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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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: 001-37467

Astria Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	**26-3687168** (IRS Employer Identification No.)
75 State Street **Suite 1400** **Boston, Massachusetts** (Address of principal executive offices)	**02109** (Zip Code)

Registrant's telephone number, including area code **(617) 349-1971**

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ATXS**	**Nasdaq Global Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§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 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 Exchange Act). Yes ☐ No ☒

Aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the last sale price for such stock on June 30, 2023: $279,504,972.

As of February 29, 2024, there were 54,903,061 shares of the registrant's common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2024 Annual Meeting of Stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The registrant intends to file such proxy statement with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Annual Report on Form 10-K relates.

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Summary of the Material Risks Associated with Our Business

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties. The principal factors and uncertainties that make investing in our common stock risky include, among others:

- We are entirely dependent on the success of our product candidates, STAR-0215 for the treatment of hereditary angioedema, or HAE, and STAR-0310 for the treatment of atopic dermatitis, or AD. We cannot give any assurance that we will generate preclinical, clinical or other data for STAR-0215 or STAR-0310 sufficiently supportive to receive regulatory approval, which will be required before either can be commercialized.

- Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more study participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.

- We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

- Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

- We have never generated any revenue from product sales and may never be profitable.

- We have never obtained marketing approval for a product candidate, and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any future product candidate we may seek to develop.

- Clinical trials are costly, time consuming, difficult to enroll and inherently risky, and we may fail to demonstrate safety and efficacy on the timelines that we expect or to the satisfaction of applicable regulatory authorities. We also expect that any later stage clinical trials we conduct for STAR-0310 will be larger and more expensive when compared to those we are conducting, and plan to conduct, for STAR-0215 because AD, the indication for which we are developing STAR-0310, is not a rare disease.

- STAR-0215, STAR-0310 or any future product candidates may cause adverse events or undesirable side effects or have other unexpected properties that could delay or halt clinical trials, delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.

- We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results.

- We rely on in-licensed patent and other intellectual property rights for our STAR-0310 program and we may need to obtain licenses from third parties to other intellectual property rights for the development and commercialization of our STAR-0310 and STAR-0215 programs; if we fail to comply with our existing or future obligations under these licenses, or if these licenses are terminated, we could lose license rights that are important to our business.

- We rely on third parties to conduct our preclinical studies and clinical trials. If they do not perform satisfactorily, our business could be significantly harmed.

- We will need to maintain a master cell bank for STAR-0215, a master cell bank for STAR-0310 and cell lines or banks for any other future biologic candidate that generate sufficient material for preclinical, nonclinical and clinical studies, and also build and maintain sufficient preclinical, clinical and commercial manufacturing drug substance and drug product capacity, in each case, through third party manufacturers, for STAR-0215, STAR-0310 and any other future product candidate that advances into such stages, on the timetables and in a manner that, in each case, are consistent with our expected development timetables and financial projections, the failure of which could materially harm our business and operating results and require us to raise capital sooner than we expect.

- Our forecasts of cash usage and how long we expect our existing cash, cash equivalents and short-term investments to fund operating expenses and capital expenditure requirements may not be accurate and we may therefore use our cash, cash equivalents and short-term investments more rapidly than we expect, which could force us to delay, reduce or eliminate our product development programs or commercialization efforts, if any, and therefore materially harm our operating results, and we could be required to raise capital sooner than we expect.

- We have incurred significant losses since inception, 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.

- If we are unable to obtain and maintain sufficient patent and/or regulatory protection for product candidates, or if the scope of the patent and/or regulatory protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize such product candidates successfully may be adversely affected.

- The price of our common stock has been and is likely to continue to be highly volatile, which could result in substantial losses for our stockholders.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "*Risk Factors*" in Part I, Item 1A of this Annual Report on Form 10-K and the other information set forth in this Annual Report on Form 10-K, including under the heading "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance, strategy, future financial condition and clinical development programs. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, clinical development programs, regulatory filings and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include but are not limited to those described under the heading "*Summary of the Material Risks Associated with our Business*" and the "*Risk Factors*" in Part I, Item 1A of this Annual Report on Form 10-K and include, among other things, statements about:

- our expectations regarding the potential significance of the results from the Phase 1a clinical trial of STAR-0215;
- our expectations regarding the timing, nature, goals and results of the ALPHA-STAR Phase 1b/2 clinical trial of STAR-0215, including the expected timing of release of proof-of-concept data from such trial, and that favorable results from such trial could allow us to move directly into a Phase 3 pivotal trial of STAR-0215 as a potential treatment for hereditary angioedema, or HAE;
- our expectations about the design and anticipated timing of a Phase 3 pivotal trial for STAR-0215 as a potential treatment for HAE, assuming positive data from the Phase 1b/2 trial;
- our expectations about the unmet medical need for HAE, the potential differentiating attributes of STAR-0215 as a potential treatment for HAE, along with the potential market impact of such differentiation, the potential of STAR-0215 to be a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE, and our vision for STAR-0215 to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE;
- the nature and anticipated growth of the global HAE market and HAE therapies;
- our plans to optimize the formulation of STAR-0215 and corresponding work to develop a drug-device combination for STAR-0215 for potential use in late-stage clinical trials and commercially, if approved;
- our expectations that we have scaled the manufacturing process for STAR-0215 in a manner to generate sufficient material for our planned STAR-0215 nonclinical and clinical studies;
- the potential therapeutic benefits and potential attributes of STAR-0310, a preclinical stage product candidate which we licensed in October 2023, and our plans to develop STAR-0310 as a treatment for atopic dermatitis, or AD;
- our expectations regarding the timing of regulatory submissions for STAR-0310;
- our expectations about the design and anticipated timing of planned clinical trials of STAR-0310;
- our expectations regarding the timing and nature of anticipated data for planned clinical trials of STAR-0310;
- the potential commercial opportunity for STAR-0310 in AD and the likelihood that it can effectively compete in AD, assuming it is approved;
- the estimated size and anticipated growth of the AD market and the need for treatments for AD;

- the potential to pursue the development of STAR-0310 in additional indications;
- our goals and visions for the STAR-0310 program;
- our expectations regarding our ability to expand our pipeline;
- the potential benefits of any future acquisition, in-license, collaboration or preclinical development activities;
- our manufacturing plans, capabilities and strategy;
- our intellectual property position and strategy;
- our estimates regarding our cash runway, expenses, future revenue, capital requirements and needs for additional financing, including additional financing to fund our long-term operations;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "*Risk Factors*" in Part I, Item 1A of this Annual Report on Form 10-K, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

You should read this Annual Report on Form 10-K with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward- looking statement, whether as a result of new information, future events or otherwise, except as required by law.

REFERENCES TO ASTRIA

Except as otherwise indicated herein or as the context otherwise requires, references in this Annual Report on Form 10-K to "Astria," "the Company," "we," "us," and "our" refer to Astria Therapeutics, Inc. and its consolidated subsidiaries.

PART I

Item 1. Business

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. Our focus is to develop first-choice therapies that improve the health and outcomes of patients with allergic and immunological diseases. Our lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema, or HAE, a rare, debilitating and potentially life-threatening disease. STAR-0215 has the potential to be the most patient-friendly chronic treatment option for HAE, based on the data generated to date and the existing HAE treatment landscape. Our second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis, or AD, an immune disorder associated with loss of skin barrier function and itching. We believe that with both of these programs, we are advancing a pipeline of products with meaningfully differentiated profiles based on validated mechanisms.

STAR-0215

The treatment options for patients with HAE have improved in recent years, however, there is remaining unmet medical need and the global market for HAE therapy is strong and growing. The goal for STAR-0215 is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE. Our vision for STAR-0215 is to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling. STAR-0215 is currently in clinical development and the U.S. Food and Drug Administration, or FDA, has granted Fast Track designation to STAR-0215 for the treatment of HAE.

We initiated a Phase 1a clinical trial of STAR-0215 in August 2022 and we announced initial results in December 2022. We presented additional preliminary results from the trial in February 2023 and further results were shared at the American College of Allergy, Asthma, and Immunology Conference in November 2023. Final results from the trial were shared at the American Academy of Allergy, Asthma, and Immunology Conference in February 2024. This Phase 1a randomized, double-blind, placebo-controlled single ascending dose clinical trial evaluated the safety, pharmacokinetics, or PK, and pharmacodynamics, or PD, of STAR-0215 at a single U.S. center. Forty-one healthy subjects received a single dose of STAR-0215 or placebo in four cohorts of 100mg, 300mg, 600mg, and 1200mg administered by subcutaneous, or SC, injection or a fifth cohort of 600mg or placebo administered by intravenous, or IV, injection. STAR-0215 was well-tolerated at all dose levels, with no serious adverse events or discontinuations due to an adverse event, and low risk of injection pain. STAR-0215 demonstrated rapid and sustained drug levels with dose-dependent PK. STAR-0215 achieved potentially therapeutic levels in less than one day after single doses greater than 100mg and showed an estimated half-life of up to 109 days. PK modeling of potential once-every-three-month and once-every-six-month clinical dose regimens over one to two years indicate STAR-0215 has the potential for PK coverage that would confer HAE attack prevention. PD data showed statistically significant inhibition of Factor XIIa-induced plasma kallikrein activity compared to levels prior to dosing, observed using two different assay formats. The percentage inhibition of plasma kallikrein observed was consistent with clinical activity for doses greater than 300mg. Treatment-emergent anti-drug antibodies, or ADAs, were observed in eleven subjects from completed cohorts, all first observed on or after 140 or more days after the single dose of STAR-0215. ADAs were determined not to affect the PK or PD of STAR-0215. With a preliminary favorable safety profile, long half-life and durable PD, STAR-0215 demonstrated early proof of concept in healthy subjects as a potential HAE therapy with robust efficacy and dosing every three or six months.

In February 2023 we advanced STAR-0215 to a Phase 1b/2 trial called ALPHA-STAR, or Astria Long-acting Prophylaxis for Hereditary Angioedema: STAR-0215. This global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE is evaluating safety, tolerability, HAE attack rate, PK, PD, and quality of life in patients three and six months after STAR-0215 administration. The trial has three cohorts, which all begin with an eight week run-in period to assess baseline attack rate. Cohort 1 receives a 450mg single dose of STAR-0215, Cohort 2 receives an initial 600mg dose followed by a 300mg dose on Day 84, to simulate a potential three-month dosing regimen with maintenance doses of 300mg every three months. Cohort 3 receives an initial 600mg dose, followed by a second 600mg dose 28 days later, to simulate a potential six-month dosing regimen with maintenance doses of 600mg every six months. All doses are administered subcutaneously and all patients in the trial are followed for six months after the last dose administered. We expect to report initial proof-of-concept data in HAE patients in the first quarter of 2024, which would include safety, tolerability, PK, PD, and HAE attack-rate reduction, and we expect these data to provide information on both three and six month administration. If the results from ALPHA-STAR are positive, we expect to progress STAR-0215 directly to a Phase 3 pivotal trial which we anticipate initiating in the first quarter of 2025.

We have initiated and are enrolling subjects in ALPHA-SOLAR, a long-term open-label trial assessing the long-term safety and efficacy of STAR-0215. We are currently administering STAR-0215 to those patients who have completed ALPHA-STAR and have enrolled in ALPHA-SOLAR, and data is accruing in patients who have received multiple doses of STAR-0215. Participants are being assigned to receive STAR-0215 in one of two dosing regimens: either 300mg every three months or 600mg every six months.

STAR-0310

We believe that OX40 inhibition has the potential to treat AD and other diseases. The current treatment options in AD are insufficient to address the needs of many patients, and standard of care treatments include steroids and topical medications which can treat symptoms but do not address the underlying disease. Our goal for STAR-0310 is to reduce disease activity, relapse rate, and treatment burden for patients with moderate-to-severe AD. STAR-0310 was engineered with YTE half-life extension technology to enable infrequent dosing. As a potential long-acting OX40 inhibitor, STAR-0310 aims to address the need for a safe, effective, and infrequently administered AD treatment.

In 2024, we plan to share preclinical profile results for STAR-0310 and we anticipate submitting an investigational new drug application, or IND, to the FDA for STAR-0310 for the treatment of AD by year-end. If the IND is cleared, we anticipate initiating a Phase 1a clinical trial of STAR-0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of STAR-0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026. The goals of the Phase 1b trial would be to demonstrate initial efficacy in AD as well as show differentiation in safety and tolerability as compared to existing therapies.

Our Product Candidates

STAR-0215

STAR-0215 is a monoclonal antibody that was designed to inhibit plasma kallikrein for the treatment of HAE. Plasma kallikrein is a critical component of the plasma contact system, which causes pathologic vascular permeability in Type I and Type II HAE. STAR-0215 is a humanized monoclonal antibody that was developed through a hybridoma screening and antibody optimization process. Following humanization and optimization for affinity and overall properties, the antibody was modified to increase its plasma half-life. This process resulted in STAR-0215, a humanized monoclonal antibody having the following desirable features: high affinity and kallikrein inhibitory activity, selectivity for plasma kallikrein compared to prekallikrein, reduced chemistry, manufacturing and controls or, CMC, liabilities and long plasma half-life. Based on these characteristics, preclinical experiments, healthy subject clinical results with STAR-0215, and the HAE market landscape, we believe that STAR-0215 has the potential to be a best-in-class and the most patient-friendly monoclonal antibody inhibitor of plasma kallikrein that could combine the benefits of infrequent dosing with the inhibition of attacks over long periods of time and low risk of injection pain while maintaining high levels of efficacy. We believe that we can establish clinical proof of concept early in the development program with our Phase 1b/2 ALPHA-STAR trial in people with HAE. If we achieve this goal, we believe that we can develop a differentiated, best-in-class new preventative therapy for HAE with a well-understood monoclonal antibody modality to provide patients with improved outcomes and quality of life.

Overview of HAE

HAE is a rare, autosomal dominant genetic disorder. The disease is characterized by recurrent, unpredictable, debilitating and potentially life-threatening edema in the skin, abdomen and airway. The vast majority of HAE cases (Type I and Type II) are caused by defects in the C1 esterase inhibitor gene. Deficiencies in the C1 esterase inhibitor gene result in overproduction of bradykinin, a key mediator of vasodilation and angioedema. In several other types of HAE, which are a small minority of cases, other mutations (e.g., in the Factor XII gene) can cause HAE. The estimated prevalence of Type I and Type II HAE range from 1 in 10,000 to 1 in 50,000 with fewer than 8,000 patients in the United States and 15,000 patients in Europe with HAE. There are active and knowledgeable HAE patient advocacy organizations in the United States and internationally.

Patients with HAE are typically diagnosed by the age of 20 with the average age of disease onset around 11. The severity and frequency of swelling attacks is highly variable even between family members.

The Role of Plasma Kallikrein in Hereditary Angioedema

Plasma kallikrein is an enzyme that cleaves high molecular weight kininogen, or HMWK, to release bradykinin. Normally, circulating C1 esterase inhibitor, or C1INH, limits the activation of plasma kallikrein from its precursor prekallikrein, and thereby prevents the release of excess bradykinin from the cleavage of HMWK by plasma kallikrein. In HAE associated with C1INH deficiency, plasma kallikrein is hyperactive, resulting in excessive bradykinin release. Bradykinin activates the bradykinin receptor, or B2R, in endothelial cells, resulting in increased vascular permeability and release of fluid into subcutaneous tissue spaces, or angioedema. Thus, unchecked plasma kallikrein activity is a critical component that causes pathologic vascular permeability and vasodilation in HAE, leading to excessive tissue swelling, a primary clinical symptom.

Unaddressed Market Opportunity

There are two treatment approaches to managing the unpredictable and recurrent edema attacks typically experienced by people with HAE. On-demand treatments are administered at the onset of an attack to reduce the severity and duration of the attack, and preventative treatments, which is the treatment approach that we are pursuing with STAR-0215, are taken chronically to reduce the frequency and severity of future attacks. The HAE treatment market is substantial and growing. We estimate that the HAE market was greater than 2 billion dollars in 2022 and that it has potential to grow to 4.5 billion dollars by 2027. This growth is predicted based on patients being diagnosed earlier, more patients taking treatments to prevent HAE attacks, as well as expansion of available therapies in more geographic regions. In the United States, the FDA has approved four therapies for on-demand treatment of HAE: BERINERT® (C1 esterase inhibitor [human]), FIRAZYR® (icatibant injection), KALBITOR® (ecallantide) and RUCONEST® (C1 esterase inhibitor [recombinant]). For long-term preventative treatment of HAE, the FDA has approved the following four therapies: CINRYZE® (C1 esterase inhibitor [human]), HAEGARDA® (C1 esterase inhibitor subcutaneous [human]), TAKHZYRO® (lanadelumab-flyo) and ORLADEYO® (berotralstat).

With the exception of KALBITOR, these therapies are also approved and commercially available outside of the United States. The approved preventative therapies have provided HAE patients with treatment options but have limitations in dosing frequency, side effects and/or efficacy. CINRYZE and HAEGARDA are administered twice a week; CINRYZE by IV infusion and HAEGARDA by SC injection. TAKHZYRO is dosed every two weeks by SC injection. Dosing every four weeks may be considered in some patients. With these injectable therapies, patients have reported a desire for less burdensome administration. ORLADEYO is an oral capsule taken daily with food, and data from its approved label, while not comparative data, suggest a lower percentage reduction in attack rate than other available therapies. Historically, androgens and antifibrinolytic treatments have also been used as preventative treatment but they are associated with side effects such as hypertension, acne, hirsutism, rashes, amenorrhea, liver enzyme elevations and increased risk of thrombosis and their overall use has been declining with the availability of more-tolerable, HAE-specific therapies. Although there has been progress with recent innovation in therapies for HAE and, as described in the section entitled “Competition” in this Business section, there are a significant number of product candidates for HAE in clinical and preclinical development, we believe that there is remaining unmet medical need for potent and long duration of action preventative therapies to provide patients with lower burden of treatment and improved outcomes and quality of life. Market research with U.S. physicians and HAE patients has shown strong interest in a product with the potential profile of STAR-0215.

Clinical Trial Results and Development Plans

We initiated a Phase 1a clinical trial of STAR-0215 in August 2022 and we announced initial results in December 2022. We presented additional preliminary results from the trial in February 2023 and further results were shared at the American College of Allergy, Asthma, and Immunology Conference in November 2023. Final results from the trial were shared at the American Academy of Allergy, Asthma, and Immunology Conference in February 2024. This Phase 1a randomized, double-blind, placebo-controlled single ascending dose clinical trial evaluated the safety, PK and PD of STAR-0215 at a single U.S. center. Forty-one healthy subjects received a single dose of STAR-0215 or placebo in four cohorts of 100mg, 300mg, 600mg, and 1200mg administered by SC injection or a fifth cohort of 600mg or placebo administered by IV injection. STAR-0215 was well-tolerated at all dose levels, with no serious adverse events or discontinuations due to an adverse event, and low risk of injection pain. STAR-0215 demonstrated rapid and sustained drug levels with dose-dependent PK. STAR-0215 achieved potentially therapeutic levels in less than one day after single doses greater than 100mg and showed an estimated half-life of up to 109 days. PK modeling of potential once-every-three-month and once-every-six-month clinical dose regimens over one to two years indicate STAR-0215 has the potential for PK coverage that would confer HAE attack prevention. PD data showed statistically significant inhibition of Factor XIIa-induced plasma kallikrein activity compared to levels prior to dosing, observed using two different assay formats. The percentage inhibition of plasma kallikrein observed was consistent with clinical activity for doses greater than 300mg. Treatment-emergent ADAs were observed in eleven subjects from completed cohorts, all first observed on or after 140 or more days after the single dose of STAR-0215. ADAs were determined not to affect the PK or PD of STAR-0215.

These results support STAR-0215's target profile as a long-acting plasma kallikrein inhibitor and supported advancing STAR-0215 to our Phase 1b/2 ALPHA-STAR trial, which we initiated in February 2023. This global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE is evaluating safety, tolerability, HAE attack rate, PK, PD, and quality of life in patients. Efficacy is planned to be assessed at three and six months after last STAR-0215 administration. The trial has three cohorts, which all begin with an eight week run-in period to assess baseline attack rate. Cohort 1 receives a 450mg single dose of STAR-0215, Cohort 2 receives an initial 600mg dose followed by a 300mg dose on Day 84, to simulate a potential three-month dosing regimen with maintenance doses of 300mg every three months. Cohort 3 receives an initial 600mg dose, followed by a second 600mg dose 28 days later, to simulate a potential six-month dosing regimen with maintenance doses of 600mg every six months. All doses are administered subcutaneously and all patients in the trial are followed for six months after the last dose administered. We expect to report initial proof-of-concept data in HAE patients in the first quarter of 2024, which would include safety, tolerability, PK, PD, and HAE attack-rate reduction, and we expect these data to provide information on both three and six month administration. If the results from ALPHA-STAR are positive, we expect to progress STAR-0215 directly to a Phase 3 pivotal trial which we anticipate initiating in the first quarter of 2025.

We have initiated and are enrolling subjects in ALPHA-SOLAR, a long-term open-label trial assessing the long-term safety and efficacy of STAR-0215. We are currently administering STAR-0215 to those patients who have completed ALPHA-STAR and have enrolled in ALPHA-SOLAR, and data is accruing in patients who have received multiple doses of STAR-0215. Participants are being assigned to receive STAR-0215 in one of two dosing regimens: either 300 mg every three months or 600 mg every six months.

Preclinical Results

Our vision for STAR-0215 is supported by preclinical data showing potent inhibition of the production of bradykinin by plasma kallikrein and a long plasma half-life that could potentially enable patients to dose less frequently. Experiments also support the ability of YTE technology, designed to enable a longer duration of action, to extend half-life. Data suggest that at equal doses STAR-0215 would have a significantly longer duration of action than lanadelumab and could result in STAR-0215 being an effective preventative therapy for patients with HAE due to inhibition of the pathologic activity of plasma kallikrein for an extended time period with the potential to enable dosing once every three or six months.

STAR-0310

STAR-0310 is a monoclonal antibody OX40 antagonist incorporating YTE half-life extension technology that we are developing as a potential best-in-class treatment for AD as well as potentially for other allergic and immunological diseases. STAR-0310 is currently in preclinical development. We licensed the rights to STAR-0310 under a license agreement, or the License Agreement, that we entered into with Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos, in October 2023, pursuant to which Ichnos granted to us an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and license to certain patent rights and related know-how, or collectively the Licensed Intellectual Property, to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as "ISB 830" as well as Ichnos' proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as "ISB 830-X8" and referred to by us as the "STAR-0310 candidate." As noted above, STAR-0310 is STAR-0310 candidate engineered with YTE half-life extension technology. Ichnos has also agreed not to develop or commercialize any product that directly modulates the OX40 receptor.

Overview of Atopic Dermatitis

AD is an immune disorder associated with loss of skin barrier function and itching. AD is caused by diverse mechanisms, spanning the spectrum of T cell-driven pathology. Approximately 90% of patients develop the disease within the first 5 years of life. AD is estimated to affect approximately 5% of the adult population in the United States, approximately half of which cases are reported to be moderate or severe. AD is a chronic disease and current treatment options are insufficient to address the needs of many patients. Standard of care treatments include steroids and topical medications, which can treat symptoms but do not address the underlying disease.

Role of OX40 in Atopic Dermatitis

OX40 is a receptor expressed on activated T cells that can target multiple effector T cell pathways with the potential for broad impact on the inflammatory cascade. Th1, Th2, and Th17/22 signaling can all contribute to AD. OX40 is upstream of Th1, Th2, and Th17/22 signaling and inhibition of OX40 could reduce the activity of this broad group of Th cells that are known to contribute to the disease.

Our goal for STAR-0310 is to reduce disease activity, relapse rate, and treatment burden for patients with moderate and severe AD in order to help normalize their lives. STAR-0310 was engineered with YTE half-life extension technology to enable infrequent dosing. As a potential long-acting OX40 inhibitor, STAR-0310 aims to address the need for a safe, effective, and infrequently administered AD treatment. By targeting OX40, STAR-0310 is designed to address a wide range of T cells involved in the heterogenous AD pathology, providing the potential for better efficacy and a broader addressable patient population.

STAR-0310 was developed as a next generation of telazorlimab with 99% sequence identity. As observed in preclinical studies, STAR-0310 candidate inhibited donor T-cell proliferation similarly to rocatinlimab, an afucosylated anti-OX40 antibody currently in Phase 3 clinical development by Amgen, and at least 10-fold better than telazorlimab. In preclinical studies of donor regulatory T-cells, STAR-0310 candidate was observed to have lower antibody-dependent cellular cytotoxicity, as compared to rocatinlimab, particularly sparing regulatory T cells. In clinical trials conducted by Ichnos, telazorlimab exhibited a favorable safety and tolerability profile. As an affinity matured next generation of telazorlimab that includes YTE modification, STAR-0310 has the potential to have a favorable safety and tolerability profile.

Unaddressed Market Opportunity

While there are available treatment options in AD, there remains unmet need for a therapy that is safe and effective for a broad patient population, with a low treatment burden. Standard of care includes systemic steroids and topical medications, which can treat symptoms but do not address underlying disease. Moderate-to-severe patients who do not respond to topical prescription therapies typically turn to biologics as their next option, and, subsequently, to Janus kinase, or JAK, inhibitors. We estimate that the moderate-to-severe AD treatment market was approximately $7 billion in 2022 and that it has the potential to grow to $26 billion by 2030 likely due to an increase in drug-treatment rates, especially with availability of new therapies and growth in biologics-treated patients owing to dermatologists' increasing comfort with biologics.

Two biologics have been approved by the FDA for the treatment of AD: DUPIXENT® (dupilumab) and ADBRY® (tralokinumab-ldrm), both of which are administered subcutaneously every two weeks and work by targeting the Th2 inflammatory pathway (IL-4/13 and IL-13, respectively). Due to the heterogenicity of AD, there are many patients using these approved biologics who do not respond to treatment or experience limited efficacy. In addition, the FDA has approved two oral JAK inhibitors for the treatment of AD: RINVOQ® (upadacitinib) and CIBINQOTM (abrocitinib), and in the European Union OLUMIAN, another JAK inhibitor, is also approved for the treatment of AD. While these JAK inhibitors tend to have better efficacy than the two approved biologics, they require daily oral administration and there are significant safety concerns, including a boxed warning, associated with JAK inhibitors.

Inhibiting OX40 could target multiple effector T cell pathways, and therefore has the potential to reduce the activity of a broader group of Th cells that are known to contribute to AD and potentially induce higher rates of clinical responses in more patients than currently available biologics. Additionally, OX40 inhibition has the potential to be disease modifying. Although there has been progress with recent innovation in therapies for AD and, as described in the section entitled "Competition" in this Business section, there are a significant number of product candidates for AD in clinical development, we believe that there is remaining unmet medical need for therapies with efficacy across a broader range of AD patients and a longer duration of action to provide patients with a lower treatment burden and improved outcomes and quality of life.

Development Plans

We anticipate sharing preclinical profile results in 2024 and submitting an IND to the FDA for STAR-0310 for the treatment of AD by the end of 2024. If the IND is cleared, we anticipate initiating a Phase 1a clinical trial of STAR-0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of STAR-0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026. The goals of the Phase 1b trial would be to demonstrate initial efficacy in AD as well as show differentiation in safety and tolerability as compared to existing therapies.

We also see an opportunity to explore the potential of STAR-0310 in additional allergic and immunological indications, such as asthma, chronic urticaria and autoimmune indications.

Competition

The development and commercialization of new drug products is highly competitive. If we successfully develop and commercialize any of our product candidates, we and any future collaborators will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of the entities developing and marketing existing and potentially competing products have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and commercialization. Even if we are able to successfully develop and commercialize a product, our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects, are more convenient or are less expensive than our product.

STAR-0215

We are developing STAR-0215 for the potential treatment of HAE. The key competitive factors affecting the success of STAR-0215, if approved, are likely to be its efficacy, safety, dosing frequency, method of administration, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

In the United States, the FDA has approved four therapies for on-demand treatment of HAE: BERINERT, FIRAZYR, KALBITOR and RUCONEST. For long-term preventative treatment of HAE, the FDA has also approved four therapies: CINRYZE, HAEGARDA, TAKHZYRO and ORLADEYO. There are four main manufacturers of therapies for HAE: CSL Behring (BERINERT and HAEGARDA), Takeda (FIRAZYR, KALBITOR, CINRYZE and TAKHZYRO), Pharming (RUCONEST) and BioCryst (ORLADEYO). With the exception of KALBITOR, these therapies are also approved and commercially available outside of the United States (HAEGARDA is marketed as BERINERT SC outside of the United States). Historically, androgens and antifibrinolytic treatments have also been used as preventative treatment for HAE, however their use is declining with the availability of more-tolerable, HAE-specific therapies.

On-demand and preventative HAE therapies target one of three primary mechanisms. BERINERT, HAEGARDA, RUCONEST and CINRYZE are C1-INH replacement therapies. FIRAZYR is a bradykinin receptor, or B2R, antagonist, and KALBITOR, TAKHZYRO and ORLADEYO target plasma kallikrein. TAKHZYRO is a monoclonal antibody and KALBITOR and ORLADEYO are small molecule inhibitors.

