercise the Option or Stock Appreciation Right, as applicable, may be terminated by the Company and the Company may suspend the Participant's right to exercise the Option or Stock Appreciation Right when it reasonably believes that the Participant may have participated in any such act or violation.

6.4 Exercise. Options and Stock Appreciation Rights may be exercised by delivering to the Company (or such other person or entity designated by the Administrator) a notice of exercise, in a form and manner the Company approves (which may be written, electronic or telephonic and may contain representations and warranties deemed advisable by the Administrator), signed or authenticated by the person authorized to exercise the Option or Stock Appreciation Right, together with, as applicable, payment in full of (a) the exercise price for the number of Shares for which the Option is exercised in a manner specified in Section 6.5 and (b)

all applicable taxes in a manner specified in Section 10.5. The Administrator may, in its discretion, limit exercise with respect to fractional Shares and require that any partial exercise of an Option or Stock Appreciation Right be with respect to a minimum number of Shares.

6.5 Payment Upon Exercise. The Administrator shall determine the methods by which payment of the exercise price of an Option shall be made, including, without limitation:

(a) cash, check or wire transfer of immediately available funds; provided that the Company may limit the use of one of the foregoing methods if one or more of the methods below is permitted;

(b) if there is a public market for Shares at the time of exercise, unless the Company otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of a notice that the Participant has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise of the Option and that the broker has been directed to deliver promptly to the Company funds sufficient to pay the exercise price, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company an amount sufficient to pay the exercise price by cash, wire transfer of immediately available funds or check; provided that such amount is paid to the Company at such time as may be required by the Company;

(c) to the extent permitted by the Administrator, delivery (either by actual delivery or attestation) of Shares owned by the Participant valued at their Fair Market Value on the date of delivery;

(d) to the extent permitted by the Administrator, surrendering Shares then issuable upon the Option's exercise valued at their Fair Market Value on the exercise date;

(e) to the extent permitted by the Administrator, delivery of a promissory note or any other lawful consideration; or

(f) to the extent permitted by the Administrator, any combination of the above payment forms.

ARTICLE VII.
RESTRICTED STOCK; RESTRICTED STOCK UNITS

7.1 General. The Administrator may grant Restricted Stock, or the right to purchase Restricted Stock, to any Employee, subject to forfeiture or the Company's right to repurchase all or part of such shares at their issue price or other stated or formula price from the Participant if conditions the Administrator specifies in the Award Agreement are not satisfied before the end of the applicable restriction period or periods that the Administrator establishes for such Award. In addition, the Administrator may grant Restricted Stock Units, which may be subject to vesting and forfeiture conditions during the applicable restriction period or periods, as set forth in an Award Agreement, to Employees. The Administrator shall establish the purchase price, if any, and form of payment for Restricted Stock and Restricted Stock Units; provided, however, that if a purchase price is charged, such purchase price shall be no less than the par value, if any, of the

Shares to be purchased, unless otherwise permitted by Applicable Law. In all cases, legal consideration shall be required for each issuance of Restricted Stock and Restricted Stock Units to the extent required by Applicable Law. The Award Agreement for each Restricted Stock and Restricted Stock Unit Award shall set forth the terms and conditions not inconsistent with the Plan as the Administrator shall determine.

7.2 Restricted Stock.

(a) *Stockholder Rights*. Unless otherwise determined by the Administrator, each Participant holding shares of Restricted Stock will be entitled to all the rights of a stockholder with respect to such Shares, subject to the restrictions in the Plan and the applicable Award Agreement, including the right to receive all dividends and other distributions paid or made with respect to the Shares to the extent such dividends and other distributions have a record date that is on or after the date on which such Participant becomes the record holder of such Shares; provided, however, that with respect to a share of Restricted Stock subject to restrictions or vesting conditions as described in Section 8.3, except in connection with a spin-off or other similar event as otherwise permitted under Section 9.2, dividends which are paid to Company stockholders prior to the removal of restrictions and satisfaction of vesting conditions shall only be paid to the Participant to the extent that the restrictions are subsequently removed and the vesting conditions are subsequently satisfied and the share of Restricted Stock vests.

(b) *Stock Certificates*. The Company may require that the Participant deposit in escrow with the Company (or its designee) any stock certificates issued in respect of shares of Restricted Stock, together with a stock power endorsed in blank.

(c) *Section 83(b) Election*. If a Participant makes an election under Section 83(b) of the Code to be taxed with respect to the Restricted Stock as of the date of transfer of the Restricted Stock rather than as of the date or dates upon which such Participant would otherwise be taxable under Section 83(a) of the Code, such Participant shall be required to deliver a copy of such election to the Company promptly after filing such election with the Internal Revenue Service along with proof of the timely filing thereof.

7.3 Restricted Stock Units. The Administrator may provide that settlement of Restricted Stock Units will occur upon or as soon as reasonably practicable after the Restricted Stock Units vest or will instead be deferred, on a mandatory basis or at the Participant's election, subject to compliance with Applicable Law.

ARTICLE VIII.
OTHER TYPES OF AWARDS

8.1 General. The Administrator may grant Performance Stock Unit awards, Performance Bonus Awards, Dividend Equivalents or Other Stock or Cash Based Awards, to one or more Employees, in such amounts and subject to such terms and conditions not inconsistent with the Plan as the Administrator shall determine.

8.2 Performance Stock Unit Awards. Each Performance Stock Unit award shall be denominated in a number of Shares or in unit equivalents of Shares or units of value (including a dollar value of Shares) and may be linked to any one or more of performance or other specific

criteria, including service to the Company or Subsidiaries, determined to be appropriate by the Administrator, in each case on a specified date or dates or over any period or periods determined by the Administrator. In making such determinations, the Administrator may consider (among such other factors as it deems relevant in light of the specific type of award) the contributions, responsibilities and other compensation of the particular Participant.

8.3 Performance Bonus Awards. Each right to receive a bonus granted under this Section 8.3 shall be denominated in the form of cash (but may be payable in cash, stock or a combination thereof) (a "***Performance Bonus Award***") and shall be payable upon the attainment of performance goals that are established by the Administrator and relate to one or more of performance or other specific criteria, including service to the Company or Subsidiaries, in each case on a specified date or dates or over any period or periods determined by the Administrator.

8.4 Dividend Equivalents. If the Administrator provides, an Award (other than an Option or Stock Appreciation Right) may provide a Participant with the right to receive Dividend Equivalents. Dividend Equivalents may, unless otherwise set forth in this Section 8.4, be paid currently or credited to an account for the Participant, settled in cash or Shares and subject to the same restrictions on transferability and forfeitability as the Award with respect to which the Dividend Equivalents are granted and subject to other terms and conditions as set forth in the Award Agreement. Notwithstanding anything to the contrary herein, Dividend Equivalents with respect to an Award subject to vesting shall either (i) to the extent permitted by Applicable Law, not be paid or credited or (ii) be accumulated and subject to vesting to the same extent as the related Award. All such Dividend Equivalents shall be paid at such time as the Administrator shall specify in the applicable Award Agreement.

8.5 Other Stock or Cash Based Awards. Other Stock or Cash Based Awards may be granted to Participants, including Awards entitling Participants to receive cash or Shares to be delivered in the future and annual or other periodic or long-term cash bonus awards (whether based on specified performance criteria or otherwise), in each case subject to any conditions and limitations in the Plan. Such Other Stock or Cash Based Awards will also be available as a payment form in the settlement of other Awards, as standalone payments and as payment in lieu of compensation to which a Participant is otherwise entitled. Other Stock or Cash Based Awards may be paid in Shares, cash or other property, as the Administrator determines. Subject to the provisions of the Plan, the Administrator will determine the terms and conditions of each Other Stock or Cash Based Award, including any purchase price, performance goal(s), transfer restrictions, and vesting conditions, which will be set forth in the applicable Award Agreement. Except in connection with a spin-off or other similar event as otherwise permitted under Article IX, dividends that are paid prior to vesting of any Other Stock or Cash Based Award shall only be paid to the applicable Participant to the extent that the vesting conditions are subsequently satisfied and the Other Stock or Cash Based Award vests.

ARTICLE IX.
ADJUSTMENTS FOR CHANGES IN COMMON STOCK AND CERTAIN OTHER EVENTS

9.1 Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Article IX the Administrator will equitably

adjust the terms of the Plan and each outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include (i) adjusting the number and type of securities subject to each outstanding Award or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article V hereof on the maximum number and kind of shares that may be issued); (ii) adjusting the terms and conditions of (including the grant or exercise price), and the performance goals or other criteria included in, outstanding Awards; and (iii) granting new Awards or making cash payments to Participants. The adjustments provided under this Section 9.1 will be nondiscretionary and final and binding on all interested parties, including the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

9.2 Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, split-up, spin off, combination, amalgamation, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Law or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon the Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company to be made available under the Plan or with respect to any Award granted or issued under the Plan, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Law or accounting principles:

(a) To provide for the cancellation of any such Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights under the vested portion of such Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of such Award or realization of the Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(b) To provide that such Award shall vest and, to the extent applicable, be exercisable as to all Shares (or other property) covered thereby, notwithstanding anything to the contrary in the Plan or the provisions of such Award;

(c) To provide that such Award be assumed by the successor or survivor corporation or entity, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation or entity, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;

(d) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to outstanding Awards or with respect to which Awards may be granted under the Plan (including, but not limited to, adjustments of the limitations in Article V hereof on the maximum number and kind of shares which may be issued) or in the terms and conditions of (including the grant or exercise price), and the criteria included in, outstanding Awards;

(e) To replace such Award with other rights or property selected by the Administrator; or

(f) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

9.3 Change in Control.

(a) Notwithstanding any other provision of the Plan, in the event of a Change in Control, unless the Administrator elects to (i) terminate an Award in exchange for cash, rights or property, or (ii) cause an Award to become fully exercisable and no longer subject to any forfeiture restrictions prior to the consummation of a Change in Control, pursuant to Section 9.2, (A) such Award (other than any portion subject to performance-based vesting) shall continue in effect or be assumed or an equivalent Award substituted by the successor corporation or a parent or subsidiary of the successor corporation and (B) the portion of such Award subject to performance-based vesting shall be subject to the terms and conditions of the applicable Award Agreement and, in the absence of applicable terms and conditions, the Administrator's discretion.