On-demand therapies are taken as needed; BERINERT and RUCONEST are IV infusions approved for adult and pediatric patients, FIRAZYR is an SC injection, approved for adults 18 and older, and KALBITOR is a series of three SC injections, approved for patients 12 years and older. KALBITOR must be administered by a healthcare professional to monitor for the risk of anaphylactic reactions.

Preventative therapies are taken chronically. CINRYZE is an IV infusion and HAEGARDA is an SC injection; both are administered twice a week and are approved for adult and pediatric patients 6 years and older. TAKHZYRO is an SC injection generally administered every two weeks; however, dosing every four weeks may be considered in some patients. TAKHZYRO is approved for patients 2 years and older.

ORLADEYO is an oral capsule taken once daily with food for patients 12 years and older. Given that TAKHZYRO is an approved monoclonal antibody inhibitor of plasma kallikrein, if STAR-0215 is approved, we expect that it will compete most directly with TAKHZYRO.

We are aware of additional programs in development for HAE, which are focused largely on preventative approaches. For example, CSL Behring's garadacimab (CSL312), a factor XIIa-inhibitory monoclonal antibody, or FXIIa mAb, has completed Phase 3 development for preventative treatment and submitted regulatory applications for marketing approval in the United States and the European Union. Ionis Pharmaceuticals, Inc.'s donidalorsen (IONIS-PKK-LRx), an antisense inhibitor of prekallikrein synthesis has also completed Phase 3 development for preventative treatment. Pharvaris is developing two oral treatments, both of which are small molecule inhibitors of B2R: PHVS416, which has completed Phase 2 development for on-demand treatment and for preventative treatment, and PHVS719, which is in Phase 1 development for preventative treatment. KalVista Pharmaceuticals, Inc. has an oral small molecule plasma kallikrein inhibitor sebetralstat (KVD900) for on-demand treatment of HAE that has completed Phase 2 development (the Phase 2 trial for KVD824 for preventative treatment was terminated). Intellia Therapeutics is in Phase 1/2 trials for NTLA-2002, a CRISPR knockout of the prekallikrein gene *KLKB1*. BioMarin Pharmaceutical Inc. is in Phase 1/2 trials for BMN 331, a C1-INH gene therapy. ADARx Pharmaceuticals, Inc. has begun a Phase 1b clinical trial for ADX-324, a prekallikrein siRNA inhibitor. Preclinical development programs for preventative treatment include KalVista's oral FXIIa inhibitor and Kyowa Kirin and Pharming's *ex vivo* hematopoietic stem cell gene therapy (OTL-105).

STAR-0310

We are developing STAR-0310 for the treatment of moderate-to-severe AD. The key competitive factors affecting the success of STAR-0310, if approved, are likely to be its safety and tolerability, efficacy, frequency of dosing, method of administration, convenience, price, and the availability of coverage and reimbursement from government and other third-party payors. In the United States, the FDA has approved two oral JAK inhibitors for the treatment of AD: RINVOQ and CIBINQO, and in the European Union OLUMIANT is also approved for the treatment of AD. Additionally, the FDA has approved two biologics for the treatment of AD: DUPIXENT and ADBRY. Standard of care also includes systemic steroids and topical medications which can treat symptoms but do not address underlying disease. Moderate-to-severe patients who do not respond to topical prescription therapies typically turn to biologics as their next option, and, subsequently, to JAK inhibitors.

Both DUPIXENT and ADBRY are administered subcutaneously every two weeks, and work by targeting the Th2 inflammatory pathway (IL-4/13, and IL-13, respectively). RINVOQ and CIBINQO require daily oral administration and are only available to patients who do not sufficiently respond to systemic therapies including biologics. While these JAK inhibitors tend to have better efficacy than the two approved biologics, there are significant safety concerns including a boxed warning associated with JAK inhibitors.

We are aware of additional programs in development for AD, which are focused largely on biologic approaches. Late-stage programs include Galderma's nemolizumab, an IL-31 antibody, and Eli Lilly's lebrikizumab, an IL-13 antibody, which are under regulatory review for approval by the FDA. Lebrikizumab has been approved in the European Union as EBGLYSS. There are other companies that have product candidates in early-stage development for moderate-to-severe AD, including Anaptys Bio (ANB032), RAPT Therapeutics (RPT193), Nektar Therapeutics (rezpegaldesleukin), Aslan Pharmaceuticals (eblasakimab), Pfizer (etrasimod, PF-07275315 and PF-07264660), LEO Pharma (LEO 138559 and 152020), Akesobio (AK120), Connect Biopharma (rademikibart), Biosion (BSI-045B), Janssen (JNJ-67484703), Bayer (zabedosertib), Sanofi (rilzabrutinib), Apogee Therapeutics (APG777), InnoCare Pharma (ICP-332), Kymera Therapeutics (KTK-474), Q32 Bio (bempikibart) and GSK (GSK1070806).

Additionally, a new class of biologics is in clinical development targeting OX40, the same target as for STAR-0310. Amlitelimab (Sanofi) is an anti-OX40 ligand (OX40L) antibody that has started a Phase 3 trial. Rocatinlimab (Amgen) is an afucosylated OX40 receptor (OX40R) antibody currently in Phase 3 trials in AD. IMG-007 (Inmagene) is an OX40 receptor (OX40R) antibody in a proof-of-concept trial in AD.

Intellectual Property

We strive to protect the proprietary technologies that we believe are important to our business. This includes plans to pursue and maintain patent protection intended to cover the composition of matter of STAR-0215 and STAR-0310, their methods of use, and other related technologies and inventions that are important to our business. In addition to seeking patent protection, we also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our commercial success depends in part upon our ability to obtain and maintain patent and other proprietary protection for commercially important technologies, inventions and know-how related to our business, defend and enforce our intellectual property rights, in particular, our patent rights, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable intellectual property rights of others.

STAR-0215 Program

We own two patent families directed to STAR-0215. The first patent family is directed to the composition of matter of our product candidate STAR-0215 and its use in treating various plasma kallikrein associated disorders including HAE. This family includes applications filed in North America (such as Canada, the U.S., and Mexico), South America (such as Argentina and Brazil), Europe, Asia (such as China, Japan, and Korea), the Middle East (such as Israel, Saudi Arabia, United Arab Emirates, and Kuwait), and Australia. These applications, if granted, would expire in 2042, assuming all maintenance fees are paid. Depending upon the circumstances, additional patent term may be available in certain jurisdictions, *e.g.*, the U.S. and Europe, via patent term extensions or supplementary protection certificates.

In the second patent family, we own one International (PCT) patent application directed to methods of treating various plasma-kallikrein associated disorders, including HAE, with specific dosing regimens of the STAR-0215 antibody. Any national or regional stage applications derived from this PCT application, if filed and granted, would expire in 2043, assuming all maintenance fees are paid. Depending upon the circumstances, additional patent term may be available in certain jurisdictions, *e.g.*, the U.S. and Europe, via patent term extensions or supplementary protection certificates; however, only one patent directed to STAR-0215 may be extended.

Anti-OX40 Program

In our anti-OX40 program, we have in-licensed from Ichnos a U.S. provisional patent application directed to the composition of matter of our product candidate STAR-0310 and its use in treating AD and other disorders. Any non-provisional patent applications, if filed and granted, claiming priority to this application would expire in 2044, assuming all maintenance fees are paid. Depending upon the circumstances, additional patent term may be available in certain jurisdictions, *e.g.*, the U.S. and Europe, via patent term extensions.

In addition, we have also in-licensed six patent families from Ichnos directed to telazorlimab and telazorlimab-containing formulations, and their use. In particular, we have in-licensed one patent family directed to the telazorlimab composition of matter and its use with patents granted in North America (such as Canada, the U.S., and Mexico), South America (such as Brazil and Chile), Europe (such as Germany, France, Italy, Spain, Switzerland, and the UK), Asia (such as China, Japan, and Korea), and Australia. These patents are expected to expire in 2032, assuming all maintenance fees are paid. In the remaining patent families, we have in-licensed four pending U.S. patent applications and three pending European patent applications directed to telazorlimab uses and formulations, which if granted will expire from 2039 to 2040.

The patent positions for biopharmaceutical companies like us are generally uncertain and can involve complex legal, scientific and factual issues. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted and even challenged after issuance. As a result, we cannot guarantee that our STAR-0215 and STAR-0310 product candidates will be protected or remain protectable by enforceable patents, even if issued. We cannot predict whether the patent applications we are currently pursuing will issue as granted patents in any particular jurisdiction or whether the claims of any granted patent will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties. The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries where we may elect to file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office, or USPTO, in granting a patent. A United States patent term may be shortened, if a patent is terminally disclaimed by its owner, over another patent.

In the United States, the term of a patent covering an FDA-approved drug may be eligible for a patent term extension under The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, as compensation for the loss of patent term during the FDA regulatory review process. The period of extension may be up to five years beyond the expiration of the patent, but cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent among those eligible for an extension may be extended. Similar provisions are available in Europe and in certain other jurisdictions to extend the term of a patent that covers an approved drug. It is possible that an issued United States patent covering STAR-0215 or STAR-0310 may be entitled to a patent term extension. If either of our STAR-0215 or STAR-0310 product candidates receives FDA approval, we intend to apply for a patent term extension, if available, to extend the term of the patent that covers the approved product candidate. We also intend to seek patent term extensions in any jurisdictions where they are available. However, there is no guarantee that the applicable authorities, including the FDA, will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions.

In addition to patent protection, we may rely on other forms of regulatory and legislative non-patent exclusivity protection that are typically triggered by marketing approval of a product. In the United States, these include orphan drug exclusivity, pediatric exclusivity, new chemical entity exclusivity and, for biologics such as STAR-0215 and STAR-0310, reference product exclusivity. The European Union, which we refer to as the European Union or EU, and many other key markets outside the United States have comparable forms of such exclusivity. However, there is no guarantee that we will obtain any of these forms of exclusivity protection for STAR-0215, STAR-0310 or any future product candidate.

We also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes. However, trade secrets can be difficult to protect. Although we take steps to protect our proprietary information, including restricting access to our premises and our confidential information, as well as entering into agreements with our employees, consultants, advisors, contract research organizations, contract manufacturing organizations and potential collaborators, third parties may independently develop the same or similar proprietary information or may otherwise gain access to our proprietary information. As a result, we may be unable to meaningfully protect our trade secrets and proprietary information.

Manufacturing and Supply

We do not own or operate manufacturing facilities. We currently rely on third-party manufacturers and suppliers to make, package, label and distribute STAR-0215 and STAR-0310. We expect to continue to do so to meet our nonclinical, clinical and commercial needs for STAR-0215, STAR-0310, and any other product candidate. We plan to develop a drug device combination product for STAR-0215 and will need to rely on third-party contract manufacturers to manufacture any drug device combination product for STAR-0215 or any other product candidate. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities and have hired qualified individuals with significant development and manufacturing experience to oversee our relationships with our contract development and manufacturing partners. Our third-party manufacturers are required to manufacture STAR-0215, STAR-0310, and any future product candidates under current good manufacturing practices, or cGMPs, and other applicable laws and regulations. We have also adopted good inventory management and warehousing practices to minimize supply chain risks related to the manufacture of STAR-0215 and STAR-0310.

We have concluded process and formulation development for STAR-0215 and are set to start process characterization and subsequent validation. We believe we have scaled and optimized the process appropriately and continue to manufacture sufficient material to cover clinical needs. We are working on the development of the drug device and combination products for STAR-0215. Cell line, process and formulation development have begun for STAR-0310.

Human Capital

As of December 31, 2023, we had 59 full-time employees, 33 of whom were primarily engaged in research and development activities. A total of 14 of our full-time employees have Ph.D. degrees. None of our employees are represented by a labor union and we believe our relations with our employees are good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. Our cash compensation, which consists of base salary and annual bonuses based upon bonus targets, are market-based and are designed to attract, retain and motivate our employees. The principal purposes of our equity incentive plans are also to attract, retain and motivate employees, selected consultants and the members of our board of directors through the granting of stock-based compensation awards, which have solely consisted of stock options, and to align such awards with the interests of our stockholders. We provide a comprehensive benefits package to help employees manage health, well-being, finances, and life outside of work, including health insurance, dental and vision insurance, life insurance, short-term and long-term disability insurance, paid sick leave, a 401(k) plan, including a matching contribution, a health savings account program, and paid vacation time.

We have pride in our people and work to create an inclusive environment where diversity is seen as a benefit and our differences are appreciated. We consider our people to be one of our biggest assets and believe that our investment in them through development opportunities, engagement, and retention is critical to our success.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of drugs and biologics. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs and Biologics in the United States

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and related regulations. Biological products are licensed for marketing under the Public Health Service Act, or PHSA, and subject to regulation under the FDCA and related regulations. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug or biological product in the United States must typically secure the following:

- completion of preclinical laboratory tests in compliance with the FDA's good laboratory practice, or GLP, regulations;
- design of a clinical protocol and submission to the FDA of an IND which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug product for each proposed indication;
- submission to the FDA of a new drug application, or NDA, for a drug candidate product and a biologics license application, or BLA, for a biological product requesting marketing for one or more proposed indications;
- review of the request for approval by an FDA advisory committee, where appropriate or if applicable;
- completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP requirements to assure the product's identity, strength, quality and purity;
- completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Before a sponsor begins testing a compound with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured substance or active pharmaceutical ingredient and the formulated product, as well as in vitro and animal studies to assess the safety and activity of the product candidate for initial testing in humans and to establish a rationale for therapeutic use. These studies are typically referred to as IND-enabling studies. The conduct of preclinical studies is subject to federal regulations and requirements, including GLP regulations and standards and the United States Department of Agriculture's Animal Welfare Act, if applicable. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is a request for FDA authorization to administer an investigational product candidate to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biologic that is not the subject of an approved NDA or BLA. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period

is designed to allow the FDA to review the IND to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency. At any time during this 30-day period, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or CMCs. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical trial or to suspend an ongoing trial. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, a trial may only resume after the FDA has notified the sponsor that the trial may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the trial can proceed.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency. Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board committee. This group provides authorization for whether a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient INDs for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol.

When considering an IND for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with the initiation, conduct, or completion of clinical trials that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its drug products available for expanded access; however, as required by the 21st Century Cures Act, or Cures Act, passed in 2016, sponsors are required to make policies for evaluating and responding to requests for expanded access for patients publicly available upon the earlier of initiation of a Phase 2 or Phase 3 clinical trial, or 15 days after the investigational drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy.

In May 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a phase 1 clinical trial and that are undergoing

investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Human Clinical Studies in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol, and any subsequent material amendment to the protocol, must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. The clinical investigation of an investigational drug or biological product is generally divided into four phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The four phases of an investigation are as follows:

- ***Phase 1.*** Phase 1 studies include the initial introduction of an investigational new drug or biological product into humans. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug or biological product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.

- ***Phase 2.*** Phase 2 includes the controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug or biological product for a particular indication(s) in patients with the disease or condition under trial, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug or biological product. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.

- ***Phase 3.*** Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug or biological product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug or biological product, and to provide an adequate basis for product approval.

- ***Phase 4.*** Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company's designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Moreover, as noted above, a pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In December 2022, with the passage of the Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

Under the PHSA, sponsors of certain clinical trials of certain FDA-regulated products, including prescription drugs and biologics, are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health. With the issuance of pre-notices for voluntary corrective action and several notices of non-compliance during the past two years, the FDA has signaled the government's willingness to enforce these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues.

Clinical Studies Outside the United States in Support of FDA Approval

Sponsors frequently conduct clinical trials at sites outside the United States. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical studies. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

The acceptance by the FDA of study data from clinical trials conducted outside the United States in support of U.S. approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Interactions with the FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the product candidate; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, there are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-NDA meetings as well as end of phase meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product candidate, including, for example, meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A Type D meeting is focused on a narrow set of issues (should be limited to no more than two focused topics) and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a

practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure.

Manufacturing and Other Regulatory Requirements

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the candidate product 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 drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Specifically, the FDA's regulations require that pharmaceutical products be manufactured in specific approved facilities and in accordance with cGMPs. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and 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. Manufacturers and other entities involved in the manufacture and distribution of approved pharmaceuticals are required to register their establishments with the FDA and some state agencies, and they are subject to periodic unannounced inspections by the FDA for compliance with cGMPs and other requirements. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

Inspections must follow a "risk-based schedule" that may result in certain establishments being inspected more frequently. Manufacturers may also have to provide, on request, electronic or physical records regarding their establishments. Delaying, denying, limiting, or refusing inspection by the FDA may lead to a product being deemed to be adulterated. Changes to the manufacturing process, specifications or container closure system for an approved product are strictly regulated and often require prior FDA approval before being implemented. The FDA's regulations also require, among other things, the investigation and correction of any deviations from cGMP and the imposition of reporting and documentation requirements upon the sponsor and any third-party manufacturers involved in producing the approved product.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, or PREA, an application or supplement thereto 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. Generally, a sponsor must submit an initial pediatric study plan before the date on which the sponsor submits the required data and no later than either 60 days after the date of the end-of-phase 2 meeting or such other time as agreed upon between FDA and the sponsor. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The sponsor, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

For investigational products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the sponsor, 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 deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. Pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, the FDA must send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. FDASIA further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response.

Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA.

Submission and Review of an NDA or BLA by the FDA

In order to obtain approval to market a drug or biological product in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the proposed drug product for the proposed indication, and the safety, purity and potency of the biological product for its intended indication. The application must include all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's CMCs and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from 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 effectiveness of the investigational drug product and the safety, purity and potency of the biological product to the satisfaction of the FDA.

The application is the vehicle through which sponsors formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new product candidate must be the subject of an approved NDA or BLA before it may be commercialized in the United States. Under federal law, the submission and review of most applications is subject to an application user fee, which may be substantial (for example, for federal fiscal year 2024 this application fee is approximately $4.05 million), and the sponsor of an approved application is also subject to an annual program fee, which for federal fiscal year 2024 is $416,734 per eligible prescription product. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses. If an application is withdrawn prior to the FDA acceptance for filing, 75% of these fees may be refunded to the sponsor. If an application is withdrawn after filing, a lower portion of these fees may be refunded in certain circumstances.

Following submission of an NDA or BLA, the FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. In pertinent part, FDA's regulations state that an application "shall not be considered as filed until all pertinent information and data have been received" by the FDA. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the applicant. Typically, an RTF will be based on administrative incompleteness, such as clear omission of information or sections of required information; scientific incompleteness, such as omission of critical data, information or analyses needed to evaluate safety and efficacy or provide adequate directions for use; or inadequate content, presentation, or organization of information such that substantive and meaningful review is precluded. 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. The FDA has agreed to specified performance goals in the review process of NDAs and BLAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within ten months from the date on which FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. The review process and the Prescription Drug User Fee Act, or PDUFA, goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA or BLA submission, including drug component manufacturing (e.g., active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. With passage of FDORA, Congress clarified the FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to the FDA as well as other persons holding study records or involved in the study process.

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

The FDA's Decision on an NDA or BLA

The FDA reviews an application to determine, among other things, whether the product is safe and whether it is effective for its intended use(s), with the latter determination being made on the basis of substantial evidence. The term "substantial evidence" is defined under the FDCA as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the product involved, on the basis of which it could fairly and responsibly be concluded by such experts that the product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." The FDA has interpreted this evidentiary standard to require at least two adequate and well-controlled clinical trials to establish effectiveness of a new product. Under certain circumstances, however, FDA has indicated that a single trial with certain characteristics and additional information may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate efficacy.

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter, or CRL, or an approval letter. To reach this determination, the FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety and efficacy in the NDA or BLA. This assessment is also informed by other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time- consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the applicant will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the applicant an additional six month extension to respond. The FDA has committed to reviewing resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The FDA has taken the position that a CRL is not final agency action making the determination subject to judicial review. Rather, for those seeking to challenge the FDA's CRL decision, the FDA has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. That is, the approval will be limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA 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.

Under the Ensuring Innovation Act, which was signed into law in April 2021, the FDA must publish action packages summarizing its decisions to approve new drugs and biologics within 30 days of approval of such products. To date, CRLs are not publicly available documents.

Expedited Review Programs

The FDA is authorized to expedite the development of candidate products and review of applications in several ways. None of these expedited programs changes the standards for approval but each may help expedite the development or approval process governing product candidates.

- *Fast Track designation*. The sponsor of a product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Candidate products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track application before the application is complete, a process known as rolling review.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.

- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.

- *Accelerated approval.* Drug or biologic 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. Accelerated approval means that a product candidate 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 a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

With passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded; require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months (until the study is completed); and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the FDA to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

- *Regenerative advanced therapy.* With passage of the Cures Act, in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or *condition* and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

Rare Pediatric Disease Priority Review Vouchers

With enactment of the FDASIA, Congress authorized the FDA under Section 529 of the FDCA to award priority review vouchers, or PRVs, to sponsors of certain rare pediatric disease product applications. This provision, which was further amended by the Advancing Hope Act of 2016, is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases.

Under this program, a sponsor who receives approval for a new drug or biologic for a rare pediatric disease may qualify for a PRV, which can be redeemed for priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product that receives a PRV may transfer, including by sale, the PRV to another sponsor and that PRV may be further transferred any number of times before it is used. A PRV entitles the holder to designate a single human drug application submitted under Section 505(b)(1) of the FDCA or Section 351 of the PHSA as qualifying for a priority review. An FDA priority review may expedite the review process of a marketing application reducing the review time from ten months after formal acceptance of the file to six months after formal acceptance of the file.

Specifically, in order for a sponsor to receive a PRV in connection with approval of a BLA or NDA, the investigational product must be designated by the FDA as a product for a rare pediatric disease prior to submission of the marketing application. A rare pediatric disease is a disease that is serious or life-threatening and which primarily affects individuals aged from birth to 18 years and fewer than 200,000 people in the United States. Alternatively, the disease may affect more than 200,000 people in the United States if there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition, to qualify for a PRV, the sponsor must request the voucher and the BLA or NDA must itself be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient.

The Rare Pediatric Disease PRV program was originally set to expire in October 2020 but was extended for an additional six years with passage of the Coronavirus Response and Relief Supplemental Consolidated Appropriations Act of 2021. Under the current statutory sunset provisions, the FDA may only award a rare pediatric disease PRV if a sponsor has a rare pediatric disease designation for the drug or biologic before September 30, 2024, and the NDA or BLA for the product is approved before September 30, 2026.

Post-Approval Regulation

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

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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

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

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug or biologic. 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. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, or HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. Moreover, with passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. In addition, in October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use.

Generic Drugs and Regulatory Exclusivity

In 1984, with passage of the Hatch-Waxman Act, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Under the Hatch-Waxman Act, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical trials, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application.

Biosimilars and Regulatory Exclusivity

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA, was enacted in the United States and included the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA amended the PHSA to create an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, the FDA has approved a number of biosimilars and it has also issued numerous guidance documents outlining its approach to reviewing and licensing biosimilars and interchangeable biosimilars under the PHSA.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is "biosimilar to" or "interchangeable with" a previously approved biological product or "reference product." In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of first licensure of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. In December 2022, Congress clarified through FDORA that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biological product intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals 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 for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA or BLA for the candidate product. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not shorten the PDUFA goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the PDUFA application fee.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same indication for seven years, except in certain limited circumstances. Orphan drug exclusivity will not bar approval of another product under certain circumstances, including if the company with orphan drug exclusivity is not able to meet market demand or the subsequent product with the same drug for the same condition is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. Orphan drug exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different indications. Orphan drug exclusivity also could block the approval of one of our product candidates for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication for which we are seeking approval, or if our product candidate is determined to be contained within the scope of the competitor's product for the same indication or disease. If a drug or biologic designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity, including orphan drug exclusivity. For drug products, the six month regulatory exclusivity may be attached to the term of any existing patent or regulatory exclusivity available under the Hatch-Waxman Act provisions of the FDCA. For biologic products, the six month period may be attached to any existing regulatory exclusivities but not to any patent terms. This six-month exclusivity may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of the IND and the submission date of an application, plus the time between the submission date of an NDA or BLA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The USPTO reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Federal and State Data Privacy Laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities, including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. While we are not a covered entity, as a business associate, we could be subject to penalties, including criminal penalties, and contractual damages if we knowingly obtain or further disclose PHI from a covered entity, such as a health care provider or clinical research site, and therefore we must ensure the proper authorizations are in place before we, or our vendors or business partners, obtain access to any PHI.

In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

The California Consumer Privacy Act, or CCPA, imposes many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the European Union's General Data Protection Regulation, or GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. Additionally, starting on January 1, 2023, the California Privacy Rights Act, or CPRA, significantly modified the CCPA, including by expanding consumers' rights, particularly with respect to certain sensitive personal information, and creating new principles, such as data minimization, purpose limitation and storage limitation. The CPRA also created a new state agency with authority to implement and enforce the CCPA and the CPRA. The CCPA and CPRA could impact our business activities depending on how they are interpreted and exemplify the vulnerability of our business to not only cyber threats but also the evolving regulatory environment related to personal data and individually identifiable health information. These provisions may apply to some of our business activities.

In addition to California, eleven other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond, including New Hampshire and New Jersey. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states (such as Vermont) are considering such legislation in 2024. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Review and Approval of Drug Products in the European Union

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable foreign regulatory authorities before it can commence clinical

trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with GLP principles as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Trial Approval in the European Union

On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one European Union Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the European Medicines Agency, or the EMA, and available to clinical trial sponsors, competent authorities of the European Union Member States and the public.

Beyond streamlining the process, the new regulation includes 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 European Union Member States in which an application for authorization of a clinical trial has been submitted, which we refer to as the Member States concerned. Part II is assessed separately by each 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 Member State concerned. However, overall related timelines will be defined by the Clinical Trials Regulation.

The new regulation did not change the preexisting requirement that a sponsor must obtain prior approval from the competent national authority of the European Union Member State in which the clinical trial is to be conducted. If the clinical trial is conducted in different European Union Member States, the competent authorities in each of these European Union Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific study site after the applicable ethics committee has issued a favorable opinion.

The Clinical Trials Regulation foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the Clinical Trials Regulation varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the Clinical Trials Regulation.

Parties conducting certain clinical trials must, as in the United States, post clinical trial information in the EU at the EudraCT website: https://eudract.ema.europa.eu.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority MEdicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated agency contact and rapporteur from the Committee for Medicinal Products for Human Use, or CHMP, or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level.

Pediatric Studies

In the European Economic Area, or EEA, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA's pediatric committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date.

Marketing Authorization

In the EEA, medicinal products can only be commercialized after obtaining a marketing authorization. Marketing authorizations, or MAs, for medicinal products may be obtained through several different procedures founded on the same basic regulatory process.

The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union Member States. The centralized procedure is compulsory for medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases. It is optional for those products that are highly innovative or for which a centralized process is in the interest of patients. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a marketing authorization application is 210 days, excluding clock stops, when additional written or oral information is to be provided by the sponsor in response to questions asked by the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases. These are defined as circumstances in which a medicinal product is expected to be of a "major public health interest." Three cumulative criteria must be fulfilled in such circumstances: the seriousness of the disease, such as severely disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In these circumstances, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure provides for approval by one or more other concerned European Union Member States of an assessment of an application for marketing authorization conducted by one European Union Member State, known as the reference European Union Member State. In accordance with this procedure, a sponsor submits an application for marketing authorization to the reference European Union Member State and the concerned European Union Member States. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference European Union Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned European Union Member States which, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned European Union Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all European Union Member States.

Conditional Approval

In particular circumstances, E.U. legislation (Article 14–a Regulation (EC) No 726/2004 (as amended by Regulation (EU) 2019/5) and Regulation (EC) No 507/2006 on Conditional Marketing Authorizations for Medicinal Products for Human Use) enables applicants to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if (1) the product candidate is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases; (2) the product candidate is intended to meet unmet medical needs of patients; (3) a marketing authorization may be granted prior to submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required; (4) the risk-benefit balance of the product candidate is positive; and (5) it is likely that the applicant will be in a position to provide the required comprehensive clinical trial data. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new clinical studies and with respect to the collection of pharmacovigilance data. Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization, but applicants can also request EMA to conduct an accelerated assessment, for instance in cases of unmet medical needs.

Exceptional Circumstances

A MA may also be granted "under exceptional circumstances" when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This MA is close to the conditional MA as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a MA. However, unlike the conditional MA, the applicant does not have to provide the missing data and will never have to. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable. Under these procedures, before granting the MA, the EMA or the competent authorities of the European Union 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. Except conditional MAs, MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance.