(b) In the event that the successor corporation in a Change in Control refuses to assume or substitute for an Award (other than any portion subject to performance-based vesting, which shall be handled as specified in the individual Award Agreement), the Administrator shall cause such Award to become fully vested and, if applicable, exercisable immediately prior to the consummation of such transaction and all forfeiture restrictions on such Award to lapse and, to the extent unexercised upon the consummation of such transaction, to terminate in exchange for cash, rights or other property. The Administrator shall notify the Participant of any Award that becomes exercisable pursuant to the preceding sentence that such Award shall be fully exercisable for a period of time as determined by the Administrator (which shall be 15 days if no period of time is determined by the Administrator) from the date of such notice, contingent upon the occurrence of the Change in Control, and such Award shall terminate upon the consummation of the Change in Control in accordance with the preceding sentence.

(c) For the purposes of this Section 9.3, an Award shall be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change in Control was not solely common stock of the successor corporation or

its parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Award, for each Share subject to an Award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per-share consideration received by holders of Common Stock in the Change in Control.

9.4 Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock (including any Equity Restructuring or any securities offering or other similar transaction) or for reasons of administrative convenience or to facilitate compliance with any Applicable Law, the Company may refuse to permit the exercise or settlement of one or more Awards for such period of time as the Company may determine to be reasonably appropriate under the circumstances.

9.5 General. Except as expressly provided in the Plan or the Administrator's action under the Plan, no Participant will have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 9.1 above or the Administrator's action under the Plan, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to an Award or the Award's grant or exercise price. The existence of the Plan, any Award Agreements and the Awards granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation, spinoff, dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares.

ARTICLE X.
PROVISIONS APPLICABLE TO AWARDS

10.1 Transferability.

(a) No Award may be sold, assigned, transferred, pledged or otherwise encumbered, either voluntarily or by operation of law, except by will or the laws of descent and distribution, or, subject to the Administrator's consent, pursuant to a domestic relations order, unless and until such Award has been exercised or the Shares underlying such Award have been issued, and all restrictions applicable to such Shares have lapsed. During the life of a Participant, Awards will be exercisable only by the Participant, unless it has been disposed of pursuant to a domestic relations order. After the death of a Participant, any exercisable portion of an Award may, prior to the time when such portion becomes unexercisable under the Plan or the applicable Award Agreement, be exercised by the Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then-Applicable Law of descent and distribution. References to a Participant, to the extent relevant in the context, will include references to a transferee approved by the Administrator.

(b) Notwithstanding Section 10.1(a), the Administrator, in its sole discretion, may determine to permit a Participant or a Permitted Transferee of such Participant to transfer an Award to any one or more Permitted Transferees of such Participant, subject to the following terms and conditions: (i) an Award transferred to a Permitted Transferee shall not be assignable or transferable by the Permitted Transferee other than (A) to another Permitted Transferee of the applicable Participant or (B) by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a domestic relations order; (ii) an Award transferred to a Permitted Transferee shall continue to be subject to all the terms and conditions of the Award as applicable to the original Participant (other than the ability to further transfer the Award to any Person other than another Permitted Transferee of the applicable Participant); (iii) the Participant (or transferring Permitted Transferee) and the receiving Permitted Transferee shall execute any and all documents requested by the Administrator, including, without limitation documents to (A) confirm the status of the transferee as a Permitted Transferee, (B) satisfy any requirements for an exemption for the transfer under Applicable Law and (C) evidence the transfer; and (iv) any transfer of an Award to a Permitted Transferee shall be without consideration, except as required by Applicable Law.

(c) Notwithstanding Section 10.1(a), a Participant may, in the manner determined by the Administrator, designate a Designated Beneficiary. A Designated Beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and any Award Agreement applicable to the Participant and any additional restrictions deemed necessary or appropriate by the Administrator. If the Participant is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Participant's spouse or domestic partner, as applicable, as the Participant's Designated Beneficiary with respect to more than 50% of the Participant's interest in the Award shall not be effective without the prior written or electronic consent of the Participant's spouse or domestic partner. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Participant at any time; provided that the change or revocation is delivered in writing to the Administrator prior to the Participant's death.

10.2 Documentation. Each Award will be evidenced in an Award Agreement in such form as the Administrator determines in its discretion. Each Award may contain such terms and conditions as are determined by the Administrator in its sole discretion, to the extent not inconsistent with those set forth in the Plan.

10.3 Discretion. Except as the Plan otherwise provides, each Award may be made alone or in addition or in relation to any other Award. The terms of each Award to a Participant need not be identical, and the Administrator need not treat Participants or Awards (or portions thereof) uniformly.

10.4 Changes in Participant's Status. The Administrator will determine how the disability, death, retirement, authorized leave of absence or any other change or purported change in a Participant's employment status affects an Award and the extent to which, and the period during which, the Participant, the Participant's legal representative, conservator, guardian or Designated Beneficiary may exercise rights under the Award, if applicable. Except to the extent otherwise required by law or expressly authorized by the Company or by the Company's

written policy on leaves of absence, no Service credit shall be given for vesting purposes for any period the Participant is on a leave of absence.

10.5 Withholding. Each Participant must pay the Company, or make provision satisfactory to the Administrator for payment of, any taxes required by law to be withheld in connection with such Participant's Awards by the date of the event creating the tax liability. The Company may deduct an amount sufficient to satisfy such tax obligations from any payment of any kind otherwise due to a Participant. The amount deducted shall be determined by the Company and may be up to, but no greater than, the aggregate amount of such obligations based on the maximum statutory withholding rates in the applicable Participant's jurisdiction for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income. Subject to any Company insider trading policy (including blackout periods), Participants may satisfy such tax obligations (i) in cash, by wire transfer of immediately available funds, by check made payable to the order of the Company; provided that the Company may limit the use of one of the foregoing methods if one or more of the exercise methods below is permitted, (ii) to the extent permitted by the Administrator, in whole or in part by delivery of Shares, including Shares delivered by attestation and Shares retained from the Award creating the tax obligation, valued at their Fair Market Value on the date of delivery, (iii) if there is a public market for Shares at the time the tax obligations are satisfied, unless the Administrator otherwise determines, (A) delivery (including electronically or telephonically to the extent permitted by the Company) of a notice that the Participant has placed a market sell order with a broker acceptable to the Company with respect to Shares then issuable upon exercise of the Option and that the broker has been directed to deliver promptly to the Company funds sufficient to satisfy the tax obligations, or (B) the Participant's delivery to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company to deliver promptly to the Company an amount sufficient to satisfy the tax withholding by cash, wire transfer of immediately available funds or check; provided that such amount is paid to the Company at such time as may be required by the Company, (iv) to the extent permitted by the Administrator, delivery of a promissory note or any other lawful consideration or (v) to the extent permitted by the Administrator, any combination of the foregoing payment forms. If any tax withholding obligation will be satisfied under clause (ii) of the immediately preceding sentence by the Company's retention of Shares from the Award creating the tax obligation and there is a public market for Shares at the time the tax obligation is satisfied, the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the applicable Participant's behalf some or all of the Shares retained and to remit the proceeds of the sale to the Company or its designee, and each Participant's acceptance of an Award under the Plan will constitute the Participant's authorization to the Company and instruction and authorization to such brokerage firm to complete the transactions described in this sentence.

10.6 Amendment of Award; Repricing. The Administrator may amend, modify or terminate any outstanding Award, including by substituting another Award of the same or a different type, and changing the exercise or settlement date. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Article IX or pursuant to Section 11.6. In addition, the Administrator shall, without the approval of the stockholders of the Company, have the authority to (a) amend any

outstanding Option or Stock Appreciation Right to reduce its exercise price per Share, or (b) cancel any Option or Stock Appreciation Right in exchange for cash or another Award.

10.7 Conditions on Delivery of Stock. The Company will not be obligated to deliver any Shares under the Plan or remove restrictions from Shares previously delivered under the Plan until (i) all Award conditions have been met or removed to the Company's satisfaction, (ii) as determined by the Company, all other legal matters regarding the issuance and delivery of such Shares have been satisfied, including any applicable securities laws and stock exchange or stock market rules and regulations, and (iii) the Participant has executed and delivered to the Company such representations or agreements as the Administrator deems necessary or appropriate to satisfy Applicable Law. The Company's inability to obtain authority from any regulatory body having jurisdiction, which the Administrator determines is necessary to the lawful issuance and sale of any securities, will relieve the Company of any liability for failing to issue or sell such Shares as to which such requisite authority has not been obtained.