Regulatory Requirements After Marketing Authorization

Following marketing authorization of a medicinal product in the European Union, the holder of the authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include compliance with the European Union's stringent pharmacovigilance or safety reporting, as well as rules potentially requiring post-authorization studies and additional monitoring obligations. In addition, the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory, must also be conducted in strict compliance with applicable European Union laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with European Union cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union. Finally, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union notably under Directive 2001/83EC, as amended, and European Union Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

Regulatory Data Protection

In the European Union, new chemical entities approved on the basis of a complete independent data package qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity pursuant to Regulation (EC) No 726/2004, as amended, and Directive 2001/83/EC, as amended. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic (abbreviated) application for a period of eight years. During the additional two-year period of market exclusivity, a generic marketing authorization application can be submitted, and the innovator's data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric Exclusivity

Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Orphan Drug Designation and Exclusivity

Regulation (EC) No 141/2000 and Regulation (EC) No. 847/2000 provide that a product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that (1) the product is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in ten thousand persons in the European Union when the application is made, or (2) the product is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and, without incentives, it is unlikely that that the marketing of the product in the European Union would generate sufficient return to justify the necessary investment in its development. In addition to either of these conditions, the sponsor must demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the sponsor's medicinal product will be of significant benefit to those affected by that condition.

Once authorized, orphan medicinal products are entitled to ten years of market exclusivity in all European Union Member States and, in addition, a range of other benefits during the development and regulatory review process, including scientific assistance for trial protocols, European Union-wide authorization through the centralized marketing authorization procedure and a reduction or elimination of registration and marketing authorization fees. During the period of market exclusivity, a marketing authorization may not be granted in the European Union for a "similar medicinal product" to the authorized orphan product for the same indication, except in the following limited circumstances: (i) the marketing authorization holder for the original orphan medicinal product consents to the authorization of the second orphan medicinal product; (ii) the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities of the product; or (iii) it is established that the second product is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication The period of market exclusivity may be reduced to six years if, at the end of the fifth year, it can be demonstrated on the basis of available evidence that the original orphan medicinal product no longer meets the criteria for orphan designation, including if it is sufficiently profitable not to justify maintenance of market exclusivity.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom's withdrawal from the European Union took place on January 31, 2020. The European Union and the United Kingdom reached an agreement on their new partnership in the Trade and Cooperation Agreement, or the Agreement, which was applied provisionally beginning on January 1, 2021, and which entered into force on May 1, 2021. The Agreement focuses primarily on free trade by ensuring no tariffs or quotas on trade in goods, including healthcare products such as medicinal products. Thereafter, the European Union and the United Kingdom will form two separate markets governed by two distinct regulatory and legal regimes, except that Northern Ireland will continue to broadly follow European Union laws as further described below. As such, the Agreement seeks to minimize barriers to trade in goods while accepting that border checks will become inevitable as a consequence that the United Kingdom is no longer part of the single market. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law whereas Northern Ireland continues to be subject to European Union rules under the Northern Ireland Protocol.

In February 2023, the UK government and the European Commission announced a political agreement in principle to replace the Northern Ireland Protocol with a new set of arrangements, known as the "Windsor Framework". This new framework fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. In particular, the MHRA will be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. A single UK-wide MA will be granted by the MHRA for all medicinal products to be sold in the United Kingdom, enabling products to be sold in a single pack and under a single authorization throughout the United Kingdom. The Windsor Framework was approved by the EU-UK Joint Committee in March 2023 and the UK government and the European Union will enact legislative measures to bring it into law. In June 2023, the MHRA announced that the medicines aspects of the Windsor Framework will apply from January 1, 2025. The Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or HMR, is the primary legal instrument for the regulation of medicines in the United Kingdom. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union.

EU laws which have been transposed into UK law through secondary legislation continue to be applicable as "retained EU law". However, new legislation such as the (EU) Clinical Trials Regulation will not be applicable in Great Britain. Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety and efficacy of pharmaceutical products, clinical trials, MAs, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, the United Kingdom is no longer covered by the centralized procedures for obtaining EU-wide MAs from the EMA, and a separate MA will be required to market our product candidates in the United Kingdom. A new international recognition framework has been in place since January 1, 2024, whereby the MHRA will have regard to decisions on the approval of MAs made by the EMA and certain other regulators when determining an application for a new MA for Great Britain.

General Data Protection Regulation

Many countries outside of the United States maintain rigorous laws governing the privacy and security of personal information. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also 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. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. and includes parallel obligations to those set forth by GDPR.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision in July 2023. The adequacy decision will permit U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, 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 healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. 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 a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that 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 a particular drug candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States.

In March 2010, President Obama signed the ACA into law. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act.

These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 (PAYGO) sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the TCJA, which was signed by President Trump on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. In December 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In June 2021, the U.S. Supreme Court dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden revoked those orders and issued a new Executive Order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this Order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020, President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. In January 2024, the FDA approved Florida's plan for Canadian drug importation.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act of 2022, or the IRA, has been delayed by Congress to January 1, 2032.

In September 2021, acting pursuant to an executive order signed by President Biden, the HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the IRA was signed into law by President Biden. The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the IRA subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the IRA by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The IRA also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The IRA also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year, and shifts some of the cost sharing for such costs to drug manufacturers.

In June 2023, Merck & Co. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

In addition, at the federal level in the United States, in February 2023, CMS announced a model that would allow CMS to pay less for drugs and biologics approved through FDA's accelerated approval pathway before a clinical benefit has been confirmed by the required confirmatory studies. If implemented, this would impact the price that CMS would pay for Medicare Part B drugs and biologics that fit within CMS's criteria for lower payments.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers and wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription pharmaceutical and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that 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 a particular drug candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. 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 products, if approved in those countries.

Healthcare Law and Regulation

Health care providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements.

Restrictions under applicable federal and state health care laws and regulations, include the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program, such as Medicare and Medicaid; the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government; HIPAA, which imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program; the Foreign Corrupt Practices Act which prohibits companies and their intermediaries from making, or offering or promising to make, improper payments to non-United States officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment; and the federal transparency requirements known as the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the CMS, within the HHS, information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Further, some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Our Corporate Information

Our executive offices are located at 75 State Street, Suite 1400, Boston, Massachusetts, 02109, and our telephone number is (617) 349-1971. Our website address is www.astriatx.com. The information contained on, or that can be accessed through, our website is not a part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available free of charge on our website located at www.astriatx.com as soon as reasonably practicable after they are filed with or furnished to the Securities and Exchange Commission, or the SEC. These reports are also available at the SEC's Internet website at www.sec.gov. Our website and the information contained therein or connected thereto are not intended to be incorporated into this Annual Report on Form 10-K.

A copy of our Corporate Governance Guidelines, Code of Business Conduct and Ethics and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee are posted on our website, www.astriatx.com, under "For Investors — Corporate Governance".

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing business environment that involves risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below, some of which have manifested and any of which may occur in the future, and in other sections of this Annual Report on Form 10-K and in our subsequent filings with the U.S. Securities and Exchange Commission, or SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

Our business is entirely dependent on the success of STAR-0215 as a potential treatment for HAE and STAR-0310 as a potential treatment for AD.

Our business is entirely dependent on the success of STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the potential treatment of hereditary angioedema, or HAE, and STAR-0310, a potential best-in-class monoclonal antibody OX40 antagonist that incorporates YTE half-life extension technology in preclinical development for the potential treatment of atopic dermatitis, or AD. We presented results from a Phase 1a clinical trial of STAR-0215 in healthy subjects in December 2022, February 2023, November 2023 and February 2024. We initiated the Phase 1b/2 ALPHA-STAR trial of STAR-0215 in patients with HAE in February 2023. We expect to report initial proof-of-concept data in patients with HAE in the first quarter of 2024. If the results from ALPHA-STAR are positive, we expect to progress STAR-0215 directly to a Phase 3 pivotal trial which we anticipate initiating in the first quarter of 2025. We also expect to submit an investigational new drug application, or IND, for STAR-0310 by the end of 2024 and, if the IND is cleared, we anticipate initiating a Phase 1a clinical trial of STAR-0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of STAR-0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026. We cannot give any assurance that we will generate preclinical, clinical or other data for STAR-0215 or STAR-0310 sufficiently supportive to receive regulatory approval, which will be required before either can be commercialized. We may, among other things, experience difficulties with patient recruitment, enrollment and retention, quality and provision of materials and supplies necessary to manufacture sufficient quantities of drug product to meet our preclinical study and clinical trial needs on a timely basis, or safety signals or pharmacodynamic, pharmacokinetic or efficacy data that does not align with our target profile for STAR-0215 or STAR-0310. STAR-0215 and STAR-0310 will require significant preclinical, clinical and nonclinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales.

We plan to develop a drug device combination for STAR-0215. There is no assurance that we will be successful in developing a drug device combination on a timely basis or at all, which could impede our development and commercialization strategy for STAR-0215. The U.S. Food and Drug Administration, or FDA or other comparable foreign regulatory authorities could require nonclinical studies or clinical trials to support introduction of a drug device combination, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay approval of STAR-0215 and jeopardize our ability to commence product sales and generate revenue from STAR-0215, if approved.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of STAR-0215 and STAR-0310, which may never occur. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize STAR-0215 or STAR-0310, we may not be able to generate sufficient revenue to continue our business and our business would be materially harmed.

Interim topline, initial proof-of-concept and preliminary data from our clinical trials that we announce or publish from time to time may change as more study participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline, initial proof-of-concept or preliminary data from our clinical trials. Interim data or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data we previously published. As a result, interim topline, initial proof-of-concept and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary data and final data could significantly harm our reputation and business prospects.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and results of later stage clinical trials may not enable marketing approval.

The outcome of preclinical studies and early clinical trials, along with interim results from clinical trials, may not be predictive of the success of later clinical trials and may not be supportive of moving into later clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant clinical and regulatory delays or setbacks in late-stage clinical trials after achieving positive interim or final results in preclinical studies or early development, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support advancing into later clinical trials or approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial or trials to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their product candidates. Even if we, or any future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities, as the case may be, may disagree and not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, differences in study design, changes in and adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to receive positive results in preclinical studies or clinical trials of STAR-0215, STAR-0310 or any other future product candidate, the development timeline and regulatory approval and commercialization prospects for such product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. If clinical trials of a product candidate fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining approval from the FDA of a biologics license application, or BLA, which would be required for approval of STAR-0215 and STAR-0310, or a new drug application, or NDA. Comparable foreign regulatory authorities, such as the European Medicines Agency, or EMA, require similar approvals. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy in humans of any product candidate that we may choose to develop before we, or they, will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials we initiate will be conducted as planned or completed on schedule, or at all. In addition, in the case of STAR-0215, for which we have designed our clinical trials, and plan to design future trials, with the goal of demonstrating that it can be dosed in HAE patients every three months or potentially less frequently, clinical trials will necessarily be longer given the length of time between doses in the trials. We also expect that later stage clinical trials we conduct for STAR-0310 will be larger and more expensive when compared to those we are conducting for STAR-0215 because AD, the indication for which we are developing STAR-0310, is not a rare disease. Further, the clinical development of product candidates is susceptible to the risk of failure or significant delays at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, failure to utilize clinically appropriate efficacy or safety targets or measurements in a clinical trial for the disease or patient population being studied, failure to have a sufficient number of patients in a clinical trial to establish sufficient safety or efficacy to enable moving into a later stage clinical trial (such as a Phase 3 trial) or regulatory approval, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, failure to enroll a sufficient number of patients on a timely basis or at all, failure to retain a sufficient number of patients to complete any of our trials, determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable, or the need to conduct additional studies or add cohorts to a trial before advancing into the next stage of development. Certain of these risks are heightened in the context of drug development for treatments for rare diseases, in which non-traditional study designs, and often smaller trials are utilized, to demonstrate efficacy and safety, including open-label studies, single arm studies, non-inferiority studies, studies utilizing active comparators or studies utilizing natural history data, biomarkers or other forms of surrogate endpoints, may be utilized due to the challenges inherent in designing and conducting clinical trials for severe diseases with small patient populations. In addition, we may amend the clinical trial protocol to address any issues that we observe as a trial is progressing, including in response to factors impacting safety and the data collected or to adapt the study design to include more clinically appropriate safety or efficacy targets or measurements, or we may be required to make certain changes to clinical trial protocols in response to issues raised by the FDA, the institutional review board, or IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and could delay, interrupt, or limit the conduct of the clinical trial. If we terminate or experience delays in the completion of any clinical trials, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed. 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.

It is possible that even if a product candidate that we choose to develop has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in any clinical trials we conduct, we may fail to detect toxicity of or intolerability caused by a product candidate, or mistakenly believe that a product candidate is toxic or not well tolerated when that is not in fact the case. We have not previously submitted an NDA or BLA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. Moreover, developing biologics is highly complex and any delay or problems in such development, including with third party contract manufacturers that we use to make and develop the drug substance and drug substance for our product candidates, may impede our ability to successfully complete clinical development of STAR-0215, and successfully initiate and complete clinical development of STAR-0310 or any future biologic product candidates we pursue and obtain FDA approval in a timely manner, if at all. Any inability to complete clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (1) we, or any future collaborators, are required to modify our trial designs, such as required modifications with respect to patient populations, endpoints, comparators or trial duration, (2) we, or any future collaborators, are required to conduct additional clinical trials or other testing of a product candidate beyond the trials and testing that we, or they contemplate, (3) we, or any future collaborators, are unable to successfully commence on a timely basis or complete clinical trials of a product candidate or other testing, (4) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (5) there are unacceptable safety concerns associated with a product candidate, we, or any future collaborators, may:

- be delayed in obtaining marketing approval for such product candidate;
- not obtain marketing approval at all;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;

- obtain marketing approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings:

- be subject to additional post-marketing testing or other requirements, such as a Risk Evaluation and Mitigation Strategy, or REMS, program; or

- be required to remove the product from the market after obtaining marketing approval.

Given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. Our failure to successfully complete clinical trials of a product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any product candidate would significantly harm our business.

Adverse events or undesirable side effects caused by, or other unexpected properties of, a product candidate may be identified during development that could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, a product candidate could cause us, any future collaborators, an IRB or regulatory authorities to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If any such product candidate is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any future collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many product candidates that initially showed promise in clinical or earlier stage testing have later been found to cause adverse events or undesirable or unexpected side effects that prevented further development of the product candidates.

If we, or any future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of a product candidate, potential marketing approval or commercialization of such product candidate could be delayed or prevented.

We, or any future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval or commercialization of a product candidate, including:

- clinical trials may produce unfavorable, inconclusive or insufficient results;

- we, or any future collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials, expand clinical trials or abandon product development programs;

- the number of patients required for clinical trials may be larger than we, or any future collaborators, anticipate, particularly with respect to STAR-0310, which is being developed as a potential treatment for AD which, unlike HAE, is not a rare disease;

- patient enrollment in these clinical trials may be slower than we, or any future collaborators, anticipate, particularly with respect to STAR-0215, which is being developed as a potential treatment for HAE, a rare disease, which has a significant number of approved products and products in clinical development, or participants may drop out of these clinical trials at a higher rate than we, or any future collaborators, anticipate or the duration of these clinical trials may be longer than we anticipate;

- the cost of planned clinical trials may be greater than we anticipate;

- our third-party contractors or those of any future collaborators, including those manufacturing such product candidate or components or ingredients thereof, including a suitable presentation of a product candidate, such as a pre-filled syringe, or any drug device combination for a product candidate, or conducting clinical trials on our behalf or on behalf of any future collaborators, may fail to comply with regulatory requirements, program timelines or meet their contractual obligations to us or any future collaborators in a timely manner or at all;

- regulators or IRBs may not authorize us, any future collaborators or our or their investigators to commence, conduct or continue a clinical trial at a prospective trial site or may not approve a protocol amendment to an ongoing clinical trial;

- we, or any future collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial's duration;

- we, or any future collaborators, may have to delay, suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, or restrictions imposed by applicable governmental authorities due to public health crises, pandemics or epidemics;

- regulators or IRBs may require that we, or any future collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;

- the FDA or comparable foreign regulatory authorities may disagree or subsequently find fault with our, or any future collaborators', clinical trial designs, including the size of the trials or inclusion or exclusion criteria, or our or their interpretation of data from preclinical studies and clinical trials or may require us to conduct a comparator trial in lieu of a placebo-controlled trial;

- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any future collaborators, enter into agreements for clinical, commercial supplies or drug device combinations for our product candidates;

- we are unable to develop or obtain a supplier for a suitable drug device combination for STAR-0215, or any other product candidate for which we seek to develop a drug device combination, that meets the requirements of the FDA or comparable foreign regulatory authorities;

- adequacy of or changes in our manufacturing process or the product formulation or method of delivery;

- the supply or quality of drug product or drug substance, raw materials or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; 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 to obtain marketing approval.

In addition, we may amend clinical trial protocols to address any issues that we observe as a trial is progressing, including in response to factors impacting safety and the data collected or to adapt the study design to include more clinically appropriate safety or efficacy targets or measurements, or we may be required to make certain changes in response to issues raised by the FDA, IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and could delay, interrupt, or limit the conduct of the clinical trial. If we terminate or experience delays in the completion of any clinical trials, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed. 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.

We are planning to conduct clinical trials outside of the United States, which are subject to the risks set forth above, and certain additional risks, such as unforeseen global instability, including political instability or geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine and the conflict in the Middle East), terrorist activity, unstable governments and legal systems, natural disasters or instability from public health crises, pandemics and epidemics, in or around any countries in which we conduct clinical trials. Such additional risks could affect our ability to enroll patients in clinical trials in these countries, prevent patients already enrolled from completing such clinical trials, and/or cause other trial delays or otherwise adversely impact such clinical trials.

Product development costs for us, or any future collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of any future product candidate. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical development or clinical trial delays also could shorten any periods during which we, or any future collaborators, may have the exclusive right to commercialize product candidates or allow our competitors, or the competitors of any future collaborators, to bring products to market before we, or any future collaborators, do or closer in proximity to the launches of our products or those of our collaborators, and impair our ability, or the ability of any future collaborators, to successfully commercialize product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any future product candidates.

If we, or any future collaborators, experience delays or difficulties in the enrollment of patients in clinical trials, our or their receipt of necessary regulatory approvals could be delayed or prevented.

We, or any future collaborators, may not be able to initiate or continue clinical trials for STAR-0215, STAR-0310 or any other future product candidate if we, or they, are unable to locate and enroll, and maintain the enrollment of, a sufficient number of eligible patients to participate in clinical trials as required by the FDA or comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any existing or newly approved drugs that may be approved for the indications we are investigating.

Our ability to successfully initiate and complete any clinical trial for STAR-0215 as a potential treatment for HAE, including our planned Phase 3 pivotal trial, assuming favorable results from the Phase 1b/2 ALPHA-STAR trial, for STAR-0310 as a potential treatment for AD, including the Phase 1a clinical trial we plan to begin in 2025 (assuming we successfully and timely submit an IND by the end of 2024), or for any other future product candidate for the potential treatment of any rare disease or any other indication will be dependent upon our ability to enroll, and maintain the enrollment of, a sufficient number of patients with such disease, which will be subject to a number of risks and uncertainties. For example, rare diseases, including HAE, have small patient populations and often have only a limited number of specialist physicians that regularly treat such patients. Further, these specialized sites typically treat a range of diseases and, at any point in time, may have constrained resources and capacity to handle clinical trials. In addition, approved products are available for the treatment of HAE, and additional products may become commercially available during the clinical development of

STAR-0215, and therefore patients and their healthcare providers may feel satisfied with their treatments. As a result, patients may not feel the need to participate in a clinical trial for another product candidate for the same disease or the criteria for the trial may not allow patients on such other therapies to enroll in the trial. Additionally, in the case of HAE, diagnosis is often delayed from onset of symptoms and patients that might be eligible for enrollment in our trials may not have been diagnosed and therefore are unaware of such eligibility. Finally, other companies are and will be conducting clinical trials in HAE or may have announced plans for future clinical trials for HAE that are seeking, or are likely to seek, to enroll patients with the disease and patients are generally only able to enroll in a single trial at a time. The small population of patients, competition for these patients and the limited trial sites and their constrained resources may make it difficult for us to enroll enough patients in our clinical trials in HAE, and to maintain the enrollment of enough patients, to complete such clinical trials.

The clinical trials that we may conduct may also have inclusion and exclusion criteria that further limit the population of patients that we are able to enroll. In the case of HAE trials, the inclusion criteria may require that participants have had a certain number of attacks that occur within a defined period of time prior to being able to participate in the trial, which may impact or slow enrollment in the trial. For example, in the case of our planned Phase 3 pivotal trial for STAR-0215, we expect that, similarly to the Phase 1b/2 ALPHA-STAR trial, the inclusion criteria will require participants to have had a certain number of attacks that occur within a defined period of time prior to being able to participate in the trial, which may impact or slow enrollment in the trial. These inclusion or exclusion criteria could limit the available patient pool and present challenges to clinical trial enrollment.

Our inability, or the inability of any future collaborators, to enroll a sufficient number of patients for any clinical trials, including clinical trials for STAR-0215 as a potential treatment for HAE and clinical trials for STAR-0310 as a potential treatment for AD, that we or they may determine to pursue could result in significant delays or may require us or them to abandon one or more clinical trials altogether. Enrollment delays in any such clinical trials may result in increased development costs for the applicable product candidates, delay or halt the development of and approval processes for any future product candidates and jeopardize our, or any future collaborators', ability to commence sales of and generate revenues from any product candidates, which could cause the value of our company to decline.

We have conducted and intend to conduct certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We have conducted and intend to continue conducting certain of our clinical trials globally. The acceptance by the FDA or other regulatory authorities of data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where foreign clinical trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the clinical trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it could result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;

- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Changes in product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates are developed through preclinical studies to later stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause a product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. If we successfully develop and commercialize any of our product candidates, we and any future collaborators will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of the entities developing and marketing potentially competing products have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and commercialization. Even if we are able to successfully develop and commercialize a product, our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer side effects, are more convenient or are less expensive than our product.

We are developing STAR-0215 for the potential treatment of HAE. The key competitive factors affecting the success of STAR-0215, if approved, are likely to be its efficacy, safety, dosing frequency, method of administration, convenience, price and the availability of coverage and reimbursement from government and other third-party payors.

In the United States, the FDA has approved four therapies for on-demand treatment of HAE: BERINERT, FIRAZYR, KALBITOR and RUCONEST. For long-term preventative treatment of HAE, the FDA has also approved four therapies: CINRYZE, HAEGARDA, TAKHZYRO and ORLADEYO. There are four main manufacturers of therapies for HAE: CSL Behring (BERINERT and HAEGARDA), Takeda (FIRAZYR, KALBITOR, CINRYZE and TAKHZYRO), Pharming (RUCONEST) and BioCryst (ORLADEYO). With the exception of KALBITOR, these therapies are also approved and commercially available outside of the United States (HAEGARDA is marketed as BERINERT SC outside of the United States). Historically, androgens and antifibrinolytic treatments have also been used as preventative treatment for HAE, however their use is declining with the availability of more-tolerable, HAE-specific therapies.

On-demand and preventative HAE therapies target one of three primary mechanisms. BERINERT, HAEGARDA, RUCONEST and CINRYZE are C1-INH replacement therapies. FIRAZYR is a bradykinin receptor, or B2R, antagonist, and KALBITOR, TAKHZYRO and ORLADEYO target plasma kallikrein. TAKHZYRO is a monoclonal antibody and KALBITOR and ORLADEYO are small molecule inhibitors.

On-demand therapies are taken as needed; BERINERT and RUCONEST are IV infusions approved for adult and pediatric patients, FIRAZYR is an SC injection, approved for adults 18 and older, and KALBITOR is a series of three SC injections, approved for patients 12 years and older. KALBITOR must be administered by a healthcare professional to monitor for the risk of anaphylactic reactions.

Preventative therapies are taken chronically. CINRYZE is an IV infusion and HAEGARDA is an SC injection; both are administered twice a week and are approved for adult and pediatric patients 6 years and older. TAKHZYRO is an SC injection generally administered every two weeks; however, dosing every four weeks may be considered in some patients. TAKHZYRO is approved for patients 2 years and older.

ORLADEYO is an oral capsule taken once daily with food for patients 12 years and older. Given that TAKHZYRO is an approved monoclonal antibody inhibitor of plasma kallikrein, if STAR-0215 is approved, we expect that it will compete most directly with TAKHZYRO.

We are aware of additional programs in development for HAE, which are focused largely on preventative approaches. For example, CSL Behring's garadacimab (CSL312), a factor XIIa-inhibitory monoclonal antibody, or FXIIa mAb, has completed Phase 3 development for preventative treatment and submitted regulatory applications for marketing approval in the United States and the European Union. Ionis Pharmaceuticals, Inc.'s donidalorsen (IONIS-PKK-LRx), an antisense inhibitor of prekallikrein synthesis has also completed Phase 3 development for preventative treatment. Pharvaris is developing two oral treatments, both of which are small molecule inhibitors of B2R: PHVS416, which has completed Phase 2 development for on-demand treatment and for preventative treatment, and PHVS719, which is in Phase 1 development for preventative treatment. KalVista Pharmaceuticals, Inc. has an oral small molecule plasma kallikrein inhibitor sebetralstat (KVD900) for on-demand treatment of HAE that has completed Phase 2 development (the Phase 2 trial for KVD824 for preventative treatment was terminated). Intellia Therapeutics is in Phase 1/2 trials for NTLA-2002, a CRISPR knockout of the prekallikrein gene KLKB1. BioMarin Pharmaceutical Inc. is in Phase 1/2 trials for BMN 331, a C1-INH gene therapy. ADARx Pharmaceuticals, Inc. has begun a Phase 1b clinical trial for ADX-324, a prekallikrein siRNA inhibitor. Preclinical development programs for preventative treatment include KalVista's oral FXIIa inhibitor and Kyowa Kirin and Pharming's ex vivo hematopoietic stem cell gene therapy (OTL-105).

We are developing STAR-0310 for the treatment of moderate-to-severe AD. The key competitive factors affecting the success of STAR-0310, if approved, are likely to be its safety and tolerability, efficacy, frequency of dosing, method of administration, convenience, price, and the availability of coverage and reimbursement from government and other third-party payors. In the United States, the FDA has approved two oral JAK inhibitors for the treatment of AD: RINVOQ and CIBINQO, and in the European Union OLUMIANT is also approved for the treatment of AD. Additionally, the FDA has approved two biologics for the treatment of AD: DUPIXENT and ADBRY. Standard of care also includes systemic steroids and topical medications which can treat symptoms but do not address underlying disease. Moderate-to-severe patients who do not respond to topical prescription therapies typically turn to biologics as their next option, and, subsequently, to JAK inhibitors.

Both DUPIXENT and ADBRY are administered subcutaneously every two weeks, and work by targeting the Th2 inflammatory pathway (IL-4/13, and IL-13, respectively). RINVOQ and CIBINQO require daily oral administration and are only available to patients who do not sufficiently respond to systemic therapies including biologics. While these JAK inhibitors tend to have better efficacy than the two approved biologics, there are significant safety concerns including a boxed warning associated with JAK inhibitors.

We are aware of additional programs in development for AD, which are focused largely on biologic approaches. Late-stage programs include Galderma's nemolizumab, an IL-31 antibody, and Eli Lilly's lebrikizumab, an IL-13 antibody, which are under regulatory review for approval by the FDA. Lebrikizumab has been approved in the European Union as EBGLYSS. There are other companies that have product candidates in early-stage development for moderate-to-severe AD, including Anaptys Bio (ANB032), RAPT Therapeutics (RPT193), Nektar Therapeutics (rezpegaldesleukin), Aslan Pharmaceuticals (eblasakimab), Pfizer (etrasimod, PF-07275315 and PF-07264660), LEO Pharma (LEO 138559 and 152020), Akesobio (AK120), Connect Biopharma (rademikibart), Biosion (BSI-045B), Janssen (JNJ-67484703), Bayer (zabedosertib), Sanofi (rilzabrutinib), Apogee Therapeutics (APG777), InnoCare Pharma (ICP-332), Kymera Therapeutics (KTK-474), Q32 Bio (bempikibart) and GSK (GSK1070806).

Additionally, a new class of biologics is in clinical development targeting OX40, the same target as for STAR-0310. Amlitelimab (Sanofi) is an anti-OX40 ligand (OX40L) antibody that has started a Phase 3 trial. Rocatinlimab (Amgen) is an afucosylated OX40 receptor (OX40R) antibody currently in Phase 3 trials in AD. IMG-007 (Inmagene) is an OX40 receptor (OX40R) antibody in a proof-of-concept trial in AD.

The enrollment and retention of patients in clinical trials for STAR-0215 or STAR-0310 may be disrupted or delayed as a result of clinicians' and patients' perceptions as to the potential advantages of STAR-0215 or STAR-0310 in relation to commercially available therapies and other programs in development, including approved products as well as any other new products that may be approved in the future, for the treatment of HAE or AD.

Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects, have more convenient dosing regimens, including the potential for biannual or annual dosing regimens, or are less costly than any product candidates that we may develop, which could render any future product candidates obsolete and noncompetitive.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we, or any future collaborators, may develop. Our competitors also may obtain FDA or other marketing approval for their products before we, or any future collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or any future collaborators, are able to enter the market.

Our potential future competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and commercializing 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, or as a result of the development of drug products that have more convenient dosing regimens. 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.

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.