10.8 Acceleration. The Administrator may at any time provide that any Award will become immediately vested and fully or partially exercisable, free of some or all restrictions or conditions, or otherwise fully or partially realizable.

ARTICLE XI.
MISCELLANEOUS

11.1 No Right to Employment or Other Status. No person will have any claim or right to be granted an Award, and the grant of an Award will not be construed as giving a Participant the right to continue employment or any other relationship with the Company. The Company expressly reserves the right at any time to dismiss or otherwise terminate its relationship with a Participant free from any liability or claim under the Plan or any Award, except as expressly provided in an Award Agreement or other written agreement between the Participant and the Company or any Subsidiary.

11.2 No Rights as Stockholder; Certificates. Subject to the Award Agreement, no Participant or Designated Beneficiary will have any rights as a stockholder with respect to any Shares to be distributed under an Award until becoming the record holder of such Shares. Notwithstanding any other provision of the Plan, unless the Administrator otherwise determines or Applicable Law requires, the Company will not be required to deliver to any Participant certificates evidencing Shares issued in connection with any Award and instead such Shares may be recorded in the books of the Company (or, as applicable, its transfer agent or stock plan administrator). The Company may place legends on any share certificate or book entry to reference restrictions applicable to the Shares (including, without limitation, restrictions applicable to Restricted Stock).

11.3 Effective Date. The Plan will become effective on the date of approval of the Plan by the Board (the "***Effective Date***").

11.4 Amendment of Plan. The Board may amend, suspend or terminate the Plan at any time and from time to time; provided that (a) no amendment requiring stockholder approval to comply with Applicable Law shall be effective unless approved by the Board, and (b) no

amendment, other than an increase to the Overall Share Limit or pursuant to Article IX or Section 11.6, may materially and adversely affect any Award outstanding at the time of such amendment without the affected Participant's consent. No Awards may be granted under the Plan during any suspension period or after Plan termination. Awards outstanding at the time of any Plan suspension or termination will continue to be governed by the Plan and the Award Agreement, as in effect before such suspension or termination. The Board will obtain stockholder approval of any Plan amendment to the extent necessary to comply with Applicable Law.

11.5 Provisions for Foreign Participants. The Administrator may modify Awards granted to Participants who are foreign nationals or employed outside the United States, establish subplans or procedures under the Plan or take any other necessary or appropriate action to address Applicable Law, including (a) differences in laws, rules, regulations or customs of such foreign jurisdictions with respect to tax, securities, currency, employee benefit or other matters, (b) listing and other requirements of any foreign securities exchange, and (c) any necessary local governmental or regulatory exemptions or approvals.

11.6 Section 409A.

(a) *General*. The Company intends that all Awards be structured to comply with, or be exempt from, Section 409A, such that no adverse tax consequences, interest, or penalties under Section 409A apply. Notwithstanding anything in the Plan or any Award Agreement to the contrary, the Administrator may, without a Participant's consent, amend this Plan or Awards, adopt policies and procedures, or take any other actions (including amendments, policies, procedures and retroactive actions) as are necessary or appropriate to preserve the intended tax treatment of Awards, including any such actions intended to (A) exempt this Plan or any Award from Section 409A, or (B) comply with Section 409A, including regulations, guidance, compliance programs and other interpretative authority that may be issued after an Award's grant date. The Company makes no representations or warranties as to an Award's tax treatment under Section 409A or otherwise. The Company will have no obligation under this Section 11.6 or otherwise to avoid the taxes, penalties or interest under Section 409A with respect to any Award and will have no liability to any Participant or any other person if any Award, compensation or other benefits under the Plan are determined to constitute noncompliant "nonqualified deferred compensation" subject to taxes, penalties or interest under Section 409A.

(b) *Separation from Service*. If an Award constitutes "nonqualified deferred compensation" under Section 409A, any payment or settlement of such Award upon a Participant's Termination of Service will, to the extent necessary to avoid taxes under Section 409A, be made only upon the Participant's "separation from service" (within the meaning of Section 409A), whether such "separation from service" occurs upon or after the Participant's Termination of Service. For purposes of this Plan or any Award Agreement relating to any such payments or benefits, references to a "termination," "termination of employment" or like terms means a "separation from service."

(c) *Payments to Specified Employees*. Notwithstanding any contrary provision in the Plan or any Award Agreement, any payment(s) of "nonqualified deferred compensation" required to be made under an Award to a "specified employee" (as defined under

Section 409A and as the Administrator determines) due to his or her "separation from service" will, to the extent necessary to avoid taxes under Section 409A(a)(2)(B)(i) of the Code, be delayed for the six-month period immediately following such "separation from service" (or, if earlier, until the specified employee's death) and will instead be paid (as set forth in the Award Agreement) on the day immediately following such six-month period or as soon as administratively practicable thereafter (without interest). Any payments of "nonqualified deferred compensation" under such Award payable more than six months following the Participant's "separation from service" will be paid at the time or times the payments are otherwise scheduled to be made.

11.7 Limitations on Liability. Notwithstanding any other provisions of the Plan, no individual acting as a director, officer or other employee of the Company or any Subsidiary will be liable to any Participant, former Participant, spouse, beneficiary, or any other person for any claim, loss, liability, or expense incurred in connection with the Plan or any Award, and such individual will not be personally liable with respect to the Plan because of any contract or other instrument executed in his or her capacity as an Administrator, director, officer or other employee of the Company or any Subsidiary. The Company will indemnify and hold harmless each director, officer or other employee of the Company or any Subsidiary that has been or will be granted or delegated any duty or power relating to the Plan's administration or interpretation, against any cost or expense (including attorneys' fees) or liability (including any sum paid in settlement of a claim with the Administrator's approval) arising from any act or omission concerning this Plan unless arising from such person's own fraud or bad faith; provided that he or she gives the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf.

11.8 Data Privacy. As a condition for receiving any Award, each Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this Section by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing the Participant's participation in the Plan. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer the Plan and Awards (the "***Data***"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage a Participant's participation in the Plan, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with Plan implementation, administration and management. These recipients may be located in the Participant's country, or elsewhere, and the Participant's country may have different data privacy laws and protections than the recipients' country. By accepting an Award, each Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage the Participant's participation in the Plan, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to a Participant will be held only as long as necessary to implement, administer, and manage the Participant's participation in the Plan. A Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the

Data regarding such Participant, recommend any necessary corrections to the Data regarding the Participant or refuse or withdraw the consents in this Section 11.8 in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Plan and, in the Administrator's sole discretion, the Participant may forfeit any outstanding Awards if the Participant refuses or withdraws the consents in this Section 11.8. For more information on the consequences of refusing or withdrawing consent, Participants may contact their local human resources representative.

11.9 Severability. If any portion of the Plan or any action taken under it is held illegal or invalid for any reason, the illegality or invalidity will not affect the remaining parts of the Plan, and the Plan will be construed and enforced as if the illegal or invalid provisions had been excluded, and the illegal or invalid action will be null and void.

11.10 Governing Documents. If any contradiction occurs between the Plan and any Award Agreement or other written agreement between a Participant and the Company (or any Subsidiary), the Plan will govern, unless such Award Agreement or other written agreement was approved by the Administrator and expressly provides that a specific provision of the Plan will not apply.

11.11 Governing Law. The Plan and all Awards will be governed by and interpreted in accordance with the laws of the State of Delaware, without regard to the conflict of law rules thereof or of any other jurisdiction.

11.12 Clawback Provisions. All Awards (including the gross amount of any proceeds, gains or other economic benefit the Participant actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to recoupment by the Company to the extent required to comply with Applicable Law or any policy of the Company providing for the reimbursement of incentive compensation, whether or not such policy was in place at the time of grant of an Award.

11.13 Titles and Headings. The titles and headings in the Plan are for convenience of reference only and, if any conflict, the Plan's text, rather than such titles or headings, will control.

11.14 Conformity to Applicable Law. Participant acknowledges that the Plan is intended to conform to the extent necessary with Applicable Law. Notwithstanding anything herein to the contrary, the Plan and all Awards will be administered only in a manner intended to conform with Applicable Law. To the extent Applicable Law permit, the Plan and all Award Agreements will be deemed amended as necessary to conform to Applicable Law.

11.15 Relationship to Other Benefits. No payment under the Plan will be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or other benefit plan of the Company or any Subsidiary, except as expressly provided in writing in such other plan or an agreement thereunder.

11.16 Unfunded Status of Awards. The Plan is intended to be an "unfunded" plan for incentive compensation. With respect to any payments not yet made to a Participant pursuant to

an Award, nothing contained in the Plan or Award Agreement shall give the Participant any rights that are greater than those of a general creditor of the Company or any Subsidiary.

11.17 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

11.18 Prohibition on Executive Officer and Director Loans. Notwithstanding any other provision of the Plan to the contrary, no Participant who is a Director or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

11.19 Broker-Assisted Sales. In the event of a broker-assisted sale of Shares in connection with the payment of amounts owed by a Participant under or with respect to the Plan or Awards, including amounts to be paid under the final sentence of Section 10.5: (a) any Shares to be sold through the broker-assisted sale will be sold on the day the payment first becomes due, or as soon thereafter as practicable; (b) such Shares may be sold as part of a block trade with other Participants in the Plan in which all participants receive an average price; (c) the applicable Participant will be responsible for all broker's fees and other costs of sale, and by accepting an Award, each Participant agrees to indemnify and hold the Company harmless from any losses, costs, damages, or expenses relating to any such sale; (d) to the extent the Company or its designee receives proceeds of such sale that exceed the amount owed, the Company will pay such excess in cash to the applicable Participant as soon as reasonably practicable; (e) the Company and its designees are under no obligation to arrange for such sale at any particular price; and (f) in the event the proceeds of such sale are insufficient to satisfy the Participant's applicable obligation, the Participant may be required to pay immediately upon demand to the Company or its designee an amount in cash sufficient to satisfy any remaining portion of the Participant's obligation.

* * * * *

ELICIO THERAPEUTICS, INC.

2024 INDUCEMENT INCENTIVE AWARD PLAN
STOCK OPTION GRANT NOTICE

Elicio Therapeutics, Inc., a Delaware corporation, (the "Company"), pursuant to its 2024 Inducement Incentive Award Plan, as may be amended from time to time (the "Plan"), hereby grants to the holder listed below ("Participant"), an option to purchase the number of shares of the Company's Common Stock (the "Shares"), set forth below (the "Option"). The Company and Participant understand and agree that the Option shall be granted in compliance with Nasdaq Listing Rule 5635(c)(4) as a material inducement to the Participant entering into employment with the Company. This Option is subject to all of the terms and conditions set forth herein, as well as in the Plan and the Stock Option Agreement attached hereto as Exhibit A (the "Stock Option Agreement"), each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Grant Notice and the Stock Option Agreement.

Participant:

Grant Date:

Vesting Commencement Date:

Exercise Price per Share: $

Total Exercise Price: $

Total Number of Shares Subject to the Option:

Expiration Date:

Vesting Schedule:

Type of Option: Non-Qualified Stock Option

By his or her signature and the Company's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Stock Option Agreement, and this Grant Notice. Participant has reviewed the Stock Option Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Stock Option Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Stock Option Agreement.

ELICIO THERAPEUTICS, INC.:		**PARTICIPANT:**
By:		By:
Print Name:	Robert Connelly	Print Name:
Title:	Chief Executive Officer	Title:
Address:	c/o Elicio Therapeutics, Inc. 451 D Street, 5th Floor Boston, MA 02210	Address:

EXHIBIT A
TO STOCK OPTION GRANT NOTICE
STOCK OPTION AGREEMENT

(Non-Qualified Stock Option)

Pursuant to the Stock Option Grant Notice (the "Grant Notice") to which this Stock Option Agreement (this "Agreement") is attached, Elicio Therapeutics, Inc., a Delaware corporation (the "Company"), has granted to Participant an Option under the Company's 2024 Inducement Incentive Award Plan, as may be amended from time to time (the "Plan"), to purchase the number of Shares indicated in the Grant Notice.

ARTICLE 1.
GENERAL

1.1 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions of the Plan which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.
GRANT OF OPTION

2.1 Grant of Option. In consideration of Participant's past and/or continued employment with or service to the Company or any Subsidiary and for other good and valuable consideration, effective as of the Grant Date set forth in the Grant Notice (the "Grant Date"), the Company irrevocably grants to Participant the Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement, subject to adjustments as provided in Article IX of the Plan.

2.2 Exercise Price. The exercise price of the Shares subject to the Option shall be as set forth in the Grant Notice, without commission or other charge; *provided*, *however*, that the price per share of the Shares subject to the Option shall not be less than 100% of the Fair Market Value of a Share on the Grant Date.

2.3 Consideration to the Company. In consideration of the grant of the Option by the Company, Participant agrees to render faithful and efficient services to the Company or any Subsidiary. Nothing in the Plan or this Agreement shall confer upon Participant any right to continue in the employ or service of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

ARTICLE 3.
PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to Sections 3.2, 3.3, 5.11 and 5.16 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) No portion of the Option which has not become vested and exercisable at the date of Participant's Termination of Service shall thereafter become vested and exercisable, except as may be otherwise provided by the Administrator or as set forth in a written agreement between the Company and Participant.

(c) Notwithstanding Section 3.1(a) hereof and the Grant Notice, but subject to Section 3.1(b) hereof, in the event of a Change in Control the Option shall be treated pursuant to Sections 9.2 and 9.3 of the Plan.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice, which shall in no event be more than ten (10) years from the Grant Date;

(b) The expiration of three (3) months from the date of Participant's Termination of Service, unless such termination occurs by reason of Participant's death or Disability; or

(c) The expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or Disability.

3.4 Tax Indemnity.

(a) Participant agrees to indemnify and keep indemnified the Company, any Subsidiary and Participant's employing company, if different, from and against any liability for or obligation to pay any Tax Liability (a "Tax Liability" being any liability for income tax, withholding tax and any other employment related taxes or social security contributions in any jurisdiction) that is attributable to (1) the grant or exercise of, or any benefit derived by Participant from, the Option, (2) the acquisition by Participant of the Shares on exercise of the Option or (3) the disposal of any Shares.

(b) The Option cannot be exercised until Participant has made such arrangements as the Company may require for the satisfaction of any Tax Liability that may arise in connection with the exercise of the Option and/or the acquisition of the Shares by Participant.

The Company shall not be required to issue, allot or transfer Shares until Participant has satisfied this obligation.

(c) Participant hereby acknowledges that the Company (i) makes no representations or undertakings regarding the treatment of any Tax Liabilities in connection with any aspect of the Option and (ii) does not commit to and is under no obligation to structure the terms of the grant or any aspect of any Award, including the Option, to reduce or eliminate Participant's liability for Tax Liabilities or achieve any particular tax result. Furthermore, if Participant becomes subject to tax in more than one jurisdiction between the date of grant of an Award, including the Option, and the date of any relevant taxable event, Participant acknowledges that the Company may be required to withhold or account for Tax Liabilities in more than one jurisdiction.

ARTICLE 4.
EXERCISE OF OPTION

4.1 Person Eligible to Exercise. Except as provided in Section 5.3 hereof, during the lifetime of Participant, only Participant may exercise the Option or any portion thereof, unless it has been disposed of pursuant to a DRO. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by the deceased Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then applicable laws of descent and distribution.

4.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof. However, the Option shall not be exercisable with respect to fractional Shares.

4.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company; for the avoidance of doubt, delivery shall include electronic delivery), during regular business hours, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof:

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator. The notice shall be signed by Participant or other person then entitled to exercise the Option or such portion of the Option;

(b) The receipt by the Company of full payment for the Shares with respect to which the Option or portion thereof is exercised, including payment of any applicable withholding tax, which shall be made by deduction from other compensation payable to Participant or in such other form of consideration permitted under Section 4.4 hereof that is acceptable to the Company;

(c) Any other written representations or documents as may be required in the Administrator's sole discretion to evidence compliance with the Securities Act, the Exchange Act or any other applicable law, rule or regulation; and

(d) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Company shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

4.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of Shares (including, without limitation, Shares otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof; or

(c) Other legal consideration acceptable to the Administrator (including, without limitation, through the delivery of a notice that Participant has placed a market sell order with a broker with respect to Shares then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale).

4.5 Conditions to Issuance of Shares. The Shares deliverable upon the exercise of the Option, or any portion thereof, may be either previously authorized but unissued Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any Shares purchased upon the exercise of the Option or portion thereof prior to fulfillment of all of the conditions in Section 10.7 of the Plan and following conditions:

(a) The admission of such Shares to listing on all stock exchanges on which such Shares are then listed;

(b) The completion of any registration or other qualification of such Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or of any other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state or federal governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable;

(d) The receipt by the Company of full payment for such Shares, including payment of any applicable withholding tax, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Administrator may from time to time establish for reasons of administrative convenience.

4.6 Rights as Stockholder. The holder of the Option shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any Shares purchasable upon the exercise of any part of the Option unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE 5.
OTHER PROVISIONS

5.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Committee or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the Option.

5.2 Whole Shares. The Option may only be exercised for whole Shares.

5.3 Option Not Transferable.

(a) Subject to Section 4.1 hereof, the Option may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until the Option has been exercised and the Shares underlying the Option have been issued, and all restrictions applicable to such Shares have lapsed. Neither the Option nor any interest or right therein shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until the Option has been exercised, and any attempted disposition thereof prior to exercise shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

(b) During the lifetime of Participant, only Participant may exercise the Option (or any portion thereof), unless it has been disposed of pursuant to a DRO; after the death of Participant, any exercisable portion of the Option may, prior to the time when such portion becomes unexercisable under the Plan or this Agreement, be exercised by Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then-applicable laws of descent and distribution.

(c) Notwithstanding any other provision in this Agreement, Participant may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of Participant and to receive any distribution with respect to the Option upon Participant's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and this Agreement, except to the extent the Plan and this Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If Participant is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than Participant's spouse or domestic partner, as applicable, as his or her beneficiary with respect to more than 50% of Participant's interest in the Option shall not be effective without the prior written consent of Participant's spouse or domestic partner. If no beneficiary has been designated or survives Participant, payment shall be made to the person entitled thereto pursuant to Participant's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by Participant at any time provided the change or revocation is filed with the Administrator prior to Participant's death.

5.4 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences as a result of the grant, vesting and/or exercise of the Option, and/or with the purchase or disposition of the Shares subject to the Option. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of such Shares and that Participant is not relying on the Company for any tax advice.