We have limited financial and managerial resources and are focused on the clinical development of STAR-0215 as a potential treatment for HAE, a rare disease with unmet medical need, and the preclinical and clinical development of STAR-0310 as a potential treatment for AD. We would expect that development of any other future product candidate would also be for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may 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 STAR-0215, STAR-0310 and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. 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 the product candidate.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials and we may be unsuccessful in identifying any new product candidates.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support the submission of an IND in the United States, or similar applications in other jurisdictions, including clinical trial application, or CTA, submissions in the European Union. Such studies are complex and may be subject to delays or increased costs due to our dependence upon third parties to assist us with such studies and the ability to source raw materials and the appropriate animals, including non-human primates, so that we can conduct such testing. There is currently a global shortage of non-human primates available for drug development. If the shortage continues, this could increase the cost of conducting our preclinical development and could also result in delays to our development timelines. In the event that the FDA or comparable foreign regulatory authorities require us to complete additional preclinical studies or we are required to satisfy other FDA requests or other requests of comparable foreign regulatory authorities prior to commencing clinical trials, the start of our clinical trials may be delayed or take longer to complete. Even after we receive and incorporate guidance from the FDA or comparable foreign regulatory authorities, such authorities may not agree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or comparable foreign regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that

we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications, including CTA submissions in the European Union, will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin or that we can meet the requirements imposed by such authorities for beginning such trials on a timely basis or at all.

In addition, any future research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds or biologics for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any future product candidate we may seek to develop.

We have never obtained marketing approval for a product candidate. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for any of our product candidates in a Phase 3 clinical trial or in obtaining marketing approval thereafter.

If we are able to advance STAR-0215, STAR-0310 or any other future product candidate into late-stage development, it is possible that the FDA, EMA or other applicable foreign regulatory authority may refuse to accept for substantive review any applications that we submit for marketing approval of such product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of such product candidate. If the FDA, EMA or other applicable foreign regulatory authority does not accept or approve any applications that we submit for marketing approval, they may require that we conduct additional clinical or nonclinical studies, or conduct manufacturing validation studies, and submit that data before they will reconsider our applications. Depending on the extent of these or any other required studies, approval of any application that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA, EMA or other applicable foreign regulatory authority.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing STAR-0215, STAR-0310 or any future product candidate, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for STAR-0215, STAR-0310 or any future product candidates, which could significantly harm our business.

If STAR-0215, STAR-0310 or any other future product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future collaborators, to market the drug could be compromised.

Clinical trials of product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that clinical trials for STAR-0215, STAR-0310 and any other future product candidate, or those of any future collaborator, may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur.

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;

- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- we may become the subject of government investigations, which would be expensive to manage and potentially result in the imposition of fines, injunctions or the imposition of civil or criminal penalties;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

Even if STAR-0215, STAR-0310 or any other future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than we estimate.

Even if STAR-0215, STAR-0310 or any other future product candidate is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of future product candidates may require significant resources and may not be successful. If STAR-0215, STAR-0310 or any other future product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of STAR-0215, STAR-0310 or any other future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to existing approved treatments or alternative treatments, including the convenience and ease of administration compared to alternative treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy and whether there is an existing standard of care;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of sales, marketing, market access and distribution support;

- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products in relation to competitive products;
- availability and amount of reimbursement from government payors, managed care plans and other third-party payors, along with any protocols implemented by such entities that require the use of competitive products prior to providing reimbursement for any of our product candidates, if approved;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for product candidates are difficult to estimate precisely. Any estimates we make as to the potential market opportunities for STAR-0215, STAR-0310 or any other future product candidates will be predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. These assumptions will involve the exercise of significant judgment on the part of our management, will be inherently uncertain and the reasonableness of these assumptions may not have been assessed by an independent source. If any such assumptions prove to be inaccurate, the actual markets for STAR-0215, STAR-0310 or any other future product candidate could be smaller than our estimates of the potential market opportunities.

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

We currently do not have a sales, marketing or distribution infrastructure. To achieve commercial success for any approved product, we would need to either develop a sales and marketing organization or outsource these functions to third parties. We expect to use a combination of focused in-house sales and marketing capabilities and third-party collaboration, licensing and distribution arrangements to sell any products that receive marketing approval.

We generally expect that we would seek to retain full commercialization rights in the United States for products that we can commercialize with a specialized sales force and to retain co-promotion or similar rights when feasible in indications requiring a larger commercial infrastructure. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, at such time as we need to, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to a product, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

We generally expect to collaborate or partner with third parties for commercialization outside the United States and both inside the United States and outside the United States for any products that require a large sales, marketing, reimbursement and product distribution infrastructure, such as STAR-0310 if approved for the treatment of moderate-to-severe AD. We would do so through collaboration, licensing and distribution arrangements. As a result of entering into arrangements with third parties to perform sales, marketing, reimbursement and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no 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 sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates that receive marketing approval.

STAR-0215, STAR-0310 and any other future biologic product candidates will be regulated as biological products, or biologics, and therefore they may be subject to competition from biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biological products that are biosimilar to or interchangeable with an FDA-licensed reference biologic.

Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and 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. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval for a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

In December 2022, Congress clarified through the Food and Drug Omnibus Reform Act, or FDORA, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

We believe that our current and any of our future product candidates we develop as biologic products under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, 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.

Nonetheless, the approval of biosimilar products referencing any of our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures. Moreover, the ultimate impact, implementation and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological products.

For more information on biosimilars and regulatory exclusivity for biologic drugs in the United States, please see the section of this Annual Report on Form 10-K entitled "Business—Government Regulation and Product Approval—Biosimilars and Regulatory Exclusivity."

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our future products that receive marketing approval through the NDA pathway, or such authorities do not grant such future products appropriate periods of non-patent exclusivity before approving generic versions of our products, our sales could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity

for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains an active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical trials, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our product candidates are approved, even if we still have patent protection for such product candidates. Competition that any such product candidates of ours may face from generic versions of such products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we may make in those product candidates.

Business disruptions could delay completion of clinical trials, seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of third-party research institution collaborators, contract research organizations, or CROs, contract manufacturing operations, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, public health crises, pandemics or epidemics, such as the COVID-19 pandemics, and other natural or man-made disasters or business interruptions, for which we may be partly uninsured, as well as impacts of geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine and the conflict in the Middle East), terrorist activity and unstable governments and legal systems. In addition, we expect that we will rely on third-party research institution collaborators for conducting research and development of STAR-0215, STAR-0310 and any other future product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could delay completion of any clinical trials for such product candidates, seriously harm our operations and financial condition and increase our costs and expenses.

We are subject to risks associated with public health crises, pandemics and epidemics.

Public health crises, pandemics and epidemics, such as the COVID-19 pandemic, may significantly disrupt our business. Such events pose the risk that we or our employees, contractors, suppliers, or other partners may be prevented from conducting business activities for an indefinite period of time due to the spread of disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities or the facilities of our contractors, suppliers, and other partners.

The development of STAR-0215, STAR-0310 or any other future product candidates could be negatively impacted by public health crises, pandemics or epidemics for a variety of reasons, including delays of the initiation, recruitment and overall timing of clinical trials, delays at the FDA and other regulatory authorities, the disruption or delays of regulatory or manufacturing activities, including due to facility shut downs, capacity constraints at third party manufacturers and increased costs or the inability to source key raw materials, or other adverse effects that negatively impact our business or operations.

A pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on. Furthermore, delays and disruptions experienced by our collaborators or other third parties due to a pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect the clinical development of our product candidates. For example, the COVID-19 pandemic adversely impacted the global supply chain, primarily through constraints on raw materials, and these constraints on raw materials also impacted companies outside of our direct industry, which resulted in a competitive supply environment causing higher costs for a period during and following the COVID-19 pandemic.

Measures taken by governments, actions taken to protect employees and the broad impact public health crises, pandemics or epidemics would have on all business activities may materially and adversely affect our business, results of operations and financial condition.

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

We face an inherent risk of product liability claims as a result of the clinical testing of product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or any future collaborators commercially sell any product that we may or they may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. 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. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any future product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any future product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend resulting litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

Although we maintain general liability insurance and clinical trial liability insurance that we believe is customary and adequate, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we begin selling any product candidate that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of any future product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Financial Position and Need for Additional Capital

We will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We are continuing to conduct clinical trials, preclinical and nonclinical studies, including our Phase 1b/2 ALPHA-STAR trial, which we initiated in February 2023, our ALPHA-SOLAR trial, a long-term open-label clinical trial assessing the long-term safety and efficacy of STAR-0215, and preparatory work for our potential Phase 3 pivotal trial, assuming favorable results from the Phase 1b/2 ALPHA-STAR trial, and preclinical and nonclinical studies to support the submission of an IND for STAR-0310 by the end of 2024. Additionally, we are ramping up manufacturing of clinical supplies for STAR-0215 and plan to begin the development of drug device combinations for our potential Phase 3 pivotal trial and commercialization of STAR-0215. We expect that our expenses will increase substantially as a result of all of these activities. We will need to raise additional capital in order to fund activities for STAR-0215 beyond our planned Phase 3 pivotal trial, and for STAR-0310, for activities beyond our planned Phase 1a trial and for any development of STAR-0310 outside of AD. In addition, we may in the future initiate new research, preclinical and clinical development efforts, and seek marketing approval, for other product candidates, and would expect our expenses to increase in connection with each of these activities. If we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator, and these activities would require substantial additional funding. In addition, while we may seek one or more collaborators for future development of our product candidates, we may not be able to enter into a collaboration for any of our product candidates on suitable terms or at all. In any event, our existing cash, cash equivalents and short-term investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Furthermore, we have incurred and will continue to incur significant additional costs associated with operating as a public company.

Accordingly, we will be required to obtain substantial additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional funding may not be available to us on acceptable terms, on a timely basis or at all, impacting our ability to execute on our strategic plans. General economic conditions, both inside and outside the United States, including heightened inflation, capital market instability and volatility, interest rate and currency rate fluctuations, and economic slowdown or recession as well as pandemics, epidemics and geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia and the conflict in the Middle East), have resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital. In addition, market volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. Our failure to raise capital on acceptable terms as and when needed may force us to delay, reduce or eliminate our research and development programs or any future efforts to seek approval for and commercialize products, and would have a material adverse effect on our business, results of operations, financial condition and ability to pursue our business strategy.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into mid-2027. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities through completion of a planned Phase 3 pivotal trial, and (ii) for STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments under a license agreement, or the License Agreement, that we entered into with Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos, in October 2023). Our estimate as to how long we expect our cash, cash equivalents and short-term investments to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including:

- our ability to meet our overall timing expectations for STAR-0215 and STAR-0310;
- the progress, timing, costs and results of clinical trials of, and research, preclinical and clinical development, and manufacturing efforts for, STAR-0215, STAR-0310 and any other future product candidates, including potential future clinical trials and all activities necessary to initiate and conduct clinical trials;

- our ability to enter into and the terms and timing of any additional collaborations, licensing or other arrangements that we may establish;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of the evaluation, selection, testing and scale up activities related to developing a drug device combination for STAR-0215, or any other product candidate for which we seek to develop a drug device combination, for late-stage clinical trials and commercialization to the extent such costs are not the responsibility of any future collaborators;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, market access, distribution, supply chain and manufacturing capabilities, scaling up the manufacturing of drug substance and drug product to clinical and commercial scale, securing all raw materials necessary to conduct such scale-up and successfully completing all other activities related thereto;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our products, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE and with respect to STAR-0310 in AD;
- our headcount growth and associated costs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;and
- the costs of operating as a public company.

Furthermore, we hold a portion of cash and cash equivalents that we use to meet our working capital and operations expense needs in deposit accounts at one financial institution. The balance in these accounts typically exceed the Federal Deposit Insurance Corporation standard deposit insurance limit of $250,000. If a financial institution in which we hold such funds fails, 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 insured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Our losses from operations were $83.0 million and $53.5 million for the years ended December 31, 2023 and December 31, 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $580.5 million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through private placements of preferred stock before we became a public company and our private placement of preferred stock in February 2021, which we refer to as the February 2021 Financing, registered offerings of our common stock and/or warrants, and our at-the-market offering programs, and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that we will continue to incur significant expenses and operating losses and we may incur increased expenses if and to the extent we:

- initiate and continue research and preclinical and clinical development efforts for STAR-0215, STAR-0310 and any other future product candidates;
- seek to identify and develop any other future product candidates;
- seek regulatory and marketing approvals for STAR-0215, STAR-0310 and any other future product candidate that successfully completes clinical trials, in the United States and other markets;
- establish sales, marketing, market access, distribution, supply chain and other commercial infrastructure in the future to commercialize products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of STAR-0215, STAR-0310 and any other future product candidates for clinical development and potentially commercialization;
- implement changes in product candidate manufacturing or formulation;
- develop drug device combinations for STAR-0215, or any other product candidate for which we seek to develop a drug device combination, for late-stage clinical trials and commercialization;
- maintain, expand and protect our intellectual property portfolio; and
- hire and retain additional personnel or add information systems, equipment or physical infrastructure to support our operations.

To become and remain profitable, we or any potential future collaborators must develop and eventually commercialize at least one product candidate with significant market potential. This will require that we or our collaborators be successful in a range of challenging activities, including completing preclinical studies and clinical trials of one or more product candidates, obtaining marketing approval for one or more these product candidates, manufacturing, marketing and selling those products for which we or our collaborators may obtain marketing approval and satisfying any post-marketing requirements. We or our collaborators may never succeed in any or all of these activities and, even if we or our collaborators do succeed, we or our collaborators may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause investors to lose all or part of their investments in us.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We will need to raise additional capital to develop and commercialize STAR-0215 and STAR-0310 or to acquire, develop and commercialize any other future product candidates or to pursue other strategic options. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our existing stockholders' ownership interests may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. For example, in connection with our acquisition of Quellis Biosciences, Inc., or Quellis, in January 2021 and our February 2021 Financing, we issued an aggregate of 86,077 shares of Series X, of which 53,532 shares of Series X Preferred Stock automatically converted into 8,921,966 shares of our common stock upon the stockholder approval of the conversion of the Series X Preferred Stock into common stock in June 2021. Subsequently, an additional 1,438 shares have converted into 239,608 shares of common stock. The remaining 31,107 shares of Series X Preferred Stock are convertible into 5,184,591 shares of common stock at the election of the holders thereof, subject to certain beneficial ownership limitations. In addition, our June 2018, February 2019 and October 2023 registered offerings of common stock and common stock warrants and our January 2020, December 2022 and February 2024 registered offerings of common stock were highly dilutive to existing stockholders' ownership

interests. Further, exercise of the common stock warrants sold in our June 2018, February 2019 and October 2023 offerings could result in additional dilution upon exercise.

Debt financing, if available, would result in periodic payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing additional financing could 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 any future product candidate.

If we raise additional funds through collaborations or marketing, distribution, licensing or royalty arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Our Dependence on Third Parties

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The development and commercialization of product candidates require substantial cash to fund expenses. We may seek one or more collaborators for the development and commercialization of STAR-0215, STAR-0310 or any other future product candidates. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. In addition, any collaboration agreements that we enter into in the future may contain, restrictions on our ability to enter into potential collaborations or to otherwise develop specified compounds or biologics.

We face significant competition in seeking appropriate collaborators and strategic partners. Whether we reach a definitive agreement for a collaboration or strategic partnership will depend, among other things, upon our assessment of the other party's resources and expertise, the terms and conditions of the proposed transaction and the proposed party's evaluation of a number of factors. Those factors may include the potential differentiation of ours or a partner's product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator or strategic partner may also be considering alternative transaction types and structures that may be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop the product candidate or bring it to market and generate product revenue.

If we enter into collaborations with third parties for the development and commercialization of a product candidate, our prospects with respect to such product candidate will depend in significant part on the success of those collaborations.

If we enter into collaborations for the development and commercialization of a product candidate, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of such product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon

research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Collaborations involving product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of a product candidate or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the market or competitive landscape, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in negative publicity for our product candidate and the need for additional capital to pursue further development or commercialization of the applicable product candidates.

In addition, all of the risks related to product development, regulatory approval and commercialization described in this "Risk Factors" section would apply to the activities of our collaborators. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination or a sale or other transaction involving our collaboration, it or the party with which it entered into a business combination, sale or other transaction could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

We rely on third parties to conduct our preclinical studies and clinical trials. If they do not perform satisfactorily, our business could be significantly harmed.

We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct ongoing and planned preclinical studies and clinical trials of STAR-0215, STAR-0310 or any other future product candidates. Any of these third parties could terminate its engagement with us under certain circumstances or encounter, for example, business challenges, such as a loss of business, public health crises, pandemics or epidemics, such as the COVID-19 pandemic, or the impacts of geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine and the conflict in the Middle East), or enter into transactions, such as business combinations, that temporarily or permanently impact the amount or type of resources that they are able or willing to devote to our engagement. We might not be able to enter into alternative arrangements or do so on commercially reasonable terms or on a timely basis. In addition, there is a natural transition period when a new CRO begins work. As a result, delays would likely occur, which could materially impact our ability to meet our expected preclinical and clinical development timelines and harm our business, financial condition and prospects.

Further, our reliance on these third parties for preclinical and clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of a product candidate, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and most other comparable regulatory authorities outside the United States require us to comply with standards, commonly referred to as current GCPs, 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. The FDA and other comparable regulatory authorities outside the United States enforce these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or any of our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other comparable regulatory authorities outside the United States may require us to perform additional clinical trials before approving a product candidate, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA or other comparable regulatory authorities outside the United States will determine that any of our clinical trials comply with GCPs. Similar standards, known as Good Laboratory Practices, apply to preclinical studies and nonclinical trials and other studies. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Other regions, including the European Union, have similar requirements. The failure to comply with these registration and posting requirements can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties that conduct preclinical studies and clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we are not able to control whether or not they devote sufficient time, skill and resources to our development programs. Any such contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our preclinical and clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for the applicable product candidates. If that occurs, we would not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be impaired.

We also rely on other third parties to store and distribute drug supplies for any clinical trials we pursue. Any performance failure on the part of any such distributors or impacts from geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia and the conflict in the Middle East), terrorist activity and unstable governments and legal systems could delay clinical development or marketing approval of any future product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

The manufacturing of pharmaceutical products and, in particular, biologics, is complex and we do not have our own manufacturing capabilities. We rely on third parties to produce preclinical, clinical and commercial supplies of any current and future product candidates.

We currently have no manufacturing facilities and rely on third-party contract manufacturers to manufacture all of our preclinical product candidate supplies and clinical trial product supplies and will need to rely on third-party contract manufacturers to manufacture any commercial supply or drug device combination for a product candidate. We are also using a contract manufacturer to build the master cell bank that will be necessary for the manufacture of STAR-0310, which we in-licensed in October 2023. We do not own, nor do we plan to own, any manufacturing facilities. There can be no assurance that our preclinical, clinical and commercial development product supplies, including drug substance, drug product, planned drug device combinations, or the master cell bank for STAR-0310, that are being manufactured by third parties will not be delayed, limited or interrupted, or be of satisfactory quality or continue to be available at acceptable prices. Additionally, the process of manufacturing pharmaceutical products and, in particular, biologics is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, difficulties in scaling the production process and use of excipients which may, among other things, impact shelf life and present concerns with process controls. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our third-party contract manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

If the contract manufacturers we engage are unable to supply us with sufficient preclinical or clinical quality and quantities of our product candidates, drug device combinations for our product candidates, or to build the master cell bank for STAR-0310, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we will experience delays in our development efforts as we seek to locate and qualify new or additional manufacturers. In particular, any replacement of our third-party contract manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. We currently rely on single source third-party manufacturers and suppliers for the antibodies used to make STAR-0215, STAR-0215 drug product and to label and pack STAR-0215, and we expect to continue to do so to meet our nonclinical, clinical and commercial needs for STAR-0215, STAR-0310, and any other product candidate, which exacerbates these and other related risks for us. Additionally, contract manufacturers may rely on single source suppliers for certain of the raw materials or drug components for our preclinical and clinical product supplies. We may be unable to obtain raw materials or drug components for an indeterminate period of time if any of our third-party suppliers and manufacturers were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or manufacturer, failure by the supplier or manufacturer to comply with current good manufacturing practices, or cGMPs, contaminations, business interruptions, or labor shortages or disputes, or if we were to terminate our relationship with any of our third-party suppliers or manufacturers for any reason. For example, we are utilizing a Chinese contract development and manufacturing organization, or CDMO, for the process and product development for STAR-0310 and proposed legislation has been introduced in Congress that could prohibit U.S. companies that receive U.S. government funding from contracting with certain Chinese companies, which given the political complexities could, even though we have not received government funding to date, cause us to reevaluate our relationship with our Chinese CDMO. Suppliers may extend lead times, limit supplies or increase prices due to capacity constraints or other factors beyond our control. We cannot be sure that single source suppliers for our raw materials or drug components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials or components for our intended purpose. If current or future suppliers are delayed or unable to supply sufficient raw materials or components to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers.

The manufacturing process for a clinical candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with their standards, such as cGMPs. In the event that any of our manufacturers fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms or on a timely basis, if at all. The transfer of the manufacturing of biologic products to a new contract manufacturer and any additional process development that may be necessary can be lengthy and involve significant additional costs. If

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. The delays associated with the verification of a new manufacturer would negatively affect our ability to develop product candidates in a timely manner or within budget.

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the:

- inability to meet our drug specifications, quality requirements or drug device combination requirements consistently;
- inability to initiate or continue preclinical studies or clinical trials of product candidates or drug device combinations under development;
- delay or inability to procure or expand sufficient manufacturing capacity;
- costs and validation of new equipment and facilities required for scale-up;
- inability of our third-party manufacturers to execute process development, manufacturing, technology transfers, manufacturing procedures and other logistical support requirements appropriately or on a timely basis;
- manufacturing and drug quality issues, including related to scale-up of manufacturing;
- failure to comply with cGMPs and similar foreign standards;
- reliance on a limited number of sources, and in some cases, potentially single sources for drug components and raw materials, such that if we are unable to secure a sufficient supply of these drug components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- price increases or decreased availability of drug components or raw materials;
- lack of qualified backup suppliers for those components and raw materials that are purchased from a sole or single source supplier;
- inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruption of operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including supply chain issues, capacity constraints, transportation and labor disruptions, global competition for resources, the bankruptcy of the manufacturer or supplier, a business combination or strategic transaction involving the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter and/or general economic conditions, heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession;
- disruptions of operations caused by geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia and the conflict in the Middle East), terrorist activity, insurrection or other wars or significant conflicts, unstable governments and legal systems man-made or natural disasters or public health crises, pandemics and epidemics, including, for example, the COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control, including increases in material, labor or other manufacturing-related costs or higher supply chain logistics costs;
- failure to deliver our drugs under specified storage conditions and in a timely manner; and

- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production, any of which could result in a failure to begin our clinical trials or having to stop or delay ongoing clinical trials. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our preclinical, clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or manufacturer's facility, which could impact the contract supplier's or manufacturer's ability to manufacture for us.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our product candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our product candidates, could adversely impact or disrupt the commercial manufacture or the production of preclinical or clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

Any of these events could lead to preclinical study or clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize such product candidates successfully may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to STAR-0215, STAR-0310 and any other future product candidates. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. See the section "Business — Intellectual Property" for more details regarding our STAR-0215 and STAR-0310 patent portfolio. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

We cannot be certain that any patent application directed to our current or future product candidates will be issued in a form that provides us with adequate protection to prevent competitors from developing competing products. As a biopharmaceutical company, our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by the United States Patent and Trademark Office, or USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from any applications that are currently pending or that we file in the future. As such, we do not know the degree of future protection that we will have for our product candidates and their use. The scope of patent protection that the USPTO and foreign patent offices will grant with respect to our product candidates is uncertain. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. For example, it is possible that the USPTO and foreign patent offices will not allow broad antibody claims that specifically cover our STAR-0215 and STAR-0310 product candidates and antibodies closely related to them. As a result, upon receipt of FDA approval, or regulatory approval in foreign jurisdictions, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market share. However, a competitor cannot submit to the FDA an application for a biosimilar product based on STAR-0215, STAR-0310 or any future biologic products until four years following the date of approval of our "reference product," and the FDA may not

approve such a biosimilar product until 12 years from the date on which the reference product was approved. See the section "Business — Government Regulation and Product Approval — Biosimilars and Regulatory Exclusivity" for more details regarding biosimilar regulatory exclusivities.

Our owned and in-licensed pending patent applications and any future patent applications we file cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, patents are granted to the party who was the first to file a patent application. However, prior to March 16, 2013, in the United States, patents were granted to the party who was the first to invent the claimed subject matter. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing antibodies or compounds similar or identical to our product candidates, or limit the duration of the patent protection of our product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Patent applications may not result in patents being issued which protect any current and future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if patent applications that we file issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with any of our future products. Alternatively, our competitors may seek to market biosimilar versions of any approved products by submitting an application for a biosimilar product under the BPCIA. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

If we do not obtain protection under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act, or under similar legislation in other countries. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. As a result, our revenue from applicable products could be reduced, possibly materially.

We rely on in-licensed patent and other intellectual property rights for our STAR-0310 program and we may need to obtain licenses from third parties to other intellectual property rights for the development and commercialization of our STAR-0310 and STAR-0215 programs; if we fail to comply with our existing or future obligations under these licenses, or if these licenses are terminated, we could lose license rights that are important to our business.

Our ability to develop and commercialize our STAR-0310 program is heavily dependent on an in-license to patent rights and other intellectual property granted to us by Ichnos. In October, 2023, we entered into the License Agreement with Ichnos, pursuant to which Ichnos granted us an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and license to certain patent rights and related know-how to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as "ISB 830" as well as Ichnos' proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as "ISB 830-X8". We are developing STAR-0310, which was engineered from ISB 830-X8 with YTE half-life extension technology modification, for AD and potentially for other allergic and immunological diseases. STAR-0310 is currently in preclinical development. Ichnos has also agreed not to develop or commercialize any product that directly modulates the OX40 receptor.

Under the License Agreement, we agreed to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product that contains or comprises a licensed compound in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan. The License Agreement imposes on us payment of development, regulatory and commercial milestones, as well as tiered royalties and other obligations. If we fail to comply with our obligations under the License Agreement, or we are subject to a bankruptcy, Ichnos may have the right to terminate the license, in which event we would not be able to market products covered by the License Agreement. Our business could suffer, for example, if the License Agreement terminates, if Ichnos fails to abide by the terms of the license, or if the licensed patents or other rights are found to be invalid or unenforceable.

In the future, we may need to obtain licenses to intellectual property rights necessary to develop and commercialize our product candidates, including STAR-0215 and STAR-0310, or may need to amend existing or future licenses. If we are unable to obtain or amend such licenses at a reasonable cost or on reasonable terms, we may be unable to develop or commercialize our product candidates, which could harm our business significantly.

As noted above, our License Agreement with Ichnos imposes, and we expect that future license agreements will impose, diligence obligations, milestone and royalty payments, indemnification and other obligations on us. If we fail to comply with our obligations under one or more of these licenses, our licensors, including Ichnos, may have the right to terminate the license agreement at issue. If one or more of these licenses is terminated, we may be unable to develop or commercialize our product candidates, including STAR-0215 and STAR-0310. Termination of any of our current or future license agreements or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms, even if available at all.

In addition, our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of the licensed rights, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over the license agreements or the in-licensed intellectual property prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive, or may not include all territories or fields of use of interest to us. Accordingly, third parties may also obtain licenses from such licensors to the same intellectual property rights they have licensed to us. As a result, the licenses granted to us may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates, which may permit competitors to develop and commercialize a competitive product.

Furthermore, in some cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in-license from third parties. Therefore, we cannot be certain that any in-licensed patent rights will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, decide not to pursue litigation against third-party infringers, fail to prosecute infringement, or fail to defend against counterclaims of patent invalidity and unenforceability, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Disputes may arise among us and our current and future licensors regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement with respect to the use of licensed technology to develop and commercialize our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know how resulting from the joint creation or use of intellectual property by our licensors and us; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

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

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

An intellectual property litigation could lead to unfavorable publicity that could harm our reputation and cause the market price of our common stock to decline.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. In such event, the market price of our common stock may decline.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing current and future product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, and market our current as well as any future product candidates, without infringing the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our current or any future product candidates or their methods of use, or other aspects of our current or future product candidates, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all, or we may incur significant legal fees or damages.

In spite of our efforts to avoid obstacles and disruptions arising from third-party intellectual property, it is impossible to establish with certainty that our programs directed to our current and any future product candidates will be free of claims by third-party intellectual property holders. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications. Even when a third-party patent is identified, we may conclude upon a thorough analysis, that we do not infringe the patent or that the patent is invalid. If the third-party patent owner disagrees with our conclusion and we continue with the business activity in question, patent litigation may be initiated against us. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or non-infringed by our activity. In either scenario, patent litigation typically is costly and time-consuming, and the outcome is uncertain. The outcome of patent litigation is subject to uncertainties that cannot be quantified in advance, for example, the credibility of expert witnesses who may disagree on technical interpretation of scientific data. Ultimately, in the case of an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our technology platform as a result of patent infringement claims asserted against us. This could have a material adverse effect on our business.