5.5 Binding Agreement. Subject to the limitation on the transferability of the Option contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the Option in such circumstances as it, in its sole discretion, may determine. In addition, upon the occurrence of certain events relating to the Shares contemplated by Article IX of the Plan (including, without limitation, an extraordinary cash dividend on such Shares), the Administrator shall make such adjustments the Administrator deems appropriate in the number of Shares subject to the Option, the exercise price of the Option and the kind of securities that may be issued upon exercise of the Option. Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

5.7 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the

Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.7, either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to Participant shall, if Participant is then deceased, be given to the person entitled to exercise his or her Option pursuant to Section 4.1 hereof by written notice under this Section 5.7. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

5.10 Conformity to Securities Laws. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all Applicable Law and regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to such Applicable Law. To the extent permitted by applicable law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

5.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of Participant.

5.12 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 5.3 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

5.13 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Option and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.14 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an employee or other service provider of the Company or any of its Subsidiaries or interfere with or restrict in any way with the right of the Company or any of its Subsidiaries, which rights are hereby expressly reserved, to discharge or to terminate for any reason whatsoever, with or without cause, the services of Participant's at any time.

5.15 Entire Agreement. The Plan, the Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

5.16 Section 409A. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the Option (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate either for the Option to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.17 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to options, as and when exercised pursuant to the terms hereof.

* * * * *

ELICIO THERAPEUTICS, INC.
STOCK OPTION GRANT NOTICE

Elicio Therapeutics, Inc., a Delaware corporation, (the "Company"), pursuant to the terms of this Stock Option Grant Notice (the "Grant Notice") and the Stock Option Agreement attached hereto (the "Agreement"), hereby grants to the holder listed below ("Participant"), an option to purchase the number of shares of the Company's Common Stock (the "Shares"), set forth below (the "Option").

Participant:

Grant Date:

Vesting Commencement Date:

Exercise Price per Share: **$**

Total Exercise Price: **$**

Total Number of Shares Subject to the Option:

Expiration Date:

Vesting Schedule:

Type of Option: **Nonqualified Stock Option**

By Participant's signature and the Company's signature below, Participant agrees to be bound by the terms and conditions of this Grant Notice and the Agreement. Participant has reviewed the Agreement and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice and the Agreement. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under this Grant Notice or the Agreement.

ELICIO THERAPEUTICS, INC.:

By: _____
Print Name: Robert Connelly
Title: Chief Executive Officer
Address: c/o Elicio Therapeutics, Inc.
451 D Street, 5th Floor
Boston, MA 02210

PARTICIPANT:

By: _____
Print Name:
Title:
Address:

ELICIO THERAPEUTICS, INC.
STOCK OPTION AGREEMENT

Pursuant to the Stock Option Grant Notice (the "Grant Notice") to which this Stock Option Agreement (this "Agreement") is attached, Elicio Therapeutics, Inc., a Delaware corporation (the "Company"), has granted to Participant an Option as an inducement material to Participant's entering into employment as [TITLE], to purchase the number of Shares indicated in the Grant Notice.

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following words and phrases have the meanings specified below, unless the context clearly indicates otherwise:

1.1 "***Administrator***" means the Board or a Committee to the extent that the Board's powers or authority under this Agreement have been delegated to such Committee. With reference to the Board's or a Committee's powers or authority under the Agreement that have been delegated to one or more officers pursuant to Section 5.1, the term "Administrator" shall refer to such officer(s) unless and until such delegation has been revoked.

1.2 "***Applicable Law***" means any applicable law, including without limitation: (a) provisions of the Code, the Securities Act, the Exchange Act and any rules or regulations thereunder; (b) corporate, securities, tax or other laws, statutes, rules, requirements or regulations, whether federal, state, local or foreign; and (c) rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

1.3 "***Award***" means the Option granted to Participant under this Agreement.

1.4 "***Board***" means the Board of Directors of the Company.

1.5 "***Change in Control***" means any of the following:

(a) A transaction or series of transactions (other than an offering of Common Stock to the general public through a registration statement filed with the Securities and Exchange Commission) whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) directly or indirectly acquires beneficial ownership (within the meaning of Rules 13d-3 and 13d-5 under the Exchange Act) of the Company's securities possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; provided, however, that the following acquisitions shall not constitute a Change in Control: (i) any acquisition by the Company or any of its Subsidiaries; (ii) any acquisition by an employee benefit plan maintained by the Company or any of its Subsidiaries, (iii) any acquisition which complies with Sections 1.5(c)(i), 2.6(c)(ii) and 2.6(c)(iii); or (iv) in respect of an Award held by a particular Participant, any acquisition by Participant or any group of persons including Participant (or any entity controlled by Participant or any group of persons including Participant);

(b) The Incumbent Directors cease for any reason to constitute a majority of the Board;

(c) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination, (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction:

(i) which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the

Company (the Company or such person, the "***Successor Entity***")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction;

(ii) after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this Section 1.5(c)(ii) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction; and

(iii) after which at least a majority of the members of the board of directors (or the analogous governing body) of the Successor Entity were Board members at the time of the Board's approval of the execution of the initial agreement providing for such transaction; or

(d) The completion of a liquidation or dissolution of the Company.

Notwithstanding the foregoing, if a Change in Control constitutes a payment event with respect to the Award (or any portion of the Award) that provides for the deferral of compensation that is subject to Section 409A, to the extent required to avoid the imposition of additional taxes under Section 409A, the transaction or event described in subsection (a), (b), (c) or (d) of this Section with respect to the Award (or portion thereof) shall only constitute a Change in Control for purposes of the payment timing of the Award if such transaction also constitutes a "change in control event," as defined in Treasury Regulation Section 1.409A-3(i)(5).

The Administrator shall have full and final authority, which shall be exercised in its sole discretion, to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of such Change in Control and any incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change in Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.

1.6 "***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and all regulations, guidance, compliance programs and other interpretative authority issued thereunder.

1.7 "***Committee***" means one or more committees or subcommittees of the Board, which may include one or more Company directors or executive officers, to the extent permitted by Applicable Law. To the extent required to comply with the provisions of Rule 16b-3, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to the Award that is subject to Rule 16b-3, a "non-employee director" within the meaning of Rule 16b-3; however, a Committee member's failure to qualify as a "non-employee director" within the meaning of Rule 16b-3 will not invalidate any Award granted by the Committee that is otherwise validly granted under this Agreement.

1.8 "***Common Stock***" means the common stock of the Company.

1.9 "***Company***" means Elicio Therapeutics, Inc., a Delaware corporation, or any successor.

1.10 "***Director***" means a Board member.

1.11 "***Disability***" means a permanent and total disability under Section 22(e)(3) of the Code.

1.12 "***DRO***" means a "domestic relations order" as defined by the Code or Title I of the Employee Retirement Income Security Act of 1974, as amended, or the rules thereunder.

1.13 "***Equity Restructuring***" means a nonreciprocal transaction between the Company and its stockholders, such as a stock dividend, stock split (including a reverse stock split), spin-off or recapitalization through a large, nonrecurring cash dividend, that affects the number or kind of Shares (or other Company securities) or the share price of Common Stock (or other Company securities) and causes a change in the per share value of the Common Stock underlying outstanding Award.

1.14 "***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended, and all regulations, guidance and other interpretative authority issued thereunder.

1.15 "***Fair Market Value***" means, as of any date, the value of a Share determined as follows: (i) if the Common Stock is listed on any established stock exchange, the value of a Share will be the closing sales price for a Share as quoted on such exchange for such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in *The Wall Street Journal* or another source the Administrator deems reliable; (ii) if the Common Stock is not listed on an established stock exchange but is quoted on a national market or other quotation system, the value of a Share will be the closing sales price for a Share on such date, or if no sales occurred on such date, then on the last date preceding such date during which a sale occurred, as reported in The Wall Street Journal or another source the Administrator deems reliable; or (iii) if the Common Stock is not listed on any established stock exchange or quoted on a national market or other quotation system, the value established by the Administrator in its sole discretion.

1.16 "***Incentive Stock Option***" means an Option that meets the requirements to qualify as an "incentive stock option" as defined in Section 422 of the Code.

1.17 "***Incumbent Directors"*** means, for any period of 12 consecutive months, individuals who, at the beginning of such period, constitute the Board together with any new Director(s) (other than a Director designated by a person who shall have entered into an agreement with the Company to effect a transaction described in Section 1.5(a) or 1.5(c)) whose election or nomination for election to the Board was approved by a vote of at least a majority (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for Director without objection to such nomination) of the Directors then still in office who either were Directors at the beginning of the 12-month period or whose election or nomination for election was previously so approved. No individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to Directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any person other than the Board shall be an Incumbent Director.

1.18 "***Nonqualified Stock Option***" means an Option that is not an Incentive Stock Option.

1.19 "***Option***" means a Nonqualified Stock Option granted as an inducement award under Nasdaq Listing Rule 5635(c)(4).

1.20 "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act.

1.21 "***Section 409A***" means Section 409A of the Code.

1.22 "***Shares***" means shares of Common Stock.

1.23 "***Subsidiary***" means any entity (other than the Company), whether domestic or foreign, in an unbroken chain of entities beginning with the Company if each of the entities other than the last entity in the unbroken chain beneficially owns, at the time of the determination, securities or interests representing at least 50% of the total combined voting power of all classes of securities or interests in one of the other entities in such chain.