There is a substantial amount of intellectual property litigation in the biopharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our current or future product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that any current or future product candidates, products, methods, processes, modeling or similar work either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. For example, we are aware of a U.S. patent directed to an antibody that binds plasma kallikrein. In the event that the owner of this patent were to bring an infringement action against us, we may have to argue that STAR-0215, its manufacture or use does not infringe a valid claim of this patent. We cannot guarantee that a court would find in our favor on questions of infringement or validity. Furthermore, even if our arguments are successful, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

Our involvement in litigation, and in, e.g., any interference, derivation, reexamination, inter partes review, opposition or post-grant proceedings or other intellectual property proceedings in the United States, or other jurisdictions, may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, manufacturing or using our products in the United States or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

Along with patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, CROs, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants.

Trade secrets and confidential know-how are difficult to maintain as confidential. Although we use reasonable efforts to protect our trade secrets, any party with whom we have executed a confidentiality agreement may breach that agreement and disclose our proprietary information, including our trade secrets.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Accordingly, we may not be able to obtain adequate remedies for such breaches, despite any legal action that we might take against persons making such unauthorized disclosures. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets.

If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed.

Those with whom we collaborate on research and development related to current and future product candidates may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient

or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries could increase those uncertainties and costs. For example, the Leahy-Smith America Invents Act of 2011, or the Leahy-Smith Act, included a number of significant changes to United States patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, for example, via post grant review and inter partes review proceedings at the USPTO. In addition, the Leahy-Smith Act transformed the United States patent system into a "first to file" system. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could harm our business, results of operations and financial condition.

The United States Supreme Court has ruled on several patent cases, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations; including the scope of patent protection for antibodies. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make antibodies that are the same as or similar to STAR-0215, STAR-0310 or any other future product candidates but that are not covered by the claims of patents that we own or have rights to;
- we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by our pending patent application;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent rights will not lead to issued patents, or that patents, if granted, may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;

- we may not develop additional technologies that are patentable; and
- third parties may allege that our development and commercialization of STAR-0215, STAR-0310 or any other future products may infringe their intellectual property rights, the outcome of which may have an adverse effect on our business.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering any future product candidates, our competitive position would be adversely affected.

We may obtain only limited geographical protection with respect to certain patent rights, which may diminish the value of our intellectual property rights in those jurisdictions and prevent us from enforcing our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Accordingly, we may not file for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. For example, the European Union opened a Unified Patent Court, or UPC, in June 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents, should they be granted, in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents or defend their validity. We may decide to opt out our patent applications, if filed, and our European patents, if granted, from the UPC. If certain formalities and requirements are not met, however, our European patent applications, if filed, and European patents, if granted, could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patent applications or granted patents will avoid falling under the jurisdiction of the UPC, even if we decide to opt out of the UPC.

Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In these countries, the patent

owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, results of operations and financial condition may be adversely affected. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities in those jurisdictions is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we may not be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of STAR-0215, STAR-0310 or any other future product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of biopharmaceutical products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, which regulations differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of a BLA from the FDA, which would be required for approval of STAR-0215 and STAR-0310, or NDA or marketing approval from applicable regulatory authorities outside the United States. Product candidates in the development phase are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including third-party clinical research organizations, to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity

and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

In addition, changes in or the enactment or promulgation of additional statutes, regulations or guidance during preclinical or clinical development, or comparable changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products.

Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one European Union Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the European Union Member States and the public. We are seeking approval of our ongoing STAR-0215 clinical trials, and if the results from the ALPHA-STAR trial are favorable, we plan to seek approval of the STAR-0215 Phase 3 clinical study in the European Union pursuant to this regulation, but we have yet to secure such an authorization and there is no assurance that we will be able to secure such an authorization for our ongoing or future clinical trials of STAR-0215, STAR-0310 or any future product candidates.

Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Further, under the Pediatric Research Equity Act, or PREA, an NDA or BLA, or supplement to an NDA or BLA, for certain drugs and biological products must contain data to assess the safety and efficacy of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Finally, our ability to develop and market new drug products may be impacted by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the United States. Among other determinations, the district court held that the plaintiffs were likely to prevail in their claim that the FDA had acted arbitrarily and capriciously in approving mifepristone without sufficiently considering evidence bearing on whether the drug was safe to use under the conditions identified in its labeling. Further, the district court read the standing requirements governing litigation in federal court as permitting a plaintiff to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS based on a showing that the plaintiff or its members would be harmed to the extent that FDA's drug approval decision effectively compelled the plaintiffs to provide care for patients suffering adverse events caused by a given drug.

In April 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit and the U.S. Supreme Court entered a stay of the district court's decision, in its entirety, pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit and the disposition of any petition for a writ of certiorari to the U.S. Supreme Court. The Court of Appeals for the Fifth Circuit held oral argument in the case in May 2023 and, in August 2023, issued its decision. The court declined to order the removal of mifepristone from the market, finding that a challenge to the FDA's initial approval in 2000 is barred by the statute of limitations. But the Court of Appeals did hold that the plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. In September 2023, the Justice Department and a manufacturer of mifepristone filed petitions for a writ of certiorari, requesting that asked the U.S. Supreme Court to review the Appeals Court decision. In December 2023, the U.S. Supreme Court granted these petitions for writ of certiorari for the appeals court decision.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the European Union and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-United States regulatory approvals and compliance with non-United States regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-United States approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-United States regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and European Union Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland Protocol, Northern Ireland is currently subject to European Union rules. The United Kingdom and European Union have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol, including with respect to the regulation of medicinal products in the United Kingdom. Once implemented, the changes introduced by the Windsor Framework will see the MHRA be responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, European Union pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (among other things, potentially reducing the duration of regulatory data protection and revising the eligibility for expedited pathways) was published in April 2023. The proposed revisions

remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets (such as the war between Ukraine and Russia and the conflict in the Middle East); compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for any future product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We, or any future collaborators, may seek orphan drug designations and may be unable to obtain such designations.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

In 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA, which among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use."

Although there have been legislative proposals to overrule this decision, they have not been enacted into law. In January 2023, the FDA announced that, in matters beyond the scope of the court's order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

In addition, to obtain orphan drug designation in the European Union, we would need to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for STAR-0215, STAR-0310 or any other product candidate. In particular, there is no assurance that STAR-0215 will be able to show, to the satisfaction of European Union regulatory authorities, that it is of significant benefit to HAE patients given the currently available commercial products for HAE in the European Union and the additional products that are ahead of STAR-0215 in clinical development for HAE.

Any product candidate for which we obtain marketing approval would remain subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a REMS. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any product candidate for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In September 2021 the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic. Moreover, with the passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. In addition, in October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

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

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;

- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union, notably under Directive 2001/83EC, as amended, and are also subject to European Union Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

Accordingly, assuming we, or any future collaborators, receive marketing approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any future collaborators, are not able to comply with post-approval regulatory requirements, our or any future collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

We may seek certain designations for our product candidates, including Breakthrough Therapy, RMAT Therapy, Fast Track and Priority Review designations in the United States, and the PRIority MEdicines, or PRIME, designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy and Regenerative Medicine Advanced Therapy, or RMAT, product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious 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. For products that have been designated as Breakthrough and RMAT therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may

be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The FDA has granted Fast Track designation to STAR-0215 for the treatment of HAE.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In the European Union, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We may seek approval of our product candidates from the FDA or comparable foreign regulatory authorities through the use of accelerated development pathways. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay or prevent the receipt of, necessary marketing approvals. Moreover, even if we receive accelerated approval from the FDA or comparable foreign regulatory authorities, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval.

Under the FDCA and implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. 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. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit. Prior to seeking such accelerated approval, we will continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval.

There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional NDAs or BLAs seeking accelerated approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval. Furthermore, for any submission of an application for accelerated approval, there can be no assurance that such submission will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation (i) authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, (ii) requires a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months until the study is completed and (iii) authorizes the FDA to use expedited procedures to withdraw accelerated approval of an NDA or a BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the FDA to publish on its website the rationale for why a post-approval study is not appropriate or necessary whenever it decides not to require such a study upon granting accelerated approval. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

In the European Union, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Accordingly, a failure to obtain and maintain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period until commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may seek a Rare Pediatric Disease priority review voucher, or PRV, for our current and future product candidates. A BLA or NDA for our current and future product candidates may not, however, meet the eligibility criteria for a PRV, even if the BLA or NDA is approved.

With enactment of the Food and Drug Administration Safety and Innovation Act of 2012 and subsequent legislation, Congress authorized the FDA to award PRVs to sponsors of certain rare pediatric disease product applications that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives approval for a new drug or biologic for a rare pediatric disease may qualify for a PRV, which can be redeemed for priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product that receives a PRV may transfer, including by sale, the PRV to another sponsor and that PRV may be further transferred any number of times before it is used. A PRV entitles the holder to designate a single human drug application submitted under Section 505(b)(1) of the FDCA or Section 351 of the Public Health Service Act as qualifying for a priority review. An FDA priority review may expedite the review process of a marketing application reducing the review time from ten months after formal acceptance of the file to six months after formal acceptance of the file.

In order for a sponsor to receive a PRV in connection with approval of a BLA or NDA, the investigational product must be designated by the FDA as a product for a rare pediatric disease prior to submission of the marketing application. A rare pediatric disease is a disease that is serious or life-threatening and which primarily affects individuals aged from birth to 18 years and fewer than 200,000 people in the United States. Alternatively, the disease may affect more than 200,000 people in the United States if there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition, to qualify for a PRV, the sponsor must request the voucher and the BLA or NDA must itself be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient.

There can be no assurance that the FDA will determine that a BLA or NDA for one or more of our product candidates meets the eligibility criteria for a PRV upon approval of the marketing application. Further, under the current statutory sunset provisions for the Rare Pediatric Disease PRV Program, the FDA may only award a PRV for an approved rare pediatric disease product application if the rare pediatric disease designation was granted by September 30, 2024. Moreover, the FDA may not award any rare pediatric disease PRVs after September 30, 2026. Accordingly, if we do not receive rare pediatric disease designation and approval of a BLA or NDA by these dates, respectively, and if the Rare Pediatric Disease PRV program is not further extended by Congressional action, we may not receive a PRV. Since a PRV may be sold for substantial amounts of money, or used by us to expedite approval of another marketing application, our business may be harmed if we do not qualify for a PRV in connection with approval of an NDA or BLA.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates, including drug substance, drug product and device combinations that may be used in combination with our product candidates, for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMPs. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. 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 our product candidates that may not be detectable in final product testing.

We or our contract manufacturers must supply all necessary documentation in support of a BLA or NDA on a timely basis and must adhere to the FDA's current good laboratory practices and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our contract manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our contract manufacturers. If any such inspection or audit identifies failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require 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 or the temporary or permanent closure of a facility, which may lead to temporary or permanent supply shortages. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, competing priorities or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services 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 may 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 FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies, including government agencies and regulatory authorities outside the United States, 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 or competing priorities at the FDA and other agencies may also slow the time necessary for new product candidates 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 and 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, 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.

If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our product candidates that do receive marketing approval.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the ACA. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 (PAYGO) sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or TCJA, in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, in December 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In June 2021, the U.S. Supreme Court dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden revoked those orders and issued a new executive order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

In the European Union, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among European Union Member States in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the European Union level for joint clinical assessments in these areas. It will permit European Union Member States to use common HTA tools, methodologies and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual European Union Member States will continue to be responsible for assessing non-clinical (e.g., economic, social and ethical) aspects of health technology, and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have been the subject of considerable discussion in the United States. There have been several recent Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020 President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the Department of Health and Human Services, or HHS, and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. In January 2024, the FDA approved Florida's plan for Canadian drug importation. Further, on November 20, 2020, HHS finalized a regulation that would eliminate the current safe harbor Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but has been delayed by Congress until January 1, 2032.

In September 2021, acting pursuant to an executive order signed by President Biden, the HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

In August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025) that would require manufacturers to cover a portion of these costs. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the IRA subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the IRA by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The IRA also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The IRA also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, price caps on annual out-of-pocket expenses, and the requirement that manufacturers cover a portion of these costs, each of which could have potential pricing and reporting implications.

In June 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

In addition, at the federal level in the United States, in February 2023, CMS announced a model that would allow CMS to pay less for drugs and biologics approved through FDA's accelerated approval pathway before a clinical benefit has been confirmed by the required confirmatory studies. If implemented, this would impact the price that CMS would pay for Medicare Part B drugs and biologics that fit within CMS's criteria for lower payments. Implementation of this model could result in reduced reimbursement for our products and also lead to further and more expansive pricing pressure from CMS and other U.S. payors, any of which could adversely affect our business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological 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. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

The insurance coverage and reimbursement status of newly approved products is uncertain. Our product candidates, if approved, may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for any of our product candidates for which we obtain approval could limit our ability to market those products and decrease our ability to generate revenue.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs and other medical products vary widely from country to country. In the United States, healthcare reform legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product 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, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize our products and product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Sales of any product we successfully develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize any product we may successfully develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the U.S. healthcare 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. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for any product we may successfully develop. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of any product we may successfully develop to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Reimbursement agencies in Europe may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug 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 drugs, 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 drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors any product we may successfully develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third-party payors for any product we may successfully develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower-priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

We may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Potentially applicable United States federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation.

False Claims Laws. The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions 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. In addition, 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.

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

False Statements Statute. The federal false statements statute prohibits 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 healthcare benefits, items or services.

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the HHS information related to physician and healthcare provider payments and other transfers of value and physician ownership and investment interests.

Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, corporate integrity or other similar forms of agreements or decrees, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and the United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information that may impact certain of our business operations. For example, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical, and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity, and availability of electronic protected health information. 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. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, 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 civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced, or applied to our operations. 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.

There are other privacy and security laws that also may be applicable to our business activities now or in the future. For example, on January 1, 2020, the California Consumer Privacy Act, or CCPA took effect and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the European Union's General Data Protection Regulation, or GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of the "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. The California Privacy Rights Act, or CPRA, went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created an enforcement agency – the California Privacy Protection Agency – whose sole responsibility is

to enforce the CPRA and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, eleven other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond, including New Hampshire and New Jersey. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states (such as Vermont) are considering such legislation in 2024. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the 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 imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our 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 places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the European Union to other countries. In July 2020 the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

Following the withdrawal of the UK from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the UK and the European Union have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The UK and the U.S. have also agreed to a U.S.-UK "Data Bridge", which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the United States. In addition to the UK, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, if approved, through increased compliance costs, costs associated with contracting, and potential enforcement actions.

Data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We are subject to United States and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the Foreign Corrupt Practices Act, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

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. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union Member States and the U.K. Bribery Act 2010. Violations of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization, and/or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and, if we commence clinical trials, 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, the European Commission and other regulatory authorities, comply with healthcare 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 healthcare 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. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such 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.

Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of any product that we may develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product will be paid by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, we, or any future collaborators, may not be able to successfully commercialize such product. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Many countries outside the United States, including many countries in the European Union, require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted and can be lengthy, involve extensive negotiations and potentially result in price caps, significant discounts or other budgetary control measures, which could correspondingly impact pricing and reimbursement in other markets through so-called informal or formal reference pricing schemes. These reviews and negotiations could ultimately result in a pricing and reimbursement structure for a drug that a company deems inadequate and therefore elects not launch in such markets. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if any future product candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize any product will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell any products we develop profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for any future products decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. For example, to obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. We cannot be sure that coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any product candidate for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Risks Related to Taxation

Changes in tax law 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 and our stockholders. Many such changes have been made and changes are likely to continue to occur in the future. For example, the TCJA was enacted in 2017 and significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense

to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and an elimination of net operating loss carrybacks (though any net operating losses generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely), and the modification or repeal of many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA was also signed into law in August 2022. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. In addition, certain tax laws that are specific to the biopharmaceutical industry, such as the orphan drug tax credit, which was enacted as part of the Orphan Drug Act, have been limited over time and continuing limitations or restrictions of the tax credit and changes to other tax laws applicable to our business could negatively impact our business and results of operations. Additional tax legislation may also be enacted, and regulatory guidance under the TCJA continues to be forthcoming. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Under Section 382, the annual limitation is determined by first multiplying the value of the corporation's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required.

As a result of, among other transactions, the shares issued in January 2021 related to the acquisition of Quellis and the February 2021 Financing, we believe we have experienced several historical ownership changes, as defined by Section 382. As a result, our utilization of the federal and state net operating loss carryforwards or research and development tax credit carryforwards are subject to annual limitation under Sections 382 and 383. Our analysis of Section 382 indicates that a significant portion of our Federal and state net operating loss carryforwards and research and development tax credit carryforwards are limited, such that a significant portion of them are anticipated to not be available or expire before utilization.

Risks Related to Employee Matters, Managing Growth and Information Technology

Our future success depends on our ability to retain our senior management and key employees.

We are highly dependent on our executive officers and key employees. If we are unable to retain our executive officers or other key employees, replacing them may be difficult and costly, and may take an extended period of time because of the nature of our current business strategy and the limited number of individuals in our industry with the relevant breadth of skills and experience. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate replacements for our executive officers or key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We rely on consultants and advisors, including financial, legal, scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us.

We may experience difficulty in locating, attracting and retaining experienced and qualified personnel, which could adversely affect our business.

We will need to attract, retain and motivate experienced clinical development and other personnel, particularly in the greater Boston area, as we expand our clinical development activities and prepare for potential commercialization of our product candidates. Personnel with the required skills and experience may be scarce or may not be available at all in this geographic region. In addition, competition for these skilled personnel is intense and recruiting and retaining skilled employees is difficult, particularly for a development-stage company such as ours. If we are unable to attract and retain qualified personnel, our clinical development activities and preparation for potential commercialization of our product candidates may be adversely affected. Even if we are successful in identifying and attracting qualified employees, recent market changes, including labor shortages, and rising inflation have increased employee-related costs substantially, which may negatively affect our operating results.

Security breaches and other disruptions to our information technology systems could compromise our information, disrupt our business and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, as well as our proprietary business information, employee data and personally identifiable information of clinical trial participants in accordance with informed consents covering such information as well as personal information of other individuals. We also rely to a large extent on computer and information technology systems to operate our business. Remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. The secure maintenance of this information is important to our operations and business strategy. Despite our security measures, our information technology infrastructure, and that of our vendors and third-party providers, may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our vendors and third-party providers could be susceptible to third party attacks on our and their information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. The risk of a security breach or disruption through cyber-attacks has generally increased as the number, intensity and sophistication of attempted attacks from around the world have increased. If a ransomware attack or other cybersecurity incident occurs, either internally or at our vendors or third-party technology service providers, we could be prevented from accessing our data or systems, which may cause interruptions or delays in our business operations, cause us to incur remediation costs, subject us to demands to pay a ransom, or damage our reputation, regardless of whether we pay the ransom amount. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. While we continue to build and improve our information technology security systems and infrastructure, there can be no assurance that our efforts will prevent service interruptions, breakdowns or security breaches. For example, we have detected common types of attempts to attack our information technology systems and data using means that have included phishing. Any service interruptions or security breaches of our information technology systems may substantially impair our ability to operate our business and could compromise our networks, or those of our vendors and third-party providers, and the information stored could be accessed, publicly disclosed, lost or stolen.

We may be required to expend significant resources (including financial), fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to detect (including performing required forensics), mitigate and remediate actual and potential vulnerabilities. Relevant laws, regulations, industry standards and contractual obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, security breaches and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, data loss or corruption, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third-party vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business. Although we maintain cyber liability insurance, it may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data.

Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If any of our vendors experiences an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Risks Related to Our Common Stock

Our principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our holders of 5% or more of our capital stock and their respective affiliates beneficially own in excess of 40% of our outstanding common stock. These stockholders, acting together or on their own, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

The price of our common stock has been and is likely to continue to be highly volatile, which could result in substantial losses for our stockholders.

Our stock price has been and is likely to continue to be highly volatile. For example, when we announced our acquisition of Quellis, our stock price increased by approximately 70% in one day. In the twelve months ending February 29, 2024, the last business day in February, our stock price has traded at a high of $15.66 and a low of $4.26.

The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our investors may lose some or all of their investments. The market price for our common stock may be influenced by many factors, including:

- the timing and results of clinical trials of STAR-0215, STAR-0310 or any future product candidate;
- commencement or termination of collaborations for any development programs we may pursue;
- failure or discontinuation of any of any development programs we may pursue;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of competitors;

- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to a product candidate or clinical development program;
- the results of any additional efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or recommendations by securities analysts that cover our stock;
- announcement or expectation of additional financing efforts;
- announcement of collaborations, licenses, acquisitions or other comparable forms of transactions;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including political instability, war or instability from public health crises, pandemics or epidemics; and
- the other factors described in this "Risk Factors" section.

Additionally, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

We have incurred and will continue to incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social and governance focused disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. Our management and other personnel devote a substantial amount of time towards maintaining compliance with the corporate governance and public disclosure rules and regulations that are applicable to us and will continue to do so. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. In addition, if we cease to be a smaller reporting company, we will need to comply with significant additional disclosure and other obligations.

Pursuant to Section 404 of SOX, we are required to furnish reports by our management on our internal control over financial reporting with our Annual Reports on Form 10-K with the SEC. If we cease to be a smaller reporting company with less than $100 million in annual revenue, we will also be required to include attestation reports on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX 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, 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 neither we nor our independent registered public accounting firm will 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 of SOX. If we identify one or more 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 significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of February 29, 2024, we had outstanding 54,903,061 shares of common stock and 31,107 shares of Series X Preferred Stock, which are convertible into 5,184,591 shares of common stock. We have registered under the Securities Act of 1933, as amended, or the Securities Act, 15,399,967 shares of our common stock issued to the former Quellis stockholders or issued or issuable upon conversion of the Series X Preferred Stock. As a result, such shares are freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any significant sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive.

As part of our registered offering of common stock in October 2023, we issued common stock warrants to purchase an aggregate of 7,368,738 shares of our common stock, and pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of our common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.001 per share. Each pre-funded warrant is exercisable from the date of issuance until exercised in full solely by means of a cashless exercise. Each common stock warrant has an exercise price per share of common stock equal to $8.025. Each common stock warrant is exercisable from the date of issuance until October 16, 2028. Each common stock warrant is exercisable solely by means of a cash exercise, except that the common stock warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of the shares of common stock underlying the common stock warrants under the Securities Act is not then effective. The common stock warrants include certain rights upon “fundamental transactions” as described in the common stock warrants, including the right of the holders thereof to receive from us or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as described in such common stock warrants) of the unexercised portion of the applicable common stock warrants on the date of the consummation of such fundamental transaction. A holder of common stock warrants (together with its affiliates) may not exercise any portion of a common stock warrant to the extent that the holder would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock immediately after exercise.

Although these warrants issued in October 2023 are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and the holders of these warrants, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly.

We have registered the issuance of shares upon exercise of these warrants under registration statements. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. Any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will likely depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Risks Relating to our Certificate of Incorporation and Bylaws

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

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

- establish a classified board of directors such that all members of the board are not elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;

- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call a special meeting of stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

In addition, as of February 29, 2024, there are 31,107 shares of our Series X Preferred Stock outstanding that we issued in connection with the acquisition of Quellis and the February 2021 Financing. Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation that authorized the Series X Preferred Stock, amend or repeal any provision of, or add any provision to, our Certificate of Incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

Our certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors and officers.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers, or employees, which may discourage such lawsuits against us and our directors, officers, and employees. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition, and operating results. This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended, which provides for exclusive jurisdiction of the federal courts. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder; provided, that with respect to claims under the Securities Act, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Cybersecurity Risk Management and Strategy

We have established processes to assess, identify, and manage cybersecurity risks. These processes are integrated into our overall risk management program and are designed to protect our information assets from internal and external cyber threats and include:

- implementing physical, procedural, and technical safeguards;
- developing and maintaining comprehensive response plans;
- conducting regular exercises and tests to identify potential vulnerabilities;
- engaging with external cybersecurity experts to enhance our oversight and keep pace with evolving threats; and
- considering the cybersecurity capabilities of partners and third-party service providers, both prior to engaging them and on an ongoing basis.

Cybersecurity Governance and Oversight

Our board of directors provides direct oversight of cybersecurity risk and has delegated to its audit committee the responsibility of reviewing and discussing with management our risk exposures relating to cybersecurity. The board of directors and the audit committee conduct periodic reviews of our cybersecurity readiness to ensure continuous improvement in our cybersecurity strategies and receive regular updates from management on cybersecurity matters and are promptly informed by management about any significant new threats or incidents.

We have implemented robust mechanisms to monitor and manage cybersecurity threats and incidents, including utilization of advanced tools for continuous monitoring of our IT environment to detect and mitigate threats, a fundamental plan for responding to cyber incidents and training for employees to recognize and report potential cybersecurity incidents and to foster a culture of cybersecurity awareness and vigilance. We have a dedicated management team, led by our Vice President of IT, that is responsible for operational oversight of our cybersecurity strategy and policies. Our Vice President of IT has an extensive background in IT management with a focus on securing sensitive biotech data and systems, having held similar roles at two previous biotech companies with

responsibilities including corporate infrastructure and cyber security readiness and response, in addition to over 20 years of professional experience in IT. Any identified cybersecurity incident is reported to our cybersecurity management team, which evaluates the severity of the incident. Based on this assessment, further steps are taken involving other members of management and, depending on the severity, the audit committee and the board of directors. We believe this structured approach allows us to effectively manage and mitigate cybersecurity risks, safeguarding our systems and data against various digital threats. Additionally, our proactive stance is supported by comprehensive cybersecurity insurance, which further reinforces our preparedness against potential cyber threats.

Cybersecurity Incident Reporting and Management

We have not identified any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect us, including our business strategy, results of operations, or financial condition. However, we remain vigilant and prepared to respond effectively to any incidents, should they arise.

Item 2. Properties

Our offices are located in Boston, Massachusetts and consist of approximately 17,136 square feet of subleased office space under a lease that expires in July 2024. In January 2024, we entered into a sublease agreement under which we agreed to sublease approximately 30,110 square feet of office space at a new location in Boston, Massachusetts, where we plan to relocate our offices. The term of the sublease is scheduled to commence on June 1, 2024 and is scheduled to end on November 30, 2028 or on such earlier date as the term may sooner cease or expire as set forth in the sublease agreement. We believe that our current and new subleased facilities are and will be sufficient for our needs for the foreseeable future.

Item 3. Legal Proceedings

From time to time we may become subject to various legal proceedings and claims that arise in the ordinary course of our business activities. Although the results of litigation and claims cannot be predicted with certainty, as of the date of this Annual Report on Form 10-K, we do not believe we are party to any claim 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

On September 9, 2021, following our name change to Astria Therapeutics, Inc., our common stock, $0.001 par value per share, commenced trading under the symbol "ATXS" on the Nasdaq Global Select Market. Prior to September 9, 2021, our common stock was publicly traded on the Nasdaq Global Market under the symbol "CATB" since June 25, 2015. Prior to that time, there was no public market for our common stock.

Holders

As of February 29, 2024, there were approximately 20 holders of record of our common stock. This number of holders of record does not include beneficial owners of our common stock whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared nor paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future.

Recent Sales of Unregistered Securities

We did not sell or issue any equity securities that were not registered under the Securities Act during the period covered by this Annual Report on Form 10-K.

Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

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 and other financial information included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. This section provides additional information regarding our businesses, current developments, results of operations, cash flows, financial condition, contractual commitments and critical accounting policies and estimates that require significant judgement and have the most potential impact on our consolidated financial statements. This discussion and analysis is intended to better allow investors to view the Company from the management's perspective.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. Our focus is to develop first-choice therapies that improve the health and outcomes of patients with allergic and immunological diseases. Our lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema, or HAE, a rare, debilitating and potentially life-threatening disease. STAR-0215 has the potential to be the most patient-friendly chronic treatment option for HAE, based on the data generated to date and the existing HAE treatment landscape. Our second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis, or AD, an immune disorder associated with loss of skin barrier function and itching. We believe that with both of these programs, we are advancing a pipeline of products with meaningfully differentiated profiles based on validated mechanisms.

STAR-0215

The treatment options for patients with HAE have improved in recent years, however, there is remaining unmet medical need and the global market for HAE therapy is strong and growing. The goal for STAR-0215 is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE. Our vision for STAR-0215 is to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling. STAR-0215 is currently in clinical development and the U.S. Food and Drug Administration, or FDA, has granted Fast Track designation to STAR-0215 for the treatment of HAE.

We initiated a Phase 1a clinical trial of STAR-0215 in August 2022 and we announced initial results in December 2022. We presented additional preliminary results from the trial in February 2023 and further results were shared at the American College of Allergy, Asthma, and Immunology Conference in November 2023. Final results from the trial were shared at the American Academy of Allergy, Asthma, and Immunology Conference in February 2024. This Phase 1a randomized, double-blind, placebo-controlled single ascending dose clinical trial evaluated the safety, pharmacokinetics, or PK, and pharmacodynamics, or PD, of STAR-0215 at a single U.S. center. Forty-one healthy subjects received a single dose of STAR-0215 or placebo in four cohorts of 100mg, 300mg, 600mg, and 1200mg administered by subcutaneous, or SC, injection or a fifth cohort of 600mg or placebo administered by intravenous, or IV, injection. STAR-0215 was well-tolerated at all dose levels, with no serious adverse events or discontinuations due to an adverse event, and low risk of injection pain. STAR-0215 demonstrated rapid and sustained drug levels with dose-dependent PK. STAR-0215 achieved potentially therapeutic levels in less than one day after single doses greater than 100mg and showed an estimated half-life of up to 109 days. PK modeling of potential once-every-three-month and once-every-six-month clinical dose regimens over one to two years indicate STAR-0215 has the potential for PK coverage that would confer HAE attack prevention. PD data showed statistically significant inhibition of Factor XIIa-induced plasma kallikrein activity compared to levels prior to dosing, observed using two different assay formats. The percentage inhibition of plasma kallikrein observed was consistent with clinical activity for doses greater than 300mg. Treatment-emergent anti-drug antibodies, or ADAs, were observed in eleven subjects from completed cohorts, all first observed on or after 140 or more days after the single dose of STAR-0215. ADAs were determined not to affect the PK or PD of STAR-0215. With a preliminary favorable safety profile, long half-life and durable PD, STAR-0215 demonstrated early proof of concept in healthy subjects as a potential HAE therapy with robust efficacy and dosing every three or six months.

In February 2023 we advanced STAR-0215 to a Phase 1b/2 trial called ALPHA-STAR, or Astria Long-acting Prophylaxis for Hereditary Angioedema: STAR-0215. This global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE is evaluating safety, tolerability, HAE attack rate, PK, PD, and quality of life in patients three and six months after STAR-0215 administration. The trial has three cohorts, which all begin with an eight week run-in period to assess baseline attack rate. Cohort 1 receives a 450mg single dose of STAR-0215, Cohort 2 receives an initial 600mg dose followed by a 300mg dose on Day 84, to simulate a potential three-month dosing regimen with maintenance doses of 300mg every three months. Cohort 3 receives an initial 600mg dose, followed by a second 600mg dose 28 days later, to simulate a potential six-month dosing regimen with maintenance doses of 600mg every six months. All doses are administered subcutaneously and all patients in the trial are followed for six months after the last dose administered. We expect to report initial proof-of-concept data in HAE patients in the first quarter of 2024, which would include safety, tolerability, PK, PD, and HAE attack-rate reduction, and we expect these data to provide information on both three and six month administration. If the results from ALPHA-STAR are positive, we expect to progress STAR-0215 directly to a Phase 3 pivotal trial which we anticipate initiating in the first quarter of 2025.

We have initiated and are enrolling subjects in ALPHA-SOLAR, a long-term open-label trial assessing the long-term safety and efficacy of STAR-0215. We are currently administering STAR-0215 to those patients who have completed ALPHA-STAR and have enrolled in ALPHA-SOLAR, and data is accruing in patients who have received multiple doses of STAR-0215. Participants are being assigned to receive STAR-0215 in one of two dosing regimens: either 300mg every three months or 600mg every six months.

STAR-0310

We believe that OX40 inhibition has the potential to treat AD and other diseases. The current treatment options in AD are insufficient to address the needs of many patients, and standard of care treatments include steroids and topical medications which can treat symptoms but do not address the underlying disease. Our goal for STAR-0310 is to reduce disease activity, relapse rate, and treatment burden for patients with moderate-to-severe AD. STAR-0310 was engineered with YTE half-life extension technology to enable infrequent dosing. As a potential long-acting OX40 inhibitor, STAR-0310 aims to address the need for a safe, effective, and infrequently administered AD treatment.

In 2024, we plan to share preclinical profile results for STAR-0310 and we anticipate submitting an investigational new drug application, or IND, to the FDA for STAR-0310 for the treatment of AD by year-end. If the IND is cleared, we anticipate initiating a Phase 1a clinical trial of STAR-0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of STAR-0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026. The goals of the Phase 1b trial would be to demonstrate initial efficacy in AD as well as show differentiation in safety and tolerability as compared to existing therapies.

Underwritten Offerings

On December 19, 2022, we closed of an underwritten public offering of 10,445,050 shares of our common stock, including the full exercise of the underwriters' option to purchase 1,362,397 shares of our common stock, at a price of $11.01 per share, which we refer to as the December 2022 Financing. The gross proceeds of the December 2022 Financing were approximately $115.0 million, before deducting underwriting discounts and commissions and other offering expenses.

On October 16, 2023, we closed an underwritten offering of (i) 8,253,895 shares of our common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock, which we refer to as the October 2023 Financing. The gross proceeds of the October 2023 Financing were approximately $64.0 million before deducting underwriting discounts and commissions and other offering expenses.

On February 1, 2024, we closed an underwritten offering of 10,340,000 shares of our common stock, which we refer to as the February 2024 Financing. The gross proceeds of the February 2024 Financing were approximately $125.0 million before deducting underwriting discounts and commissions and other offering expenses.

At-the-Market Offerings

On June 30, 2021, we entered into an Open Market Sale AgreementSM with Jefferies LLC, or Jefferies, pursuant to which we were able to issue and sell shares of common stock under an at-the-market offering program, or the Jefferies ATM Program. In the year ended December 31, 2023, we sold an aggregate of 4,738,606 shares of common stock under the Jefferies ATM Program for gross proceeds of $29.4 million and net proceeds of $28.5 million. In January 2024, we sold an aggregate of 2,945,806 shares of common stock under the Jefferies ATM Program for gross proceeds of $20.6 million and net proceeds of $20.0 million which completed the sale of all available amounts under the Jefferies ATM Program.

Financial Overview

Our business is almost entirely dependent on the success of STAR-0215, which is in the early clinical stages of development, and has only produced results in a Phase 1a clinical trial, preclinical and nonclinical settings, and STAR-0310, which is in the preclinical stage of development. Our net losses were $72.9 million (including $15.2 million of in-process research and development, or IPR&D, expenses) and $51.8 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $580.5 million. We have not generated any product revenues and have financed our operations primarily through public offerings and private placements of our equity securities and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs.

As of December 31, 2023, we had $246.5 million in cash, cash equivalents and short-term investments, which, together with the net proceeds from shares sold under the Jefferies ATM Program in January 2024 and the net proceeds from the February 2024 Financing, we expect will enable us to fund our operating expenses and capital expenditure requirements into mid-2027. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities through completion of a planned Phase 3 pivotal trial, and (ii) for STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments under our license agreement, or the License Agreement, that we entered into with Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos). Advancing the development of STAR-0215, STAR-0310, or any future product candidates will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will not be sufficient to enable us to fund the completion of development of any of our product candidates, including STAR-0215, STAR-0310 or any future product candidate. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215, STAR-0310 or any future product candidates and support our continuing operations, future clinical trials and expansion of our pipeline. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. See the section titled “Liquidity and Capital Resources” below for additional information.

Revenue

As of December 31, 2023, we have not generated any revenue from product sales.

Research and Development Expenses

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

- employee-related expenses including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct clinical trials and research and development and preclinical activities on our behalf;
- the cost of consultants;
- the cost of lab supplies and acquiring, developing and manufacturing study and clinical trial materials; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs. We record our research and development expenses net of any research and development tax incentives we are entitled to receive from government authorities.

The following table summarizes our research and development expenses by program (in thousands):

	Year Ended December 31,	
	2023	2022
STAR-0215	$ 24,186	$ 20,307
STAR-0310	677	—
Other programs	4,144	1,967
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	11,162	7,866
Consultants and professional expenses, including stock-based compensation	1,278	3,310
Facilities	325	487
Other	355	327
Total costs not directly allocated to programs	13,120	11,990
Total research and development expenses	$ 42,127	$ 34,264

We expect to incur significant research and development expenses in the year ending December 31, 2024, and in future periods in connection with the clinical trials and other activities related to the development of STAR-0215 and the preclinical studies, planned clinical trials and other activities related to the development of STAR-0310. Because of this, we expect that our research and development expenses over the next several quarters will be higher than the prior year periods. Development of STAR-0215, STAR-0310 and any future product candidates is highly uncertain and we cannot reasonably estimate at this time the nature, timing and costs of the efforts that would be necessary to complete the development of any such product candidates. We are also unable to predict when, if ever, material net cash inflows would commence from STAR-0215, STAR-0310 or any other future product candidates. This is due to the fact that we would need to raise substantial additional capital to fund the completion of the clinical development of any such product candidates and the numerous risks and uncertainties associated with developing and commercializing product candidates, including the uncertainties of:

- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful design, enrollment in, and completion of clinical trials;
- feedback from the FDA and foreign regulatory authorities on planned trial designs, pre-clinical studies and manufacturing capabilities and plans;
- changes in the FDA and foreign regulatory approval processes or perspectives that may delay or prevent the approval of new products;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- launching commercial sales, if we are able to obtain marketing approval, whether alone or in collaboration with others, and our ability to compete successfully with other products; and
- maintaining a continued acceptable safety profile following approval.

A change in the outcome of any of these variables with respect to the development of STAR-0215, STAR-0310 or any future product candidate, would significantly change the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, IT, new product planning, business development, legal and human resources functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase from their current levels as we continue to grow our company, develop STAR-0215 and STAR-0310, and potentially expand our pipeline to include other product candidates.

Acquired In-process Research and Development Expense

Acquired IPR&D expense resulted from the License Agreement. In the estimation of fair value of the asset purchase consideration, we primarily used the upfront license fee of $15.0 million as the most reliable indicator of fair value attributable to the acquired IPR&D. As the single identifiable asset, "ISB 830-X8", referred to by us as the STAR-0310 candidate, had not, at the time of the License Agreement, received regulatory approval in any territory, the acquisition cost allocated to acquire IPR&D with no alternative future use was recorded as expense at the acquisition date and no additional IPR&D expense relating to the License Agreement is expected to be reported in future periods.

Other Income (Expense)

Other income (expense), net consists of interest income earned on our cash, cash equivalents and short-term investments and net amortization expense on short-term investments, and gains and losses related to foreign currency fluctuations.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with United States generally accepted accounting principles, or U.S. GAAP. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

License Agreement

We have concluded that the License Agreement was not the acquisition of a business, as substantially all of the fair value of the gross assets acquired was concentrated in the STAR-0310 candidate. STAR-0310 is STAR-0310 candidate engineered with YTE half-life extension technology.

We determined that the cost to acquire the licensed intellectual property assets was $15.2 million, primarily based on the fair value of the upfront license fee of $15.0 million attributable to the acquired IPR&D. As the STAR-0310 candidate had not, at the time of the License Agreement, received regulatory approval in any territory, the cost attributable to the IPR&D was expensed in our consolidated statements of operations and comprehensive loss for the year ended December 31, 2023 as the acquired IPR&D had no alternative future use, as determined by us in accordance with U.S. GAAP.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing contracts, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The estimate of accrued research and development expense is dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party service providers. The significant estimates in our accrued research and development expenses include the costs

incurred for services performed by CROs in connection with research and development activities for which we have not yet been invoiced.

We base our expenses related to CROs on our estimates of the services received and efforts expended pursuant to contracts with CROs that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our CROs will exceed the level of services provided and result in a prepayment of the research and development expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting expense amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts actually incurred.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022, together with the dollar change in those items (in thousands):

	Year Ended December 31,		Period-to-Period Change
	2023	2022	
Operating expenses:			
Research and development	$ 42,127	$ 34,264	$ 7,863
General and administrative	25,704	19,239	6,465
Acquired in-process research and development	15,199	—	15,199
Total operating expenses	83,030	53,503	29,527
Loss from operations	(83,030)	(53,503)	(29,527)
Other income, net	10,139	1,669	8,470
Net loss	$ (72,891)	$ (51,834)	$ (21,057)

Research and Development Expenses

Research and development expenses increased by $7.8 million to $42.1 million for the year ended December 31, 2023 (excluding acquired IPR&D from the License Agreement) from $34.3 million for the year ended December 31, 2022, an increase of 23%. The increase in research and development expenses was primarily associated with our STAR-0215 program's advancement from IND-enabling activities and a single-site clinical trial in healthy volunteers in 2022 into multi-site international clinical trials in patients in 2023. Our Phase 1a trial of STAR-0215 initiated in August 2022, the ALPHA-STAR Phase 1b/2 trial initiated in February 2023, and the ALPHA-SOLAR long-term open-label trial initiated in late 2023. The increase in research and development expenses was attributable to a $3.9 million increase in CRO expenses to support the ALPHA-STAR and ALPHA-SOLAR clinical trials, a $3.3 million increase in employee expenses, and a $2.8 million increase in STAR-0310 and other research programs. These increases were partially offset by a $2.0 million decrease in consulting expenses and a $0.2 million decrease in facilities costs. As noted above, we expect that our research and development expenses over the next several quarters will be higher than prior periods.

General and Administrative Expenses

General and administrative expenses increased by $6.5 million to $25.7 million for the year ended December 31, 2023 from $19.2 million for the year ended December 31, 2022, an increase of 33%. The increase in general and administrative expenses was attributable to a $3.6 million increase in employee expenses due to company growth, a $3.0 million increase in professional services primarily due to increased legal fees and recruiting expenses, and a $0.3 million increase in general office expense, partially offset by a decrease of $0.2 million in insurance expenses and a $0.2 million decrease in the general and administrative portion of facilities.

Acquired In-Process Research and Development

Acquired IPR&D expense was $15.2 million during the year ended December 31, 2023. Acquired IPR&D expense resulted from the License Agreement with Ichnos that was entered into in October 2023. The upfront costs of the License Agreement and external legal fees attributable to the License Agreement were allocated to acquired IPR&D with no alternative future use and were recorded as an expense as of the date of the License Agreement. No acquired IPR&D expenses were incurred during the year ended December 31, 2022.

Other Income, Net

Other income, net increased by $8.5 million for the year ended December 31, 2023 compared to the year ended December 31, 2022, which was primarily attributable to interest income due to our higher cash balance from the proceeds of the December 2022 Financing and the October 2023 Financing in addition to higher investment yields in the year ended December 31, 2023.

Liquidity and Capital Resources

From our inception through December 31, 2023, we raised an aggregate of $673.0 million through equity financings including private placements of preferred stock before we became a public company, our private placement of preferred stock in February 2021, registered offerings of our common stock and/or warrants and our at-the-market programs. Subsequent to December 31, 2023, we raised an additional $117.1 million in net proceeds in the February 2024 Financing and $20.0 million in net proceeds under the Jefferies ATM Program.

As of December 31, 2023, we had $246.5 million in cash, cash equivalents and short-term investments, which, together with the net proceeds from shares sold under the Jefferies ATM Program in January 2024 and the net proceeds from the February 2024 Financing, we expect will enable us to fund our operating expenses and capital expenditure requirements into mid-2027. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities through completion of a planned Phase 3 pivotal trial, and (ii) for STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments under the License Agreement). Advancing the development of STAR-0215, STAR-0310, or any future product candidates will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments will not be sufficient to enable us to fund the completion of development of any of our product candidates, including STAR-0215, STAR-0310 or any future product candidate. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned.

We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215, STAR-0310 or any future product candidates, support our continuing operations, future clinical trials and the expansion of our pipeline. In addition, STAR-0215, STAR-0310, or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders. General economic conditions, both inside and outside the United States, including heightened inflation, capital market instability and volatility, interest rate and currency rate fluctuations and economic slowdown or recession as well as pandemics, epidemics and geopolitical events, including civil or political unrest (such as the Ukraine-Russian war and the conflict in the Middle East), may have a significant impact on the availability of funding sources and the terms on which any funding may be available. In addition, market instability and volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. If we fail to raise capital as, and when, needed, we may be unable to continue our operations at planned levels and be forced to modify our business strategies and reduce or terminate our operations. Although we will continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations when needed or at all.

December 2022 Financing

On December 19, 2022, we closed the December 2022 Financing, in which we sold 10,445,050 shares of our common stock for gross proceeds of approximately $115.0 million, and net proceeds of $107.6 million.

October 2023 Financing

On October 16, 2023, we closed the October 2023 Financing, in which we sold (i) 8,253,895 shares of our common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock for aggregate gross proceeds of approximately $64.0 million, and net proceeds of $59.5 million.

The common stock warrants and pre-funded warrants were classified within additional paid-in capital and were recorded on a relative fair value basis as of the issuance date. The common stock warrants and pre-funded warrants are freestanding instruments, are indexed to our common stock and meet the equity classification requirements.

February 2024 Financing

On February 1, 2024, we closed the February 2024 Financing, in which we sold 10,340,000 shares of our common stock for gross proceeds of approximately $125.0 million, and net proceeds of approximately $117.1 million.

At-the-Market Offerings

On June 30, 2021, we entered into an Open Market Sale Agreement[SM] with Jefferies LLC, or Jefferies, pursuant to which we were able to issue and sell shares of common stock of up to $25.0 million under the Jefferies ATM Program. We were obligated to pay Jefferies sales agent commissions of 3% of the gross proceeds from any common stock sold through the Jefferies ATM Program. In September 2022, the Jefferies ATM Program was modified to increase the amount of our common stock that was able to be offered thereunder to an aggregate offering price of up to $50.0 million, with $30.5 million of such amount then being available for future issuance. In November 2022, the Jefferies ATM Program was once again modified to increase the amount of our common stock that was able to be offered thereunder to an aggregate offering price of up to $88.1 million, with $50.0 million of such amount then being available for future issuance. In the year ended December 31, 2022, we sold an aggregate of 4,012,003 shares of common stock under the Jefferies ATM Program for gross proceeds of $38.2 million and net proceeds of $37.0 million. In the year ended December 31, 2023, we sold an aggregate of 4,738,606 shares of common stock under the Jefferies ATM Program for gross proceeds of $29.4 million and net proceeds of $28.5 million. As of December 31, 2023, $20.6 million of common stock remained available for sale under the Jefferies ATM Program. In January 2024, we sold an aggregate of 2,945,806 shares of common stock under the Jefferies ATM Program for gross proceeds of $20.6 million and net proceeds of $20.0 million which completed the sale of all available amounts under the Jefferies ATM Program.

Funding Requirements

Our primary uses of capital are for compensation and related expenses, manufacturing costs for preclinical and clinical materials, third party preclinical research and development services, legal and other regulatory expenses and general overhead.

As of December 31, 2023, we had an accumulated deficit of $580.5 million. We have been primarily involved with research and development activities and have incurred operating losses and negative cash flows from operations since our inception.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements into mid-2027. Our estimate as to how long we expect our cash, cash equivalents and short-term investments to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including:

- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for STAR-0215, STAR-0310 and any future product candidates, including potential future clinical trials;
- our ability to enter into and the terms and timing of any collaborations, licensing or other arrangements that we may establish;

- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, market access, distribution, supply chain and manufacturing capabilities, and scaling up the manufacturing of drug substance and drug product to clinical and commercial scale and developing a drug device combination, if applicable, securing all raw materials necessary to conduct such scale-up and successfully completing all other activities related thereto;
- if we obtain marketing approval of any of our product candidates, revenue, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our product candidates, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE and STAR-0310 in AD;
- our headcount growth and associated costs;
- the amount and timing of future milestone and royalty payments potentially payable to Ichnos pursuant to the License Agreement;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, STAR-0215, STAR-0310 or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing, if available, would result in periodic payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

Comparison of the Years Ended December 31, 2023 and 2022

The following table provides information regarding our cash flows for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (68,445)	$ (43,533)
Net cash provided by (used in) by investing activities	135,052	(167,129)
Net cash provided by financing activities	88,398	144,721
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 155,005	$ (65,941)

Net Cash Used in Operating Activities

Net cash used in operating activities was $68.4 million for the year ended December 31, 2023 and consisted primarily of a net loss of $72.9 million adjusted for stock-based compensation expense of $6.3 million, an adjustment to our right of use asset of $0.6 million, and a net increase in net assets of 2.4 million, which resulted primarily from an increase in prepaid expenses and long term deposits of $4.5 million and a decrease in the lease liability of $0.6 million, partially offset by an increase in accrued expenses of $2.0 million, and an increase in accounts payable of $0.7 million.

Net cash used in operating activities was $43.5 million for the year ended December 31, 2022 and consisted primarily of a net loss of $51.8 million, adjusted for non-cash expenses, stock-based compensation expense of $4.6 million, expense on warrants inherited in the acquisition of Quellis Biosciences, Inc. of $1.5 million, an increase in accrued expenses of $4.4 million, an increase in the right of use asset of $0.6 million, an increase in other non-cash items of $0.1 million, a decrease in accounts payable of $0.8 million, and a decrease in prepaid expenses of $1.6 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $135.1 million for the year ended December 31, 2023 and primarily consisted of proceeds from maturities of short-term investments of $2.1 billion, partially offset by purchases of short-term investments of $1.9 billion. Refer to Note 4- “Short-Term Investments” to our consolidated financial statements included in this Annual Report on Form 10-K for additional information. Net cash used in investing activities was $167.1 million for the year ended December 31, 2022 and consisted primarily of purchases of short-term investments of $396.1 million, partially offset by proceeds from maturities of short-term investments of $229.0 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $88.4 million during the year ended December 31, 2023, which was attributable to net proceeds of $59.5 million from the October 2023 Financing, net proceeds of $28.5 million from the Jefferies ATM Program and proceeds from exercises of stock options of $0.4 million. Net cash provided by financing activities was $144.7 million during the year ended December 31, 2022, which was primarily attributable to net proceeds of $107.6 million from the December 2022 Financing and net proceeds of $37.0 million from the Jefferies ATM Program.

Material Cash Requirements from Known Contractual Obligations

The following table summarizes our significant contractual obligations as of the payment due date as of December 31, 2023:

	Payments due by period		
(In thousands)	**Total**	**1 - 3 Years**	**More than 3 Years**
Operating lease obligations (1)	338	338	—
Payments under vendor agreements (2)	4,207	4,207	—
Total contractual cash obligations	$ 4,545	$ 4,545	$ —

(1) Represents future minimum lease payments under our sublease. The minimum lease payments above do not include any related common area maintenance charges or real estate taxes.
(2) Represents future milestone payments under vendor agreements if certain milestones related to the planned Phase 3 clinical trial of the STAR-0215 program are met and if certain clinical milestones related to the planned Phase 1 clinical trials of the STAR-0310 program are met.

As of December 31, 2023, our only material contractual obligations were our sublease pursuant to which we are required to make payments of $0.3 million until its expiration in June 2024, payment obligations of $2.2 million if certain clinical milestones related to the planned Phase 3 clinical trial of STAR-0215 are met and payment obligations of $2.0 million if certain clinical milestones related to the planned Phase 1 clinical trials of STAR-0310 are met. In January 2024, we entered into a new sublease as described under “Properties” in Part I, Item 2 of this Annual Report on Form 10-K, pursuant to which we are obligated to make lease payments of $6.9 million in the aggregate from September 2024 through November 2028.

We enter into agreements in the normal course of business with vendors for research studies, manufacturing, and other services and products for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts are cancelable at any time by us, generally upon 60 days' prior written notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, for this reporting period and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements together with the report of our independent registered public company accounting firm (PCAOB ID: 42) required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those consolidated financial statements is found in Item 15 of this Annual Report on Form 10-K.

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

There has been no change of accountants nor any disagreements with accountants on any matter of accounting principles or practices or financial disclosure required to be reported under this Item.

Item 9A. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2023, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our 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 generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the company;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2023. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013). Based on its assessment, our management believes that, as of December 31, 2023, our internal control over financial reporting was effective based on those criteria.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting in accordance with an exemption established for smaller reporting companies with annual revenue of less than $100 million.

Changes in Internal Control over Financial Reporting

During the three months ended December 31, 2023, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K) during the fourth quarter of 2023.

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 set forth under the captions "Election of Class III Directors — Information Regarding Directors," "Election of Class III Directors — Members of our Board of Directors Continuing in Office," "Executive Officers," "Corporate Governance — Code of Business Conduct and Ethics" "Corporate Governance — Director Nomination Process" and "Corporate Governance — Committees of the Board of Directors — Audit Committee" in our definitive proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2023, and is incorporated into this Annual Report on Form 10-K by reference.

We are also required under Item 405 of Regulation S-K to provide information concerning delinquent filers of reports under Section 16 of the Securities Exchange Act of 1934, as amended. If applicable, this information will be set forth under the caption "Delinquent Section 16(a) Reports" in our definitive proxy statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2023 and is incorporated into this Annual Report on Form 10-K by reference.

We have adopted a code of ethics, our Code of Business Conduct and Ethics, that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions. Our Code of Business Conduct and Ethics, as well as our corporate governance guidelines and the charters for the audit, compensation, nominating and corporate governance, and science and technology committees of our Board of Directors, are each accessible under the "Corporate Governance" heading of the "For Investors" section of our website, http://www.astriatx.com. We also intend to disclose in the same location on our website, any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

Item 11. Executive Compensation

The information required by this Item is set forth under the captions "Executive Compensation" (except for the section titled "Executive Compensation—Pay Versus Performance") and "Corporate Governance — Director Compensation" in our definitive proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2023, and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this Item is set forth under the captions "Executive Compensation — Securities Authorized for Issuance under Equity Compensation Plans" and "Principal Stockholders" in our definitive proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2023, and is incorporated into this Annual Report on Form 10-K by reference.

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

The information required by this Item is set forth under the captions "Corporate Governance — Director Independence" and "Certain Relationships and Related Person Transactions" in our definitive proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2023, and is incorporated into this Annual Report on Form 10-K by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item is set forth under the caption "Ratification of the Appointment of Ernst & Young LLP as Astria's Independent Registered Public Accounting Firm for the Fiscal Year Ending December 31, 2024" in our definitive proxy statement for our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of December 31, 2023, and is incorporated into this Annual Report on Form 10-K by reference.

PART IV

Item 15.

Exhibits and Financial Statement Schedules

(a)(1) Financial Statements

The financial statements listed below are filed as part of this Annual Report on Form 10-K and are incorporated herein by reference.

(a)(2) Financial Statement Schedules

All financial schedules have been omitted because the required information is either presented in the consolidated financial statements filed as part of this Annual Report on Form 10-K or the notes thereto or is not applicable or required.

(a)(3) Exhibits

The exhibits required for this Annual Report on Form 10-K by Item 601 of Regulation S-K and Item 15(b) of Form 10-K are listed in the following Exhibit Index:

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
2.1**	Agreement and Plan of Merger, dated January 28, 2021, by and among Catabasis Pharmaceuticals, Inc., Cabo Merger Sub I, Inc., Cabo Merger Sub II, LLC and Quellis Biosciences, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on January 29, 2021)
3.1	Restated Certificate of Incorporation of the Registrant, as amended (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on June 6, 2023)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on June 6, 2023)
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on October 12, 2023)
4.2	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on October 12, 2023)
4.3	Description of Registered Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form10-K (File No. 001-37467) filed with the SEC on March 10, 2022)
10.1	Warrant to Purchase Shares of Series X Preferred Stock issued on January 28, 2021 to Viridian LLC (incorporated by reference to Exhibit 10.9 to the Registrant's Annual Report on Form 10-K (File No. 001-37467) filed with the SEC on March 11, 2021)
10.2	Warrant to Purchase Shares of Common Stock issued on January 28, 2021 to Viridian LLC (incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K (File No. 001-37467) filed with the SEC on March 11, 2021)
10.3*	Amended and Restated 2008 Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-204144) filed with the SEC on May 13, 2015)
10.4*	Form of Incentive Stock Option Agreement under Amended and Restated 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-204144) filed with the SEC on May 13, 2015)
10.5*	Form of Nonstatutory Stock Option Agreement under Amended and Restated 2008 Equity Incentive Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-204144) filed with the SEC on May 13, 2015)
10.6*	Amended and Restated 2015 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on August 7, 2023)
10.7*	Form of Incentive Stock Option Agreement under Amended and Restated 2015 Stock Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on May 12, 2022)
10.8*	Form of Nonstatutory Stock Option Agreement under 2015 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on May 12, 2022)
10.9*	2015 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on May 12, 2022)
10.10*	2022 Inducement Stock Incentive Plan, as amended (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on December 20, 2023)
10.11*	Form of Nonstatutory Stock Option Agreement under the 2022 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on February 22, 2022)
10.12*	Amended and Restated Employment Agreement, dated as of April 7, 2010, by and between the Registrant and Jill C. Milne, as amended (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-204144) filed with the SEC on May 13, 2015)
10.13*	Form of Amended and Restated Executive Severance Benefit Plan effective October 7, 2020 (incorporated by reference to Exhibit 10.8 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on May 12, 2022)

10.14*	Form of Indemnification Agreement by and between the Registrant and each of its executive officers and directors (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-204144) filed with the SEC on May 13, 2015)
10.15	Sublease Agreement, dated as of January 28, 2022, by and between Grant Thornton LLP and the Registrant (incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K (File No. 001-37467) filed with the SEC on March 10, 2022)
10.16*	Quellis Biosciences, Inc. 2019 Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-254151) filed with the SEC on March 11, 2021)
10.17	Master Consulting Agreement between the Registrant and Joanne Beck dated as of April 3, 2023 with Statement of Work No. 1 thereto dated as of April 3, 2023 and Statement of Work No. 2 thereto dated as of July 6, 2023 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on August 7, 2023)
10.18+	License Agreement, dated as of October 4, 2023, by and between Ichnos Sciences SA, Ichnos Sciences Inc. and the Registrant
10.19	Sublease Agreement, dated as of January 3, 2024, by and between Duck Creek Technologies LLC and the Registrant
21.1	Subsidiaries of the Registrant
23.1	Consent of Ernst & Young LLP, independent registered public accounting firm
24.1	Power of Attorney (see signature page of this Annual Report on Form 10-K)
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Compensation Recovery Policy of the Registrant
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Calculation Linkbase
101.LAB	XBRL Taxonomy Labels Linkbase Document
101.PRE	XBRL Taxonomy Presentation Linkbase Document
101.DEF	Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Management contract or compensatory plan arrangement.