1.24 "***Termination of Service***" means the time when the employee-employer relationship between Participant and the Company or any Subsidiary is terminated for any reason, including, without limitation, a termination by resignation, discharge, death, disability or retirement; but excluding terminations where Participant simultaneously commences or remains in employment or service with the Company or any Subsidiary. The Company, in its sole discretion, shall determine the effect of all matters and questions relating to any Termination of Service, including, without limitation, whether a Termination of Service has occurred, whether a Termination of Service resulted from a discharge for "cause" and all questions of whether particular leaves of absence constitute a Termination of Service. For purposes of this Agreement, Participant's employee-employer relationship shall be deemed to be terminated in the event that the Subsidiary employing or contracting with Participant ceases to remain a Subsidiary following any merger, sale of stock or other corporate transaction or event (including, without limitation, a spin-off), even though Participant may subsequently continue to perform services for that entity.

ARTICLE 2
GRANT OF OPTION

2.1 Grant of Option. As an inducement material to Participant's entering into employment as [TITLE] of the Company, effective as of the Grant Date set forth in the Grant Notice (the "Grant Date"), the Company irrevocably grants to Participant the Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice, upon the terms and conditions set forth in this Agreement, subject to adjustments as provided in Section 5.6 hereof.

2.2 Exercise Price. The exercise price of the Shares subject to the Option shall be as set forth in the Grant Notice, without commission or other charge; *provided*, *however*, that the price per share of the Shares subject to the Option shall not be less than 100% of the Fair Market Value of a Share on the Grant Date.

2.3 Consideration to the Company. In consideration of the grant of the Option by the Company, Participant agrees to render faithful and efficient services to the Company or any Subsidiary. Nothing in this Agreement shall confer upon Participant any right to continue in the employ or service of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

ARTICLE 3
PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to Sections 3.2, 3.3, 5.11 and 5.17 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) No portion of the Option which has not become vested and exercisable at the date of Participant's Termination of Service shall thereafter become vested and exercisable, except as may be otherwise provided by the Administrator or as set forth in a written agreement between the Company and Participant; provided that if Participant's Termination of Service without cause (or a material diminishment of Participant's role) occurs within three months prior to or 12 months following a Change of Control, any unvested portion of the Option shall immediately become vested and exercisable in full.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice, which shall in no event be more than ten (10) years from the Grant Date;

(b) The expiration of three (3) months from the date of Participant's Termination of Service, unless such termination occurs by reason of Participant's death or Disability; or

(c) The expiration of one (1) year from the date of Participant's Termination of Service by reason of Participant's death or Disability.

3.4 Tax Indemnity.

(a) Participant agrees to indemnify and keep indemnified the Company, any Subsidiary and Participant's employing company, if different, from and against any liability for or obligation to pay any Tax Liability (a "Tax Liability" being any liability for income tax, withholding tax and any other employment related taxes or social security contributions in any jurisdiction) that is attributable to (1) the grant or exercise of, or any benefit derived by Participant from, the Option, (2) the acquisition by Participant of the Shares on exercise of the Option or (3) the disposal of any Shares.

(b) The Option cannot be exercised until Participant has made such arrangements as the Company may require for the satisfaction of any Tax Liability that may arise in connection with the exercise of the Option and/or the acquisition of the Shares by Participant. The Company shall not be required to issue, allot or transfer Shares until Participant has satisfied this obligation.

(c) Participant hereby acknowledges that the Company (i) makes no representations or undertakings regarding the treatment of any Tax Liabilities in connection with any aspect of the Option and (ii) does not commit to and is under no obligation to structure the terms of the grant or any aspect of any Award, including the Option, to reduce or eliminate Participant's liability for Tax Liabilities or achieve any particular tax result. Furthermore, if Participant becomes subject to tax in more than one jurisdiction between the date of grant of the Option and the date of any relevant taxable event, Participant acknowledges that the Company may be required to withhold or account for Tax Liabilities in more than one jurisdiction.

ARTICLE 4
EXERCISE OF OPTION

4.1 Person Eligible to Exercise. Except as provided in Section 5.3 hereof, during the lifetime of Participant, only Participant may exercise the Option or any portion thereof, unless it has been disposed of pursuant to a DRO. After the death of Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by the deceased Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then applicable laws of descent and distribution.

4.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof. However, the Option shall not be exercisable with respect to fractional Shares.

4.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company; for the avoidance of doubt, delivery shall include electronic delivery), during regular business hours, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof:

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator. The notice shall be signed by Participant or other person then entitled to exercise the Option or such portion of the Option;

(b) The receipt by the Company of full payment for the Shares with respect to which the Option or portion thereof is exercised, including payment of any applicable withholding tax, which shall be made by deduction from other compensation payable to Participant or in such other form of consideration permitted under Section 4.4 hereof that is acceptable to the Company;

(c) Any other written representations or documents as may be required in the Administrator's sole discretion to evidence compliance with the Securities Act, the Exchange Act or any other applicable law, rule or regulation; and

(d) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Company shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

4.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of Shares (including, without limitation, Shares otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof; or

(c) Other legal consideration acceptable to the Administrator (including, without limitation, through the delivery of a notice that Participant has placed a market sell order with a broker with respect to Shares then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale).

4.5 Conditions to Issuance of Shares. The Shares deliverable upon the exercise of the Option, or any portion thereof, may be either previously authorized but unissued Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any Shares purchased upon the exercise of the Option or portion thereof prior to fulfillment of the following conditions:

(a) The admission of such Shares to listing on all stock exchanges on which such Shares are then listed;

(b) The completion of any registration or other qualification of such Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or of any other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state or federal governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable;

(d) The receipt by the Company of full payment for such Shares, including payment of any applicable withholding tax, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Administrator may from time to time establish for reasons of administrative convenience.

4.6 Rights as Stockholder. The holder of the Option shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any Shares purchasable upon the exercise of any part of the Option unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 5.6 hereof.

ARTICLE 5
OTHER PROVISIONS

5.1 Administration.

(a) The Administrator shall have the power to interpret this Agreement and to adopt such rules for the administration, interpretation and application of this Agreement as consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons. No member of the Committee or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to this Agreement or the Option.

(b) To the extent permitted by Applicable Law, the Board or any Committee may delegate any or all of its powers under the Agreement to one or more Committees or officers of the Company or any of its Subsidiaries; provided, however, that in no event shall an officer of the Company or any of its Subsidiaries be delegated the authority to grant Awards to, or amend Awards held by, the following individuals: (a) individuals who are subject to Section 16 of the Exchange Act, or (b) officers of the Company or any of its Subsidiaries or Directors to whom authority to grant or amend Awards has been delegated hereunder. Any delegation hereunder shall be subject to the restrictions and limits that the Board or Committee specifies at the time of such delegation or that are otherwise included in the applicable organizational documents, and the Board or Committee, as applicable, may at any time rescind the authority so delegated or appoint a new delegatee. At all times, the delegatee appointed under this Section 5.1 shall serve in such capacity at the pleasure of the Board or the Committee, as applicable, and the Board or the Committee may abolish any committee at any time and re-vest in itself any previously delegated authority. Further, regardless of any delegation, the Board or a Committee may, in its discretion, exercise any and all rights and duties as the Administrator under the Agreement delegated thereby, except with respect to Awards that are required to be determined in the sole discretion of the Committee under the rules of any securities exchange or automated quotation system on which the Shares are listed, quoted or traded.

5.2 Whole Shares. The Option may only be exercised for whole Shares.

5.3 Option Not Transferable.

(a) Subject to Section 4.1 hereof, the Option may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until the Option has been exercised and the Shares underlying the Option have been issued, and all restrictions applicable to such Shares have lapsed. Neither the Option nor any interest or right therein shall be liable for the debts, contracts or engagements of Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until the Option has been exercised, and any attempted disposition thereof prior to exercise shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

(b) During the lifetime of Participant, only Participant may exercise the Option (or any portion thereof), unless it has been disposed of pursuant to a DRO; after the death of Participant, any exercisable portion of the Option may, prior to the time when such portion becomes unexercisable under this Agreement, be exercised by Participant's personal representative or by any person empowered to do so under the deceased Participant's will or under the then-applicable laws of descent and distribution.

(c) Notwithstanding any other provision in this Agreement, Participant may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of Participant and to receive any distribution with respect to the Option upon Participant's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to this Agreement is subject to all terms and conditions of this Agreement, except to the extent this Agreement otherwise provides, and to any additional restrictions deemed necessary or appropriate by the Administrator. If Participant is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person

other than Participant's spouse or domestic partner, as applicable, as his or her beneficiary with respect to more than 50% of Participant's interest in the Option shall not be effective without the prior written consent of Participant's spouse or domestic partner. If no beneficiary has been designated or survives Participant, payment shall be made to the person entitled thereto pursuant to Participant's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by Participant at any time provided the change or revocation is filed with the Administrator prior to Participant's death.

5.4 Tax Consultation. Participant understands that Participant may suffer adverse tax consequences as a result of the grant, vesting and/or exercise of the Option, and/or with the purchase or disposition of the Shares subject to the Option. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of such Shares and that Participant is not relying on the Company for any tax advice.

5.5 Binding Agreement. Subject to the limitation on the transferability of the Option contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Adjustments Upon Specified Events.