** Exhibits and/or schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Registrant hereby undertakes to furnish supplementally copies of any of the omitted exhibits and schedules upon request by the SEC; provided, however, that the Registrant may request confidential treatment pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, for any exhibits or schedules so furnished. A list identifying the contents of all omitted exhibits and schedules can be found on page iii of Exhibit 2.1.

\+ Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary

Not applicable.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Astria Therapeutics, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, 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 at 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 U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

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

STAR-0215 Accrued and Prepaid Research and Development Costs

Description of the Matter

The Company's accrued contracted costs for research and development expenses totaled $3.9 million at December 31, 2023, including accruals related to the Company's STAR-0215 clinical trials. In addition, the Company's other assets were $3.4 million, which included amounts that were paid in advance of services incurred pursuant to the STAR-0215 clinical trials. As discussed in Note 2 to the consolidated financial statements, the Company analyzes the progress of the clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued and prepaid balances at the end of any reporting period for the Company's STAR-0215 clinical trials. The Company is required to estimate such accruals and prepaids using judgment based on certain information, including actual costs incurred or level of effort expended, as provided by its vendors. Payments for such activities are based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected on the consolidated balance sheet within accrued contracted costs or other assets.

Auditing the Company's accrued and prepaid research and development costs for the Company's STAR-0215 clinical trials was complex, as accounting for the costs associated with the clinical trials requires subjective estimates of the level of services performed and the associated costs incurred by service providers. Furthermore, due to the duration of the Company's STAR-0215 clinical trials, and the timing of information received from third parties, the actual amounts incurred are not typically known at the time the consolidated financial statements are issued.

How We Addressed the Matter in Our Audit

To evaluate the accrued and prepaid research and development costs for the STAR-0215 clinical trials, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating the significant judgments and estimates made by management to determine the recorded accruals and prepayments. To test the significant judgments and estimates, we discussed the progress of research and development activities with the Company's research and development personnel that oversee the research and development projects and inspected the Company's contracts with third parties and pending change orders to assess the impact on amounts recorded. In addition, we inspected information obtained by the Company from third party vendors, which included the vendors' estimate of costs incurred to date. We also analyzed fluctuations in accruals by vendor and by trial throughout the period subject to audit and tested subsequent invoices received from third party vendors.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2010.

Boston, Massachusetts

March 4, 2024

Astria Therapeutics, Inc.
Consolidated Balance Sheets
(in thousands, except share and per share data)

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 175,530	$ 20,525
Short-term investments	71,000	205,912
Prepaid expenses and other current assets	4,412	1,253
Total current assets	250,942	227,690
Right-of-use asset	363	948
Other assets	3,361	1,995
Total assets	$ 254,666	$ 230,633
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,513	$ 788
Accrued expenses	9,708	7,690
Current portion of operating lease liabilities	329	582
Total current liabilities	11,550	9,060
Long term portion of operating lease liabilities	—	357
Total liabilities	11,550	9,417
Commitments (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share, 4,908,620 shares authorized and no shares issued and outstanding	—	—
Series X redeemable convertible preferred stock, $0.001 par value per share, 91,380 shares authorized; 31,107 and 31,455 shares issued and outstanding as of December 31, 2023 and December 31, 2022, respectively	95,324	96,398
Common stock, $0.001 par value per share, 150,000,000 shares authorized; 41,034,797 and 27,501,340 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	41	28
Additional paid-in capital	728,285	632,512
Accumulated other comprehensive loss	—	(79)
Accumulated deficit	(580,534)	(507,643)
Total stockholders' equity	243,116	221,216
Total liabilities and stockholders' equity	$ 254,666	$ 230,633

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

Astria Therapeutics, Inc.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 42,127	$ 34,264
General and administrative	25,704	19,239
Acquired in-process research and development	15,199	—
Total operating expenses	83,030	53,503
Loss from operations	(83,030)	(53,503)
Other income (expense):		
Interest and investment income	10,201	1,724
Other expense, net	(62)	(55)
Total other income, net	10,139	1,669
Net loss	(72,891)	(51,834)
Net loss per share attributable to common shareholders - basic and diluted	$ (2.42)	$ (3.55)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	30,123,316	14,620,618

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

Astria Therapeutics, Inc.
Consolidated Statements of Comprehensive Loss
(in thousands)

	Year Ended December 31,	
	2023	**2022**
Net loss	$ (72,891)	$ (51,834)
Other comprehensive gain (loss):		
Unrealized gain (loss) on short-term investments, net of tax of $0	79	(79)
Total other comprehensive gain (loss):	79	(79)
Comprehensive loss	$ (72,812)	$ (51,913)

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

Astria Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity
(in thousands, except share data)

	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Common stock, shares	Common stock, par value	Additional paid - in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity (deficit)
Balance at December 31, 2021	31,455	$ 96,398	13,016,955	$ 13	$ 481,709	$ (455,809)	$ —	$ 122,311
Expense related to warrants inherited in acquisiton of Quellis	—	—	—	—	1,542	—	—	1,542
Issuance of common stock pursuant to an underwriting agreement, net of underwriter's discount and issuance costs	—	—	10,445,050	10	107,636	—	—	107,646
Issuance of common stock for at-the-market offerings, net of issuance costs	—	—	4,012,003	4	36,987	—	—	36,991
Issuance of common stock upon exericse of options	—	—	27,332	1	84	—	—	85
Stock-based compensation expense	—	—	—	—	4,554	—	—	4,554
Unealized loss on short-term investments	—	—	—	—	—	—	(79)	(79)
Net loss	—	—	—	—	—	(51,834)	—	(51,834)
Balance at December 31, 2022	31,455	96,398	27,501,340	28	632,512	(507,643)	(79)	$ 221,216
Issuance of common stock upon the conversion of preferred stock	(348)	(1,074)	57,910	—	1,074	—	—	—
Issuance of common stock and warrants pursuant to an underwriting agreement, net of underwriter's discount and issuance costs	—	—	8,253,895	8	59,472	—	—	59,480
Issuance of common stock for at-the-market offerings, net of issuance costs	—	—	4,738,606	5	28,493	—	—	28,498
Issuance of common stock upon exercise of options and warrants	—	—	483,046	—	420	—	—	420
Stock-based compensation expense	—	—	—	—	6,314	—	—	6,314
Unealized gain on short-term investments	—	—	—	—	—	—	79	79
Net loss	—	—	—	—	—	(72,891)	—	(72,891)
Balance at December 31, 2023	31,107	95,324	41,034,797	41	728,285	(580,534)	—	243,116

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

Astria Therapeutics, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2023	2022
Operating activities		
Net loss	$ (72,891)	$ (51,834)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation expense	6,314	4,554
Net gain on warrants inherited in acquisition of Quellis	—	1,542
Right-of-use asset- operating lease	585	(554)
Other non-cash items	(40)	112
Changes in assets and liabilities:		
Prepaid expenses and other assets	(4,546)	(1,568)
Lease liability - operating lease	(610)	574
Accounts payable	725	(766)
Accrued expenses	2,018	4,407
Net cash used in operating activities	(68,445)	(43,533)
Investing activities		
Purchases of short-term investments	(1,924,423)	(396,064)
Sales and maturities of short-term investments	2,059,500	229,026
Purchases of property and equipment	(25)	(91)
Net cash provided by (used in) investing activities	135,052	(167,129)
Financing activities		
Proceeds from public offering, net of underwriting discounts and issuance costs	59,480	107,646
Proceeds from at-the-market offering, net of issuance costs	28,498	36,991
Proceeds from exercise of stock options and warrants	420	84
Net cash provided by financing activities	88,398	144,721
Net increase (decrease) in cash, cash equivalents and restricted cash	155,005	(65,941)
Cash, cash equivalents and restricted cash, beginning of period	20,688	86,629
Cash, cash equivalents and restricted cash, end of period	$ 175,693	$ 20,688
Supplemental disclosure of non-cash investing and financing activities:		
Operating lease right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 1,268
Supplemental disclosure of non-cash transactions:		
Conversion of Series X Preferred Stock into common stock	$ 1,074	$ —
Purchases of property and equipment in accounts payable and accrued liabilities	$ 17	$ —
Public offering issuance costs in accrued expenses	$ 120	$ 100

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

Astria Therapeutics, Inc.
Notes to Consolidated Financial Statements

1. Organization and Operations

The Company

Astria Therapeutics, Inc. (the "Company"), is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. The Company's lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema ("HAE"), a rare, debilitating and potentially life-threatening disease. The Company's second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis ("AD"), an immune disorder associated with loss of skin barrier function and itching. The Company was incorporated in the State of Delaware on June 26, 2008.

December 2022 Financing

On December 15, 2022, the Company entered into an underwriting agreement with Jefferies LLC and Evercore Group LLC, representatives of several underwriters, relating to an underwritten public offering (the "December 2022 Financing") of 9,082,653 shares (the "Shares) of common stock at a public offering price of $11.01 per share. The underwriters were also granted a 30-day option to purchase up to an additional 1,362,397 shares of common stock (the "Additional Shares") on the same terms and conditions as the Shares. The underwriters elected to purchase the full amount of the Additional Shares on December 19, 2022 for a total amount of shares issued of 10,445,050. This resulted in gross proceeds of $115.0 million, and net proceeds of $107.6 million. The December 2022 Financing included 2,270,663 shares issued to related parties.

License Agreement

On October 4, 2023, the Company entered into a license agreement (the "License Agreement") with Ichnos Sciences SA and Ichnos Sciences Inc. (collectively, "Ichnos") pursuant to which Ichnos granted to the Company an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and license to certain patent rights and related know-how (collectively, the "Licensed Intellectual Property"), to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as "ISB 830" as well as Ichnos' proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as "ISB 830-X8" and referred to by the Company as "STAR-0310 candidate" (collectively, the "Licensed Compounds"). The Company agreed to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product that contains or comprises a Licensed Compound (a "Licensed Product") in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

Under the terms of the License Agreement, the Company paid Ichnos a one-time upfront license fee of $15.0 million in October 2023. The Company is obligated to pay Ichnos up to $305.0 million in milestones, consisting of up to $20.0 million upon the achievement of certain development milestones, up to $70.0 million upon the achievement of certain regulatory milestones and up to $215.0 million upon the achievement of certain commercial milestones, in each case in up to three indications with respect to the first applicable Licensed Product to achieve such milestone events. The Company is also obligated to pay Ichnos tiered royalties ranging from a mid-single-digit percentage to a low-double-digit percentage on aggregate annual net sales of all Licensed Products. The Company is obligated to pay royalties on a Licensed Product-by-Licensed Product and country-by-country basis until the latest of: (i) the expiration of the last valid claim covering the composition of matter of such Licensed Product in such country; (ii) the expiration of the last regulatory exclusivity with respect to such Licensed Product in such country; and (iii) twelve years following the first commercial sale of such Licensed Product in such country. The royalty rate is subject to reduction on a Licensed Product-by-Licensed Product and country-by-country basis under certain circumstances.

October 2023 Financing

On October 16, 2023, the Company entered into an underwriting agreement with Jefferies LLC and Evercore Group LLC, representatives of several underwriters, relating to an underwritten offering (the "October 2023 Financing") of (i) 8,253,895 shares of common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock for aggregate gross proceeds of approximately $64.0 million, and net proceeds of $59.5 million. The October 2023 Financing included 2,727,340 shares of common stock, 3,223,824 common stock warrants, and 1,571,093 pre-funded warrants issued to related parties.

Liquidity

On June 30, 2021, the Company entered into an Open Market Sale AgreementSM with Jefferies LLC, or Jefferies, pursuant to which the Company was able to issue and sell shares of common stock of up to $25.0 million under an at-the-market offering program, or the Jefferies ATM Program. The Company was obligated to pay the sales agent commissions of 3% of the gross proceeds from any common stock sold through the Jefferies ATM Program. In September 2022, the Jefferies ATM Program was modified to increase the amount of the Company's common stock that was able to be offered thereunder to an aggregate offering price of up to $50.0 million, with $30.5 million of such amount then being available for future issuance. In November 2022, the Jefferies ATM Program was once again modified to increase the amount of the Company's common stock that was able to be offered thereunder to an aggregate offering price of up to $88.1 million, with $50.0 million of such amount then being available for future issuance. In the year ended December 31, 2022, the Company sold an aggregate of 4,012,003 shares of common stock under the Jefferies ATM Program for gross proceeds of $38.2 million and net proceeds of $37.0 million. In the year ended December 31, 2023, the Company sold an aggregate of 4,738,606 shares of common stock under the Jefferies ATM Program for gross proceeds of $29.4 million and net proceeds of $28.5 million. As of December 31, 2023, $20.6 million of common stock remained available for sale under the Jefferies ATM Program.

As of December 31, 2023, the Company had an accumulated deficit of $580.5 million and had available cash, cash equivalents and short-term investments $246.5 million. The Company estimates its existing cash, cash equivalents, and short-term investments are sufficient to sustain operations for at least twelve months from the issuance of these consolidated financial statements. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities. There can be no assurance that the Company will be able to obtain additional debt, equity or other financing or generate product revenue or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and regulatory approval and market acceptance of the Company's products. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Astria Securities Corporation and Quellis Biosciences, LLC, successor in interest to Quellis. All intercompany balances and transactions have been eliminated in consolidation. These consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP") and include all adjustments necessary for the fair presentation of the Company's financial position for the periods presented.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilizes certain estimates to record expenses relating to research and development contracts. These contract estimates, which are primarily related to the length of service of each contract and the amount of service provided as of each measurement date, are determined by the Company based on input from internal project management, as well as from service providers.

Off-Balance Sheet Risk

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

Concentrations of Credit Risk and Significant Suppliers

Financial instruments that subject the Company to credit risk primarily consist of cash, cash equivalents, short-term investments and restricted cash. The primary objectives for the Company's investment portfolio are the preservation of capital and the maintenance of liquidity. The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines allowable investments that the Company believes minimizes the exposure to concentration of credit risk.

The Company is dependent on third-party manufacturers to supply products for research and development activities in its programs. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients, other raw materials and formulated drugs related to these programs. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients, other raw materials and formulated drugs.

Cash and Cash Equivalents and Restricted Cash

The reconciliation of cash, cash equivalents and restricted cash reported within the applicable balance sheet that sum to the total of the same such amount shown in the statement of cash flows is as follows (in thousands):

	December 31,	
	2023	2022
Cash and cash equivalents	$ 175,530	$ 20,525
Restricted cash (1)	163	163
Total	$ 175,693	$ 20,688

(1) Included as a component of prepaid expenses and other current assets at December 31, 2023 and other long-term assets at December 31, 2022.

Short-Term Investments

The Company classifies all corporate debt securities with a remaining maturity of greater than three months and reverse repurchase agreements with a remaining maturity of greater than one business day at the time of purchase as short-term investments. Short-term investments are recorded at fair value, with the unrealized gains and losses reported in other comprehensive loss. The amortized cost of debt securities is adjusted for the amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest and investment income. Realized gains and losses, interest, dividends and declines in value judged to be other-than-temporary are included in interest and investment income.

At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis,

the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

The cost of securities sold is based on the specific identification method for purposes of recording realized gains and losses. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary.

Fair Value of Financial Instruments

The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels as follows: Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities; Level 2 inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly; and Level 3 inputs are unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

The carrying amounts reflected in the balance sheets for cash equivalents, restricted cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values at December 31, 2023 and 2022, due to their short-term nature. There have been no changes to the valuation methods during the years ended December 31, 2023 and 2022. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of assets or liabilities between levels during the years ended December 31, 2023 and 2022.

The Company's investment portfolio may include fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company apply other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare valuations. The Company validates the prices provided by its third party pricing services by obtaining market values from other pricing sources and analyzing pricing data in certain instances. The Company also invests in certain reverse repurchase agreements which are collateralized by deposits in the form of United States Government Securities and Obligations for an amount no less than 102% of their value. The Company does not record an asset or liability for the collateral as the Company is not permitted to sell or re-pledge the collateral. The collateral has at least the prevailing credit rating of United States Government Treasuries and Agencies. The Company utilizes a third party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the reverse repurchase agreements on a daily basis.

The Company accounted for warrants to purchase its stock pursuant to Accounting Standards Codification ("ASC") Topic 470, Debt, and ASC Topic 480, Distinguishing Liabilities from Equity, and classifies warrants for common stock and preferred stock as liabilities or equity. The warrants classified as liabilities are reported at their estimated fair value and any changes in fair value are reflected in research and development expense. The warrants classified as equity are reported at their estimated fair value with no subsequent remeasurement.

Impairment of Long-Lived Assets

The Company continually evaluates whether events or circumstances have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. The Company has not recognized any significant impairment charges from inception through December 31, 2023.

Accrued and Prepaid Research and Development Costs

Research and development costs are expensed as incurred. Research and development costs include salaries and personnel-related costs, stock-based compensation, consulting fees, fees paid for contract research services, the costs of laboratory equipment and facilities and other external costs. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred. The deferred amounts are expensed as the related goods are delivered or the services are performed.

The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances and prepaid balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation (*"ASC 718"). ASC 718 requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their grant date fair values. For granted stock options, the Company estimates the grant date fair value of each option award using the Black-Scholes option-pricing model. The use of the Black-Scholes option-pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the Company's common stock consistent with the expected term of the option, risk-free interest rates and expected dividend yields of the Company's common stock.

For awards subject to service-based vesting conditions, the Company recognizes stock-based compensation expense equal to the grant date fair value of stock options on a straight-line basis over the requisite service period.

The Company expenses restricted stock awards based on the fair value of the award on a straight-line basis over the associated service period of the award.

During the years ended December 31, 2023 and 2022, the Company recorded stock-based compensation expense for employee and non-employee stock options and restricted stock, which was allocated as follows in the statements of operations (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 1,304	$ 1,318
General and administrative	5,010	3,236
Total	$ 6,314	$ 4,554

No related tax benefits were recognized for the years ended December 31, 2023 and 2022.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. The Company has included pre-funded warrants to purchase 1,571,093 shares of common stock at an exercise price of $0.001 in its computation of basic net loss per share. Diluted net loss per share attributable to common stockholders is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the Company's dilutive net loss per share attributable to common stockholders calculation, stock options and warrants to purchase the Company's common stock were considered to be common stock equivalents but were excluded from the calculation of diluted net loss per share attributable to common stockholders, as their effect would be anti-dilutive; therefore, basic and diluted net loss per share attributable to common stockholders were the same for all periods presented.

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2023	2022
Series X Preferred Stock	5,184,591	5,242,501
Stock options	3,553,969	2,253,431
Common stock warrants	7,700,596	1,530,176
	16,439,156	9,026,108

Income Taxes

The Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse. A valuation allowance is provided to reduce the deferred tax assets to the amount that will more likely than not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC Topic 740, *Expenses—Income Taxes*. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company did not have any uncertain tax positions for any periods presented.

The Company assesses the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where it has operations to determine the potential effect on its business and any assumptions the Company has made about its future taxable income. The Company cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on its business if they were to be enacted. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures and requires taxpayers to amortize expense incurred in the United States over five years, and expense incurred outside of the United States over fifteen years. The United States Congress is considering legislation that would defer the amortization requirement to future periods, however, the Company has no assurance that the provision will be repealed or otherwise modified.

Segment Information

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker, the Company's chief executive officer, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business in one operating segment. The Company operates in one geographic segment.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. Other comprehensive loss for all periods presented consists solely of unrealized gains (losses) on available-for-sale securities.

Leases

The Company determines if an arrangement is a lease at inception. Leases that are economically similar to the purchase of assets are generally classified as finance leases; otherwise the leases are classified as operating leases. The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. Leases with a term greater than one year are recognized on the balance sheet as right-of-use ("ROU") assets, current portion of lease obligations, and long-term lease obligations. The Company does not currently hold any financing leases.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease obligations represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and obligations are recognized at the commencement date based on the present value of lease payments over the lease term. However, certain adjustments to the ROU asset may be required for items such as incentives received. The Company has elected as an accounting policy to combine lease and non- lease components, such as common area maintenance, for all classes of underlying assets. As the Company's facility leases do not provide an implicit interest rate, the Company uses its estimated 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 at the commencement date. To estimate its incremental borrowing rate, a credit rating applicable to the Company is estimated using synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating.

The Company's ROU lease assets also include any lease payments made and excludes lease incentives. The Company would recognize facility leases that include options to terminate the lease that would affect the lease period when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments under facility leases are recognized on a straight-line basis over the lease term.

Acquired In-Process Research and Development

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is charged to expense at the acquisition date. Refer to "License Agreement" below in this Note 2 for a more detailed description of the accounting policy utilized for the recent asset acquisition.

Preferred Stock Discount

In February 2021, the Company issued Series X Preferred Stock in a private placement transaction. It was determined that this transaction resulted in recognition of a beneficial conversion feature, which was valued based on the difference between the price of the shares of common stock on the date of commitment and the conversion price on the closing date, resulting in a total value of $19.6 million. Additionally, the Company incurred total issuance costs of $5.7 million related to the private placement. Both of these features were recorded as a discount on Series X Preferred Stock recognized at the close of the transaction. These features are analogous to preferred dividends and are recorded as a non-cash return to holders of Series X Preferred Stock through additional paid in capital. The discount related to the beneficial conversion feature is recognized through the earliest possible date of conversion, which occurred upon the stockholder approval of the conversion in June 2021. The issuance costs are recognized as a dividend at the time of conversion to common shares. As of December 31, 2023, $24.4 million of the above amounts were accounted for as a non-cash dividend related to shares of Series X Preferred Stock, and $0.9 million remained to be recognized upon future conversion.

Financing Costs

Costs incurred in connection with the issuance of equity units and shares are recorded as a reduction of proceeds to the equity carrying value. The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process financings as deferred offering costs until such financings are consummated. After consummation of the financing, these costs are recorded as a reduction of the proceeds received from the financing. If a planned financing is abandoned, the deferred offering costs are expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. There were no deferred offering costs on the Company's consolidated balance sheet at December 31, 2023 and December 31, 2022.

Recent Accounting Pronouncements – Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date.

In June 2016, the FASB issued Accounting Standards Update 2016-13, Financial Instruments-Credit Losses (Topic 326). This standard requires a financial asset to be presented at amortized cost basis at the net amount expected to be collected. It also requires that credit losses relating to available-for-sale debt securities should be recorded through an allowance for credit losses. In November 2019, the FASB issued an amendment making this standard effective for annual reporting periods beginning after December 15, 2022 for

smaller reporting companies. Early adoption was permitted. The Company adopted this standard on January 1, 2023 with no material impact on the consolidated financial statements.

Recent Accounting Pronouncements – Not Yet Adopted

In August 2020, the FASB issued Accounting Standards Update 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) ("ASU 2020-06"), which reduces the number of accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU 2020-06 is effective for the Company for the fiscal year beginning on January 1, 2024, with early adoption permitted. The Company plans to adopt this standard on January 1, 2024 with no material impact on the consolidated financial statements expected.

In November 2023, the FASB issued Accounting Standards Update 2023-07, Segment Reporting (Topic 280: Improvements to Reportable Segment Disclosures ("ASU 2023-07"). The amendments in this update improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses. All disclosure requirements of the update are required for entities with a single reportable segment. The amendments are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, and should be applied on a retrospective basis to all periods presented. The Company will adopt this standard as of January 1, 2024 with no material impact on the consolidated financial statements expected.

License Agreement

On October 4, 2023, the Company entered into the License Agreement, with Ichnos as discussed in Note 1, "Organization and Operations". Under the terms of the License Agreement, the Company paid Ichnos a one-time upfront license fee of $15.0 million in October 2023. The Company concluded that the License Agreement was not the acquisition of a business, as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset "ISB 830-X8", referred to by the Company as the STAR-0310 candidate. STAR-0310 is STAR-0310 candidate engineered with YTE half-life extension technology.

The Company determined that the cost to acquire the Licensed Intellectual Property assets was $15.2 million, primarily based on the fair value of the upfront license fee of $15.0 million and external legal fees of $0.2 million attributable to the acquired IPR&D. As the STAR-0310 candidate had not, at the time of the License Agreement, received regulatory approval in any territory, the cost attributable to the IPR&D was expensed in the Company's consolidated statements of operations and comprehensive loss for the year ended December 31, 2023 as the acquired IPR&D had no alternative future use, as determined by the Company in accordance with U.S. GAAP.

3. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities that have been measured at fair value and indicates the fair value hierarchy of the valuation inputs utilized to determine such fair value. During the years ended December 31, 2023 and 2022, there were no transfers between Level 1, Level 2 and Level 3.

Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	As of December 31, 2023			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 7,709	$ —	$ —	$ 7,709
Short-term investments:				
Reverse repurchase agreements	—	71,000	—	71,000
Total	$ 7,709	$ 71,000	$ —	$ 78,709

	As of December 31, 2022			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 1,944	$ —	$ —	$ 1,944
Short-term investments:				
Corporate debt securities	—	16,445	—	16,445
Yankee securities	—	1,999	—	1,999
Bonds	—	2,988	—	2,988
Treasury bills	5,980	—	—	5,980
Reverse repurchase agreements	—	178,500	—	178,500
Total	$ 7,924	$ 199,932	$ —	$ 207,856

At December 31, 2023 and 2022, cash equivalents approximated their fair value due to their short-term nature.

4. Short-Term Investments

The following tables summarize the short-term investments held at December 31, 2023 and 2022 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2023				
Reverse repurchase agreements	$ 71,000	$ —	$ —	$ 71,000
Total	$ 71,000	$ —	$ —	$ 71,000

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2022				
Corporate debt securities	$ 16,508	$ —	$ (63)	$ 16,445
Treasury bills	5,983	—	(3)	5,980
Yankee securities	2,000	—	(1)	1,999
U.S. agency bonds	3,000	—	(12)	2,988
Reverse repurchase agreements	178,500	—	—	178,500
Total	$ 205,991	$ —	$ (79)	$ 205,912

The contractual maturities of all short-term investments held at December 31, 2023 and December 31, 2022 were one year or less. There were no short-term investments in an unrealized loss position at December 31, 2023. There were 16 short-term investments in an unrealized loss position at December 31, 2022 with an aggregate value of $25.6 million. These investments were in a loss position for less than 12 months and the Company considered the loss to be temporary in nature. The Company considered the decline in market value for these securities to be primarily attributable to economic and market conditions.

Gross realized gains and losses on the sales of short-term investments are included in other income, net. Unrealized holding gains or losses for the period that have been included in accumulated other comprehensive income, as well as gains and losses reclassified out of accumulated other comprehensive income into other income, net, were not material to the Company's consolidated results of operations. The cost of investments sold or the amount reclassified out of the accumulated other comprehensive income into other income, net is based on the specific identification method for purposes of recording realized gains and losses. All proceeds in the years ended December 31, 2023 and 2022 related to maturities of underlying investments. The gains on proceeds from maturities of short-term investments were not material to the Company's consolidated results of operations for the years ended December 31, 2023 and 2022.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Accrued contracted costs	$ 3,861	$ 2,822
Accrued compensation	4,047	3,373
Accrued professional fees	1,485	588
Accrued other	315	407
Accrued milestones	—	500
Total	$ 9,708	$ 7,690

6. Commitments

On January 28, 2022, the Company entered into a sublease agreement (the "Sublease") with Grant Thornton LLP for new office space to replace its existing office space. The Sublease commenced on May 1, 2022 and will end on July 31, 2024 (or on such earlier date as the term may cease or expire as set forth in the Sublease).

Future minimum payments required under the Sublease as of December 31, 2023 are summarized as follows (in thousands):

Period Ending December 31,	Amount
2024	$ 338
Total lease payments	$ 338
Less: imputed interest	$ (9)
Total operating lease liabilities	$ 329

Rent expense was $0.6 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively. Lease payments were $0.7 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively.

7. Stockholders' Equity

Preferred Stock

Under the Company's amended and restated certificate of incorporation, the Company has 5,000,000 shares of preferred stock authorized for issuance, with a $0.001 par value per share. Preferred stock may be issued from time to time in one or more series, each series to have such terms as stated or expressed in the resolutions providing for the issue of such series adopted by the board of directors of the Company. Preferred stock which may be redeemed, purchased or acquired by the Company may be reissued except as otherwise provided by law. As of December 31, 2023, the Company had 31,107 shares of Series X Preferred Stock outstanding. Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock and therefore the number of shares of underlying common stock issuable upon conversion of the Series X Preferred Stock is 5,184,591.