(a) Equity Restructuring. In connection with any Equity Restructuring, notwithstanding anything to the contrary in this Section 5.6 the Administrator will equitably adjust the terms of the Agreement and outstanding Award as it deems appropriate to reflect the Equity Restructuring, which may include (i) adjusting the number and type of securities subject to the outstanding Award; (ii) adjusting the terms and conditions of (including the grant or exercise price) the outstanding Award; and (iii) granting new Awards or making cash payments to Participant. The adjustments provided under this Section 5.6 will be nondiscretionary and final and binding on all interested parties, including the affected Participant and the Company; provided that the Administrator will determine whether an adjustment is equitable.

(b) Corporate Transactions. In the event of any dividend or other distribution (whether in the form of cash, Common Stock, other securities, or other property), reorganization, merger, consolidation, split-up, spin off, combination, amalgamation, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or sale or exchange of Common Stock or other securities of the Company, Change in Control, issuance of warrants or other rights to purchase Common Stock or other securities of the Company, other similar corporate transaction or event, other unusual or nonrecurring transaction or event affecting the Company or its financial statements or any change in any Applicable Law or accounting principles, the Administrator, on such terms and conditions as it deems appropriate, either by the terms of the Award or by action taken prior to the occurrence of such transaction or event (except that action to give effect to a change in Applicable Law or accounting principles may be made within a reasonable period of time after such change) and either automatically or upon Participant's request, is hereby authorized to take any one or more of the following actions whenever the Administrator determines that such action is appropriate in order to (x) prevent dilution or enlargement of the benefits or potential benefits intended by the Company with respect to the Award granted or issued under this Agreement, (y) to facilitate such transaction or event or (z) give effect to such changes in Applicable Law or accounting principles:

(i) To provide for the cancellation of the Award in exchange for either an amount of cash or other property with a value equal to the amount that could have been obtained upon the exercise or settlement of the vested portion of the Award or realization of Participant's rights under the vested portion of the Award, as applicable; provided that, if the amount that could have been obtained upon the exercise or settlement of the vested portion of the Award or realization of Participant's rights, in any case, is equal to or less than zero, then the Award may be terminated without payment;

(ii) To provide that the Award shall vest and, to the extent applicable, be exercisable as to all Shares (or other property) covered thereby, notwithstanding anything to the contrary in this Agreement;

(iii) To provide that the Award be assumed by the successor or survivor corporation or entity, or a parent or subsidiary thereof, or shall be substituted for by awards covering the stock of the successor or survivor corporation or entity, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and applicable exercise or purchase price, in all cases, as determined by the Administrator;

(iv) To make adjustments in the number and type of shares of Common Stock (or other securities or property) subject to the outstanding Award or in the terms and conditions of (including the grant or exercise price), and the criteria included in, the outstanding Award;

(v) To replace the Award with other rights or property selected by the Administrator; or

(vi) To provide that the Award will terminate and cannot vest, be exercised or become payable after the applicable event.

(c) Change in Control.

(i) Notwithstanding any other provision of this Agreement, in the event of a Change in Control, unless the Administrator elects to (i) terminate the Award in exchange for cash, rights or property, or (ii) cause the Award to become fully exercisable and no longer subject to any forfeiture restrictions prior to the consummation of a Change in Control, pursuant to Section 5.6(b), the Award shall continue in effect or be assumed or an equivalent Award substituted by the successor corporation or a parent or subsidiary of the successor corporation.

(ii) In the event that the successor corporation in a Change in Control refuses to assume or substitute for the Award, the Administrator shall cause the Award to become fully vested and, if applicable, exercisable immediately prior to the consummation of such transaction and all forfeiture restrictions on the Award to lapse and, to the extent unexercised upon the consummation of such transaction, to terminate in exchange for cash, rights or other property. The Administrator shall notify Participant in the event the Award becomes exercisable pursuant to the preceding sentence that the Award shall be fully exercisable for a period of time as determined by the Administrator (which shall be 15 days if no period of time is determined by the Administrator) from the date of such notice, contingent upon the occurrence of the Change in Control, and the Award shall terminate upon the consummation of the Change in Control in accordance with the preceding sentence.

(iii) For the purposes of this Section 5.6, the Award shall be considered assumed if, following the Change in Control, the Award confers the right to purchase or receive, for each Share subject to the Award immediately prior to the Change in Control, the consideration (whether stock, cash, or other securities or property) received in the Change in Control by holders of Common Stock for each Share held on the effective date of the transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the Change in Control was not solely common stock of the successor corporation or its parent, the Administrator may, with the consent of the successor corporation, provide for the consideration to be received upon the exercise of the Award, for each Share subject to the Award, to be solely common stock of the successor corporation or its parent equal in fair market value to the per-share consideration received by holders of Common Stock in the Change in Control.

(d) Administrative Stand Still. In the event of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other extraordinary transaction or change affecting the Shares or the share price of Common Stock (including any Equity Restructuring or any securities offering or other similar transaction) or for reasons of administrative convenience or to facilitate compliance with any Applicable Law, the Company may refuse to permit the exercise or settlement of one or more Awards for such period of time as the Company may determine to be reasonably appropriate under the circumstances.

(e) General. Except as expressly provided in this Agreement or the Administrator's action under this Agreement, Participant will not have any rights due to any subdivision or consolidation of Shares of any class, dividend payment, increase or decrease in the number of Shares of any class or dissolution, liquidation, merger, or consolidation of the Company or other corporation. Except as expressly provided with respect to an Equity Restructuring under Section 5.6(a) above or the Administrator's action under this Agreement, no issuance by the Company of Shares of any class, or securities convertible into Shares of any class, will affect, and no adjustment will be made regarding, the number of Shares subject to the Award or the Award's grant or exercise price. The existence of this Agreement and the Award granted hereunder will not affect or restrict in any way the Company's right or power to make or authorize (i) any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, (ii) any merger, consolidation, spinoff, dissolution or liquidation of the Company or sale of Company assets or (iii) any sale or issuance of securities, including securities with rights superior to those of the Shares or securities convertible into or exchangeable for Shares.

5.7 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.7, either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to Participant shall, if Participant is then deceased, be given to the person entitled to exercise his or her Option pursuant to Section 4.1 hereof by written notice under this Section 5.7. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

5.10 Conformity to Securities Laws. Participant acknowledges that this Agreement is intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all Applicable Law and regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, this Agreement shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to such Applicable Law. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

5.11 Amendment, Suspension and Termination. This Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board, including by substituting another Award of the same or a different type or changing the exercise or settlement date; *provided, however,* that, except as may otherwise be provided by this Agreement, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of Participant. The Participant's consent to such action will be required unless (i) the action, taking into account any related action, does not materially and adversely affect the Participant's rights under the Award, or (ii) the change is permitted under Section 5.6 and Section 5.17 hereof. In addition, the Administrator shall, without the approval of the stockholders of the Company, have the authority to (a) amend the Option to reduce its exercise price per Share, or (b) cancel the Option in exchange for cash or another Award.

5.12 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 5.3 hereof, this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

5.13 Clawback Provisions. The Award (including the gross amount of any proceeds, gains or other economic benefit Participant actually or constructively receives upon receipt or exercise of the Award or the receipt or resale of any Shares underlying the Award) will be subject to recoupment by the Company to the extent required to comply with Applicable Law or any policy of the Company providing for the reimbursement of incentive compensation, whether or not such policy was in place at the time of grant of the Award.

5.14 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Option and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.15 Not a Contract of Service Relationship. Nothing in this Agreement shall confer upon Participant any right to continue to serve as an employee or other service provider of the Company or any of its Subsidiaries or interfere with or restrict in any way with the right of the Company or any of its Subsidiaries, which rights are hereby expressly reserved, to discharge or to terminate for any reason whatsoever, with or without cause, the services of Participant's at any time.

5.16 Entire Agreement. The Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

5.17 Section 409A. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Grant Notice or this Agreement, if at any time the Administrator determines that the Option (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify Participant or any other person for failure to do so) to adopt such amendments to the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate either for the Option to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.18 Limitation on Participant's Rights. This Agreement confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither this Agreement nor any underlying program, in and of itself, has any assets. Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to options, as and when exercised pursuant to the terms hereof.

5.19 Data Privacy. As a condition for receiving the Award, Participant explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of personal data as described in this Section by and among the Company and its Subsidiaries and affiliates exclusively for implementing, administering and managing Participant's participation in this Agreement. The Company and its Subsidiaries and affiliates may hold certain personal information about a Participant, including the Participant's name, address and telephone number; birthdate; social security, insurance number or other identification number; salary; nationality; job title(s); any Shares held in the Company or its Subsidiaries and affiliates; and Award details, to implement, manage and administer this Agreement and the Award (the "Data"). The Company and its Subsidiaries and affiliates may transfer the Data amongst themselves as necessary to implement, administer and manage Participant's participation

in this Agreement, and the Company and its Subsidiaries and affiliates may transfer the Data to third parties assisting the Company with implementation, administration and management. These recipients may be located in Participant's country, or elsewhere, and Participant's country may have different data privacy laws and protections than the recipients' country. By accepting this Award, Participant authorizes such recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, to implement, administer and manage Participant's participation in this Agreement, including any required Data transfer to a broker or other third party with whom the Company or the Participant may elect to deposit any Shares. The Data related to Participant will be held only as long as necessary to implement, administer, and manage Participant's participation in the Agreement. Participant may, at any time, view the Data that the Company holds regarding such Participant, request additional information about the storage and processing of the Data regarding such Participant, recommend any necessary corrections to the Data regarding Participant or refuse or withdraw the consents in this Section 5.19 in writing, without cost, by contacting the local human resources representative. The Company may cancel Participant's ability to participate in the Agreement and, in the Administrator's sole discretion, Participant may forfeit any outstanding Options if Participant refuses or withdraws the consents in this Section 5.19. For more information on the consequences of refusing or withdrawing consent, Participant may contact the local human resources representative.

* * * * *

Exhibit 21.1

Name of Subsidiary	Jurisdiction
Elicio Operating Company, Inc.	Delaware
Elicio Australia Pty Ltd.	Australia
Elicio Securities Corp.	Massachusetts

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-264994) and Form S-8 (Nos. 333-252906, 333-264995, 333-270676 and 333-274127) of Elicio Therapeutics, Inc. of our report dated March 29, 2024, relating to the consolidated financial statements, which includes an explanatory paragraph relating to the Company's ability to continue as a going concern, which appears in this Form 10-K.

/s/ BAKER TILLY US, LLP

Tewksbury, Massachusetts
March 29, 2024

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: March 29, 2024

ELICIO THERAPEUTICS, INC.

By: /s/ Robert Connelly
Robert Connelly
Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Robert Connelly and Brian Piekos, and each of them acting individually, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution, for him or her in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorneys-in-fact and agents, with full power of each to act alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully for all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/s/ Robert Connelly Robert Connelly	Chief Executive Officer, President and Director (Principal Executive Officer)	March 29, 2024
/s/ Brian Piekos Brian Piekos	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2024
/s/ Jay Venkatesan, M.D. Jay Venkatesan, M.D.	Director	March 29, 2024
/s/ Julian Adams, Ph.D. Julian Adams, Ph.D.	Director	March 29, 2024
/s/ Carol Ashe Carol Ashe	Director	March 29, 2024
/s/ Yekaterina (Katie) Chudnovsky Yekaterina (Katie) Chudnovsky	Director	March 29, 2024

/s/ Robert R. Ruffolo, Jr., Ph.D. Robert R. Ruffolo, Jr., Ph.D.	Director	March 29, 2024
/s/ Karen Wilson Karen Wilson	Director	March 29, 2024
/s/ Allen Nissenson, M.D. Allen Nissenson, M.D.	Director	March 29, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Robert Connelly, certify that:

1. I have reviewed this Annual Report on Form 10-K of Elicio Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

ELICIO THERAPEUTICS, INC.

By: /s/ ROBERT CONNELLY
Robert Connelly
President and Chief Executive Officer
and Director (Principal Executive Officer)

Date: March 29, 2024

Exhibit 31.2

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian Piekos, certify that:

1. I have reviewed this Annual Report on Form 10-K of Elicio Therapeutics, Inc.;

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

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

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

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

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

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

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

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

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

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

ELICIO THERAPEUTICS, INC.

By: /s/ Brian Piekos
Brian Piekos
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: March 29, 2024

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

The undersigned officer of Elicio Therapeutics, Inc. (the "Company") certifies to such officer's knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Annual Report on Form 10-K of the Company for the period ended December 31, 2023 (the "Annual Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

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

ELICIO THERAPEUTICS, INC.

By: /s/ ROBERT CONNELLY
Robert Connelly
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 29, 2024

Exhibit 32.2

CERTIFICATIONS PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

The undersigned officer of Elicio Therapeutics, Inc. (the "Company") certifies to such officer's knowledge, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Annual Report on Form 10-K of the Company for the period ended December 31, 2023 (the "Annual Report"), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and

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

ELICIO THERAPEUTICS, INC.

By: /s/ BRIAN PIEKOS
Brian Piekos
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: March 29, 2024

ELICIO THERAPEUTICS, INC.

CLAWBACK POLICY

I. Introduction

The Board of Directors (the "**Board**") of Elicio Therapeutics, Inc. (the "**Company**") believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this policy which provides for the recoupment of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**") and final rules and amendments adopted by the Securities and Exchange Commission (the "**SEC**") to implement the aforementioned legislation.

II. Administration

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board, in which case references herein to the Board shall be deemed references to the Compensation Committee. Any determinations made by the Board shall be final and binding on all affected individuals.

III. Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are listed, and such other employees who may from time to time be deemed subject to the Policy by the Board ("**Covered Executives**").

IV. Incentive-Based Compensation

For purposes of this Policy, incentive-based compensation ("**Incentive-Based Compensation**") includes any compensation that is granted, earned, or vested based wholly or in part upon the attainment of any financial reporting measures that are determined and presented in accordance with the accounting principles ("**GAAP Measures**") used in preparing the Company's financial statements and any measures derived wholly or in part from such measures, as well as non-GAAP Measures, stock price, and total shareholder return (collectively, "**Financial Reporting Measures**"); however, it does not include: (i) base salaries; (ii) discretionary cash bonuses; (iii) awards (either cash or equity) that are solely based upon subjective, strategic or operational standards or standards unrelated to Financial Reporting Measures, and (iv) equity awards that vest solely on completion of a specified employment period or without any performance condition. Incentive-Based Compensation is considered received in the fiscal period during which the applicable reporting measure is attained, even if the payment or grant of such award occurs after the end of that period. If an award is subject to both time-based and performance-based vesting conditions, the award is considered received upon satisfaction of the performance-based conditions, even if such an award continues to be subject to the time-based vesting conditions.

For the purposes of this Policy, Incentive-Based Compensation may include, among other things, any of the following:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock or restricted stock units.
- Performance shares or performance units.

For purposes of this Policy, Financial Reporting Measures may include, among other things, any of the following:

- Company stock price.
- Total shareholder return.
- Revenues.
- Net income.

- Earnings before interest, taxes, depreciation, and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital or operating cash flow.
- Return measures such as return on invested capital or return on assets.
- Earnings measures such as earnings per share.

V. Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that (i) is material to the previously issued financial statements or (ii) is not material to previously issued financial statements, but that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period, the Board will require reimbursement or forfeiture of any excess Incentive-Based Compensation received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare the accounting restatement (the "**Look-Back Period**"). For the purposes of this Policy, the date on which the Company is required to prepare an accounting restatement is the earlier of (i) the date the Board concludes or reasonably should have concluded that the Company is required to prepare a restatement to correct a material error, and (ii) the date a court, regulator, or other legally authorized body directs the Company to restate its previously issued financial statements to correct a material error. The Company's obligation to recover erroneously awarded compensation is not dependent on if or when the restated financial statements are filed.

Recovery of the Incentive-Based Compensation is only required when the excess award is received by a Covered Executive (i) after the beginning of their service as a Covered Executive, (ii) who served as an executive officer at any time during the performance period for that Incentive-Based Compensation, (iii) while the Company has a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Look-Back Period immediately preceding the date on which the Company is required to prepare an accounting restatement.

VI. Excess Incentive Compensation: Amount Subject to Recovery

The amount of Incentive-Based Compensation subject to recovery is the amount the Covered Executive received in excess of the amount of Incentive-Based Compensation that would have been paid to the Covered Executive had it been based on the restated financial statements, as determined by the Board. The amount subject to recovery will be calculated on a pre-tax basis.

For Incentive-Based Compensation received as cash awards, the erroneously awarded compensation is the difference between the amount of the cash award that was received (whether payable in a lump sum or over time) and the amount that should have been received applying the restated Financial Reporting Measure. For cash awards paid from bonus pools, the erroneously awarded Incentive-Based Compensation is the pro rata portion of any deficiency that results from the aggregate bonus pool that is reduced based on applying the restated Financial Reporting Measure.

For Incentive-Based Compensation received as equity awards that are still held at the time of recovery, the amount subject to recovery is the number of shares or other equity awards received or vested in excess of the number that should have been received or vested applying the restated Financial Reporting Measure. If the equity award has been exercised, but the underlying shares have not been sold, the erroneously awarded compensation is the number of shares underlying the award.

In instances where the Company is not able to determine the amount of erroneously awarded Incentive-Based Compensation directly from the information in the accounting restatement, the amount will be based on the Company's reasonable estimate of the effect of the accounting restatement on the applicable measure. In such instances, the Company will maintain documentation of the determination of that reasonable estimate.

VII. Method of Recoupment

The Board will determine, in its sole discretion, subject to applicable law, the method for recouping Incentive-Based Compensation hereunder, which may include, without limitation:

- requiring reimbursement of cash Incentive-Based Compensation previously paid;

- seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive;
- cancelling outstanding vested or unvested equity awards; and/or
- taking any other remedial and recovery action permitted by law, as determined by the Board.

VIII. No Indemnification; Successors

The Company shall not indemnify any Covered Executives against the loss of any incorrectly awarded Incentive-Based Compensation. This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

IX. Exception to Enforcement

The Board shall recover any excess Incentive-Based Compensation in accordance with this Policy unless such recovery would be impracticable, as determined by the Board in accordance with Rule 10D-1 of the Exchange Act and any applicable rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed.

X. Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are listed.

XI. Effective Date

This Policy shall be effective as of the date it is adopted by the Board (the "**Effective Date**") and shall apply to Incentive-Based Compensation that is received by a Covered Executive on or after October 2, 2023, as determined by the Board in accordance with applicable rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed.

XII. Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to comply with any rules or standards adopted by the SEC and the listing standards of any national securities exchange on which the Company's securities are listed. The Board may terminate this Policy at any time.

XIII. Other Recoupment Rights

Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement, or similar agreement and any other legal remedies available to the Company.