Outstanding Warrants

The following table presents information about warrants that are issued and outstanding at December 31, 2023:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2019	Common Stock	331,858	$ 37.50	2/7/2024
2023 (1)	Common Stock	7,368,738	$ 8.03	10/16/2028
Total		7,700,596		
Weighted average exercise price			$ 9.30	
Weighted average life in years				4.60

(1) 1,571,093 pre-funded warrants were issued and outstanding in 2023, not included in the table above, with an exercise price of $0.001 and are exercisable until all pre-funded warrants are exercised in full.

Common Stock

As of December 31, 2023, the Company had 150,000,000 shares of common stock authorized for issuance, $0.001 par value per share, with 41,034,797 shares issued and outstanding. The voting, dividend and liquidation rights of holders of common stock are subject to and qualified by the rights, powers and preferences of the holders of any outstanding preferred stock.

Reserved for Future Issuance

The Company has reserved for future issuance the following shares of common stock:

	December 31, 2023	December 31, 2022
Warrants for the purchase of common stock	9,271,689	1,530,176
Reserve under the 2015 Amended and Restated Stock Incentive Plan and the 2022 Inducement Stock Incentive Plan	5,334,301	1,013,520
Series X Preferred Stock	5,184,591	5,242,501
Options outstanding to purchase common stock	3,553,969	2,253,431
Shares reserved for the employee stock purchase plan	43,060	36,982
Total	23,387,610	10,076,610

8. Stock Incentive Plans

Prior to the Company's initial public offering in June 2015 (the "IPO"), the Company granted awards to eligible participants under its 2008 Equity Incentive Plan. In May 2015, the Company's board of directors adopted and, in June 2015, the Company's stockholders approved the 2015 Stock Incentive Plan, as amended and amended and restated since the IPO ("2015 Plan"), which became effective immediately prior to the effectiveness of the IPO. Subsequent to the IPO, no option grants have been awarded to eligible participants under the 2008 Equity Incentive Plan.

The 2015 Plan provides for the grant of incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock-based awards. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2015 Plan.

Terms of stock option agreements, including vesting requirements, are determined by the Company's board of directors, subject to the provisions of the applicable stock incentive plan. Options granted by the Company generally vest ratably over four years, with a one-year cliff, and options are exercisable from the date of grant for a period of ten years.

On February 1, 2023, the Company issued stock options exercisable for 855,000 shares of common stock to certain officers of the Company subject to stockholder approval of the authorization of additional shares of common stock for issuance under the 2015 Plan on or before January 31, 2024. On June 2, 2023, the Company's stockholders approved the addition of 4,300,000 shares of common stock to the shares of common stock authorized for issuance under the 2015 Plan, which satisfied the grant condition on such officer grants. As of December 31, 2023, 755,000 of these options remain outstanding.

On February 17, 2022, the Company's Board of Directors adopted the 2022 Inducement Stock Incentive Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards with respect to an aggregate of 300,000 shares of the Company's common stock. On January 31, 2023, the Company's Board of Directors approved an amendment to the Inducement Plan to increase the number of shares of common stock authorized for issuance thereunder from 300,000 shares of common stock to 700,000 shares of common stock. On December 14, 2023, the Company's Board of Directors approved an additional amendment to the Inducement Plan to increase the number of shares of common stock authorized for issuance thereunder from 700,000 shares of common stock to 1,700,000 shares of common stock. Awards under the Inducement Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). As of December 31, 2023, options to purchase 687,900 shares of common stock have been granted under the Inducement Plan, which are included in the table above.

A summary of the Company's stock option activity and related information for employees and non-employees follows:

	Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	2,253,431	$ 15.43	8.57	$ 9,733
Granted	1,906,050	$ 12.01		
Exercised	(78,050)	$ 5.37		
Cancelled or forfeited	(526,939)	$ 16.80		
Expired	(523)	$ 138.60		
Outstanding at December 31, 2023	3,553,969	$ 13.59	8.39	$ 1,912
Vested and exercisable at December 31, 2023	1,107,936	$ 18.62	7.42	$ 821
Vested and expected to vest at December 31, 2023	3,553,969	$ 13.59	8.39	$ 1,912

The total intrinsic value of options exercised in the years ended December 31, 2023 and 2022 was $0.5 million and $0.2 million respectively. The total grant date fair value of stock options vested for the year ended December 31, 2023 and 2022 was $4.4 million and $5.6 million, respectively. The weighted-average grant date fair value of options granted to employees and non-employees for the years ended December 31, 2023 and 2022 was $7.20 and $3.82, respectively.

At December 31, 2023, the total unrecognized compensation expense related to unvested stock option awards was $13.8 million. The Company expects to recognize that cost over a weighted-average period of approximately 2.5 years.

Stock-Based Compensation Expense

The fair value of stock options granted to employees and non-employees was estimated using the Black-Scholes option-pricing model based on the following assumptions:

	Year Ended December 31,	
	2023	2022
Weighted-average expected volatility	65.86%-73.68%	65.60-70.22%
Expected term (in years)	5.5-6.25	5-6.25
Risk-free interest rate	3.42%-4.67%	1.48-4.17%
Expected dividend yield	0%	0%

Volatility

Due to the lack of company-specific historical and implied volatility data of its common stock, the Company does not have sufficient relevant historical data to support its expected volatility. As such, the Company has used a weighted average of expected volatility based on a combination of the Company's own historical volatility and volatilities of a representative group of publicly traded biopharmaceutical companies. For purposes of identifying representative companies, the Company considered characteristics such as number of product candidates in early stages of product development, area of therapeutic focus, and length of trading history. The expected volatility was determined using the weighted average of the Company's own historical volatility and an average of the historical volatilities of the representative group of companies for a period equal to the expected term of the option grant. The Company intends to continue to consistently apply this process using the same representative companies until sufficient historical information regarding the volatility of the Company's own share price becomes available or until circumstances change, such that the identified entities are no longer representative companies. In the latter case, more suitable, similar entities whose share prices are publicly available would be utilized in the calculation.

Expected Term

The Company uses the "simplified method" to estimate the expected term of stock option grants. Under this approach, the weighted-average expected life is presumed to be the average of the contractual term (ten years) and the vesting term (generally four years) of the Company's stock options, taking into consideration multiple vesting tranches. The Company utilizes this method due to lack of historical exercise data and the plain-vanilla nature of the Company's share-based awards.

Risk-Free Rate

The risk-free rate was based on the yield curve of United States Treasury securities with periods commensurate with the expected term of the options being valued.

9. Income Taxes

For the years ended December 31, 2023 and 2022, the Company did not record a provision for federal or state income taxes as it has incurred cumulative net operating losses since inception.

A reconciliation of the U.S. statutory income tax rate to the Company's effective tax rate is as follows for the years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Federal income tax (benefit) at statutory rate	21.00 %	21.00 %
Permanent differences	(0.12)	(0.66)
Federal research and development credits and adjustments	3.44	3.88
State income tax, net of federal benefit	6.25	5.67
Stock compensation	(1.61)	(1.25)
Other	0.05	(0.58)
Change in valuation allowance	(29.01)	(28.11)
Effective income tax rate	— %	— %

The Company's deferred tax assets consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets		
Net operating loss carryforwards	$ 85,734	$ 80,136
Tax credit carryforwards	14,576	12,073
Capitalized research and development	16,927	8,094
Capitalized licenses	4,041	—
Capitalized legal expenses	918	964
Lease liability	90	257
Other differences	2,587	2,365
Total gross deferred tax assets	124,873	103,889
Less valuation allowance	(124,774)	(103,630)
Net deferred tax assets	99	259
Deferred tax liabilities		
ROU asset	(99)	(259)
Net deferred taxes	$ —	$ —

For taxable years beginning after December 31, 2021, the Tax Cuts and Jobs Act (the "Tax Act") eliminated the option to deduct research and development expenditures in the current year and requires taxpayers to capitalize such expenses pursuant to Internal Revenue Code ("IRC") Section 174. As a result of this provision of the Tax Act, deferred tax assets related to capitalized research

expenses pursuant to IRC Section 174 increased to approximately $16.9 million for the year ended December 31, 2023, and $8.1 million for the year ended December 31, 2022.

The Company recorded an increase to the valuation allowance of $21.1 million during the year ended December 31, 2023 due primarily to the federal and state net operating losses and tax credits generated in the current year. The Company recorded an increase to the valuation allowance of $14.6 million during the year ended December 31, 2022 which was also primarily due to the federal and state net operating losses, and tax credits generated.

In assessing the realizability of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Due to the Company's history of losses and expectation of future losses, the deferred tax assets were fully offset by a valuation allowance at December 31, 2023 and 2022.

As of December 31, 2023, the Company had approximately $314.4 million of federal and $312.0 million of state net operating loss respectively, which may be available to offset future taxable income, if any, of which $150.6 million of federal and $312.0 million of state carryforwards will expire at various dates from 2028 through 2043. Additionally, $163.8 million of federal net operating loss carryforwards will carry forward indefinitely. The Company had $11.8 million of federal and $3.5 million of state tax credit carryforwards available to reduce future tax liabilities as of December 31, 2023, which will expire at varying times through the year 2043.

The IRC provides for a limitation of the annual use of net operating losses and other tax attributes (such as research and development tax credit carryforwards) following certain ownership changes (as defined by the IRC) that could limit the Company's ability to utilize these carryforwards. The Company has completed a study to assess whether an ownership change under Section 382 of the IRC has occurred and as a result the Astria Federal and State net operating loss and research and development credit carryforwards are significantly limited for use. Accordingly, the Company's ability to utilize the aforementioned carryforwards are limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be applied against future taxes. Therefore, the Company will not be able to take full advantage of all of its current carryforwards for federal or state income tax purposes.

As of December 31, 2023 and 2022, the Company did not have any significant unrecognized tax benefits. Interest and penalty charges, if any, related to uncertain tax positions would be classified as income tax expenses in the accompanying consolidated statements of operations. The Company has not had any accrued interest or penalties related to uncertain tax positions.

The federal and state income tax returns are generally subject to tax examinations for the tax years ended December 31, 2020 through December 31, 2023. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service or state taxing authorities to the extent utilized in a future period.

10. Defined Contribution Benefit Plan

The Company sponsors a 401(k) retirement plan, in which substantially all of its employees are eligible to participate. Participants may contribute a percentage of their annual compensation to this plan, subject to statutory limitations. The Company provided $0.2 million and $0.1 million in matching contributions during the years ended December 31, 2023 and 2022, respectively.

11. Subsequent Events

Operating Lease

On January 3, 2024, the Company entered into a sublease agreement (the "Sublease Agreement") with Duck Creek Technologies LLC, a Delaware limited liability company (the "Sublandlord"), pursuant to which the Company will sublease approximately 30,110 square feet of office space located at 22 Boston Wharf Road, Boston, Massachusetts 02210 (the "Premises"). The Premises is the subject of a lease, dated as of August 7, 2017, by and between MEPT Seaport 13 Stillings LLC, a Delaware limited liability company (the "Landlord"), and the Sublandlord, as tenant (the "Lease"). The term of the sublease of the Premises to the Company under the Sublease Agreement is scheduled to commence on the later to occur of (i) June 1, 2024 and (ii) the date that the Landlord grants its consent to the Sublease Agreement and will end on November 30, 2028 (or on such earlier date as the term may sooner cease or expire as set forth in the Sublease Agreement). The Sublease Agreement will increase the future minimum lease payments described in Note 6 from approximately $0.3 million to approximately $6.9 million.

At-the-Market Offerings

On January 5, 2024, the Company sold an aggregate of 2,945,806 shares of common stock under the Jefferies ATM Program for gross proceeds of $20.6 million and net proceeds of $20.0 million which completed the sale of all available amounts under the Jefferies ATM Program.

February 2024 Financing

On February 1, 2024, the Company announced the closing of an underwritten public offering of 10,340,000 shares of our common stock at a price of $12.09 per share (the "February 2024 Financing"). The gross proceeds of the February 2024 Financing were approximately $125.0 million, and net proceeds were approximately $117.1 million.

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.

Astria Therapeutics, Inc.

Date: March 4, 2024

By: /s/ Jill C. Milne
Jill C. Milne
President and Chief Executive Officer

We, the undersigned directors and officers of Astria Therapeutics, Inc. (the "Company"), hereby severally constitute and appoint Jill C. Milne and Noah Clauser, and each of them singly, our true and lawful attorneys, with full power to them, and to each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to this Annual Report on Form 10-K, and to file or cause to be filed the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys, and each of them, 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 to all intents and purposes as each of us might or could do in person, and hereby ratifying and confirming all that said attorneys, and each of them, or their substitute or substitutes, shall do or cause to be done by virtue of this Power of Attorney.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jill C. Milne Jill C. Milne	President and Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2024
/s/ Noah Clauser Noah Clauser	Chief Financial Officer and Treasurer (Principal Financial Officer, Principal Accounting Officer)	March 4, 2024
/s/ Kenneth Bate Kenneth Bate	Chairman	March 4, 2024
/s/ Joanne Beck Joanne Beck	Director	March 4, 2024
/s/ Frederick C. Callori Frederick C. Callori	Director	March 4, 2024
/s/ Hugh Cole Hugh Cole	Director	March 4, 2024
/s/ Michael Kishbauch Michael Kishbauch	Director	March 4, 2024
/s/ Gregg Lapointe Gregg Lapointe	Director	March 4, 2024
/s/ Jonathan Violin Jonathan Violin	Director	March 4, 2024

Exhibit 10.18

EXECUTION COPY

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

LICENSE AGREEMENT

by and between

ICHNOS SCIENCES SA

ICHNOS SCIENCES INC.

and

ASTRIA THERAPEUTICS, INC.

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LICENSE AGREEMENT

This License Agreement (this "Agreement") is entered into as of October 4, 2023 (the "Effective Date") by and between Ichnos Sciences SA, a company organized under the laws of Switzerland with its registered address at 5 chemin de la Combetta, 2300 La Chaux-de-Fonds, Switzerland and registered with the register of commerce of the Canton of Neuchatel under registration number CHE-111.750.689 ("Ichnos SA"), and Ichnos Sciences Inc., a corporation organized under the laws of Delaware, USA ("Ichnos Inc." and, together with Ichnos SA, "Ichnos"), and Astria Therapeutics, Inc., a corporation organized under the laws of Delaware, USA ("Astria"). Astria and Ichnos are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

INTRODUCTION

WHEREAS, Astria, among other things, conducts programs to discover, develop, manufacture, and commercialize innovative therapeutic products for the treatment and prevention of diseases;

WHEREAS, Ichnos has developed the Licensed Compounds and Licensed Products (each, as defined below) and owns or Controls certain Know-How and Patents (each as defined below) related thereto; and

WHEREAS, Astria desires to obtain, and Ichnos desires to grant to Astria, an exclusive license under such Know-How and Patents to develop, manufacture, and commercialize the Licensed Compounds and Licensed Products in accordance with the terms and subject to conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the respective representations, warranties, covenants, and agreements contained herein, and for other valuable consideration, the receipt and adequacy of which are hereby acknowledged, Ichnos and Astria hereby agree as follows:

Article I
Definitions

When used in this Agreement, each of the following terms shall have the meanings set forth in this Article I:

Section 1.1 "Accounting Standards" means: (a) the United States Generally Accepted Accounting Principles ("US GAAP"); or (b) International Financial Reporting Standards ("IFRS") of the International Accounting Standards Boards; in each case ((a) and (b)) as generally and consistently applied throughout the applicable Person's organization.

Section 1.2 "Acquirer" has the meaning set forth in Section 1.20.

Section 1.3 "Acting Party" has the meaning set forth in Section 6.6(a).

Section 1.4 "Affiliate" means, as to any Person, any other Person that, directly or indirectly, controls, is controlled by, or is under common control with such Person, as the case

may be, for so long as such control exists. As used in this Section 1.4, "control" means: (a) to possess, directly or indirectly, the power to direct the management and policies of a Person, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect beneficial ownership of at least fifty percent (50%) (or such lesser percentage that is the maximum allowed to be owned by a foreign Person in a particular jurisdiction and is sufficient to grant the holder of such voting stock or interest the power to direct the management and policies of such entity) of the voting share capital in a Person.

Section 1.5 "Agreement" has the meaning set forth in the Preamble to this Agreement.

Section 1.6 "Annual Net Sales" means, in relation to a Licensed Product, the total Net Sales of such Licensed Product by all Selling Parties in a particular Calendar Year in all countries in the Territory in which the Royalty Term for such Licensed Product has not expired.

Section 1.7 "Applicable Law" means, with respect to the activities of a Party, all Law applicable to such Party or such Party's activities under this Agreement.

Section 1.8 "Astria" has the meaning set forth in the Preamble to this Agreement.

Section 1.9 "Astria Indemnified Parties" has the meaning set forth in Section 10.2.

Section 1.10 "Astria Initial Press Release" has the meaning set forth in Section 8.3(a).

Section 1.11 "Audit Team" has the meaning set forth in Section 6.5(a).

Section 1.12 "Bankruptcy Code" means the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party or its assets.

Section 1.13 "beneficial owner," "beneficially owns," "beneficial ownership" and terms of similar import used in this Agreement will, with respect to a Person, have the meaning set forth in Rule 13d-3 under the Securities Exchange Act of 1934, as amended, (a) assuming the full conversion into, and exercise and exchange for, shares of common stock, other voting stock, or any securities exercisable for common stock or other voting stock beneficially owned by such Person and (b) determined without regard for the number of days in which such Person has the right to acquire such beneficial ownership.

Section 1.14 "Biosimilar Competition" means, on a Licensed Product-by-Licensed Product, country-by-country, and Calendar Quarter-by-Calendar Quarter basis, that (a) there are [**] or more Biosimilar Products being sold in such country with respect to such Licensed Product in such Calendar Quarter and (b) such Biosimilar Product(s), by unit equivalent volume in such country in such Calendar Quarter, exceed a [**] percent ([**]%) share of the aggregate market in such country of such Licensed Product and all such Biosimilar Product(s) (based on the number of units of such Licensed Product and such Biosimilar Product(s) in the aggregate sold in such country, as reported by a well-known reporting service agreed between the Parties acting reasonably (*e.g.*, IQVIA)).

Section 1.15 "Biosimilar Product" means, with respect to a given Licensed Product in a given country, any biological product that (a) has received all necessary approvals and licensures

by the applicable Regulatory Authorities in such country to market and sell such product as a biosimilar product; (b) is marketed or sold by a Third Party that has not obtained the rights to market or sell such product as a licensee, sublicensee, or distributor of Astria or any of its Affiliates or Sublicensees with respect to such product (other than a Third Party who obtains such rights as a result of settlement of any litigation arising under the Biologics Price Competition and Innovation Act or any equivalent law in a jurisdiction outside the U.S.); and (c) is approved as (i) a "biosimilar" of such Licensed Product (as defined in 42 U.S.C. § 262(i)(2)) or "interchangeable" with such Licensed Product (as defined in 42 U.S.C. § 262(i)(3)), (ii) a "similar biological medicinal product" with respect to which such Licensed Product is the "reference medicinal product," or (iii) if not in the United States or European Union, as the foreign equivalent of a "biosimilar" or "similar biological medicinal product" of such Product; in each case ((i)-(iii)), for use in such country pursuant to an abbreviated regulatory approval process governing approval of biosimilars based on the then-current standards for regulatory approval in such country, and where such regulatory approval was based in part upon findings by the Regulatory Authority of clinical safety and efficacy based on clinical data generated by either Party or any of either Party's Affiliates or any Sublicensee with respect to such Licensed Product.

Section 1.16 "Business Day" means a day other than a Saturday or Sunday or any other day regularly recognized as a holiday by the Party responsible for performance.

Section 1.17 "Calendar Quarter" means a calendar quarter ending on the last day of March, June, September, or December; except that: (a) the first Calendar Quarter will begin on the Effective Date and end on December 31, 2023; and (b) the final Calendar Quarter will end on the last day of the Term.

Section 1.18 "Calendar Year" means a period of time commencing on January 1 and ending on the following December 31; except that: (a) the first Calendar Year will begin on the Effective Date and end on December 31, 2023; and (b) the final Calendar Year will end on the last day of the Term.

Section 1.19 "Cell Line License Agreement" means that [**].

Section 1.20 "Change of Control" of a Party means any of the following, in a single transaction or a series of related transactions: (a) the sale or disposition of all or substantially all of the assets of such Party to a Third Party (or multiple Third Parties acting in concert), (b) the direct or indirect acquisition by a Third Party (or multiple Third Parties acting in concert) (other than an employee benefit plan (or related trust) sponsored or maintained by such Party or any of its Affiliates) of beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of such Party or any direct or indirect parent entity that holds, directly or indirectly, beneficial ownership of more than fifty percent (50%) of the then-outstanding common shares or voting power of such Party (a "Parent Entity"), or (c) the merger or consolidation of such Party or any of its Parent Entities with or into any Third Party, unless, following such merger or consolidation, the stockholders of such Party or Parent Entity (as applicable) immediately prior to such merger or consolidation beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding common shares or voting power of the entity resulting from such merger or consolidation. The Third Party (or group of Third Parties acting in concert, as applicable) in any of clauses (a), (b), or (c) is referred to herein as the

"Acquirer," and any of such Acquirer's Affiliates (whether in existence as of or any time following the applicable transaction, but other than the Party subject to the Change of Control and its Affiliates as in existence immediately prior to the applicable transaction or Persons that such Party or such Affiliates control (directly or indirectly) after the applicable transaction) are referred to collectively herein as the "New Affiliates."

Section 1.21 "Claim" means any suit, claim, action, proceeding, or demand brought by any Third Party.

Section 1.22 "Clinical Trial" means any clinical study conducted on human subjects. Without limiting the foregoing, "Clinical Trial" includes any Phase I Clinical Trial, Phase II Clinical Trial, Phase III Clinical Trial, Phase IV Clinical Trial, or combination of any of the foregoing studies.

Section 1.23 "Collaboration Affiliates" means, with respect to a Change of Control of Ichnos, all Persons that are Ichnos' Affiliates: (a) immediately prior to such Change of Control of Ichnos; or (ii) after such Change of Control of Ichnos, other than the applicable Acquirer and any New Affiliates.

Section 1.24 "Combination Product" has the meaning set forth in Section 1.69.

Section 1.25 "Commercialization" or "Commercialize" means any activities directed to using, marketing, promoting, distributing, importing, offering to sell, or selling a product, after or in expectation of receipt of Regulatory Approval for such product (but excluding Development).

Section 1.26 "Commercially Reasonable Efforts" means, with respect to any efforts or resources relating to the Exploitation of Licensed Products by Astria, generally or with respect to any particular country in the Territory, such efforts and resources comparable to the efforts and resources that Astria would, acting in good faith, [**].

Section 1.27 "Confidential Information" means all confidential or proprietary technology, Know-How, or other information (whether or not patentable) disclosed or made available by or on behalf of one Party or any of its Affiliates (the "Disclosing Party") to the other Party or any of its Affiliates (the "Receiving Party") prior to or after the Effective Date in connection with this Agreement or the Confidentiality Agreement, including information regarding a Party's technology, products, business or financial information, or objectives, and all proprietary chemical or biological materials of a Party; except that "Confidential Information" shall exclude any information that:

(a) was known by the Receiving Party prior to its disclosure to the Receiving Party by or on behalf of the Disclosing Party, as established by written evidence;

(b) is rightfully disclosed to the Receiving Party, without any obligation of confidentiality, by a source, other than by or on behalf of the Disclosing Party, rightfully in possession of the information;

(c) is or becomes published or generally known to the public through no fault or omission on the part of the Receiving Party; or

(d) is independently developed by or for the Receiving Party without reference to or reliance upon any of the Disclosing Party's Confidential Information, as established by the Receiving Party's contemporaneously-maintained written records.

Notwithstanding anything to the contrary in the foregoing, the terms of this Agreement shall be considered Confidential Information of both Parties, with each Party deemed both the Disclosing Party and the Receiving Party with respect thereto.

Section 1.28 "Confidentiality Agreement" means the Confidentiality and Non-Disclosure Agreement between Ichnos Inc. and Astria, dated as of [**], as subsequently amended.

Section 1.29 "Control" or "Controlled" means, with respect to any Know-How, Patent, or other intellectual property right, the possession (whether by license (other than a license granted under this Agreement) or ownership) by a Party of the ability to grant to the other Party access or a license to such Know-How, Patent, or other intellectual property right (as applicable), as provided herein, without violating the terms of any agreement with any Third Party.

Section 1.30 "Cover," "Covering," or "Covered" means, with respect to a product or technology and a Patent, that, but for ownership of or a license under such Patent, the Development, Manufacture, Commercialization, or other Exploitation of such product or practice of such technology by a Person would infringe a claim of such Patent or, with respect to a claim included in any patent application, would infringe such claim if such patent application were to issue as a patent.

Section 1.31 "Cure Period" has the meaning set forth in Section 11.2(b)(i).

Section 1.32 "Damages" means all damages, losses, liabilities, costs (including reasonable legal expenses, costs of litigation, and attorney's fees), expenses, judgments and settlements, whether for money or equitable relief, of any kind.

Section 1.33 "Deductible Third Party Payments" means all royalties, milestones, and other payments that Astria or any of its Affiliates or Sublicensees pays to any Third Party (other than a Sublicensee) for a license under (i) [**] or (ii) [**].

Section 1.34 "Develop" or "Development" means discovery, research, preclinical, non-clinical, and clinical development activities, including activities relating to screening, assays, test method development and stability testing, toxicology, pharmacology, formulation, quality assurance/quality control development, Clinical Trials, technology transfer, statistical analysis, process development and scale-up, pharmacokinetic studies, data collection and management, report writing, and other pre-Regulatory Approval activities.

Section 1.35 "Directly Competitive Program" means a program to Develop or Commercialize a product containing or comprising a [**].

Section 1.36 "Disclosing Party" has the meaning set forth in Section 1.27.

Section 1.37 "Dispute" has the meaning set forth in Section 12.1.

Section 1.38 "Drug Approval Application" means any marketing authorization application (and any amendments thereto), in each case, filed with any applicable Regulatory Authority in a country or other regulatory jurisdiction, which application is required to obtain a Regulatory Approval.

Section 1.39 "Effective Date" has the meaning set forth in the Preamble to this Agreement.

Section 1.40 "Electronic Delivery" has the meaning set forth in Section 12.12.

Section 1.41 "EMA" means the European Medicines Agency.

Section 1.42 "Executive Officer" means: (a) with respect to Astria, Astria's Chief Executive Officer (or the officer or employee of Astria then serving in a substantially equivalent capacity) or his or her designee; and (b) with respect to Ichnos, Ichnos Inc.' Chief Executive Officer (or the officer or employee of Ichnos then serving in a substantially equivalent capacity) or his or her designee; in each case ((a) and (b)), as long as such designee has decision-making authority on behalf of the applicable Party.

Section 1.43 "Exploit" or "Exploitation" means to Develop, Commercialize, Manufacture, or otherwise exploit, including the right to make, have made, import, export, use, have used, sell, have sold, or offer for sale, register, modify, enhance, improve, hold, keep (whether for disposal or otherwise), or dispose of.

Section 1.44 "FDA" means the United States Food and Drug Administration, or any successor agency thereof.

Section 1.45 "Field" means all fields of use.

Section 1.46 "First Commercial Sale" means the first commercial sale of a Licensed Product by Astria or any of its Affiliates or Sublicensees to a non-Sublicensee Third Party in a country for monetary value for use or consumption by the end user following receipt of applicable Regulatory Approval for such Licensed Product in such country. Sales prior to receipt of Regulatory Approval for a Licensed Product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale. Sales or transfers of a Licensed Product that are not for value, and sales or transfers of reasonable quantities of a Licensed Product for Clinical Trial purposes or for compassionate or similar use, shall not be considered a First Commercial Sale.

Section 1.47 "Force Majeure Event" means an occurrence beyond the reasonable control of a Party (and which did not occur as a result of such Party's financial condition, negligence, or fault), including pandemic, fire, earthquake, flood, embargo, power shortage or failure, acts of war or terrorism, insurrection, riot, lockout or other labor disturbance, governmental acts or orders or restrictions, or acts of God.

Section 1.48 "Governmental Authority" means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district, or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign, or other government; (c) governmental or quasi-

governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body, or entity, and any court or other tribunal); (d) supranational or multinational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military, or taxing authority or power of any nature.

Section 1.49 "Ichnos" has the meaning set forth in the Preamble to this Agreement.

Section 1.50 "Ichnos Indemnified Parties" has the meaning set forth in Section 10.1.

Section 1.51 "Ichnos Initial Press Release" has the meaning set forth in Section 8.3(a).

Section 1.52 "ISB 830" has the meaning set forth in Section 1.61.

Section 1.53 "IND" means (a) in the United States, an Investigational New Drug Application that is required to be filed with the FDA before conducting a Clinical Trial (including all supplements and amendments that may be filed with respect to the foregoing); and (b) any foreign counterpart of the foregoing.

Section 1.54 "Indemnitee" has the meaning set forth in Section 10.3(a).

Section 1.55 "Indemnitor" has the meaning set forth in Section 10.3(a).

Section 1.56 "Indication" means each separate and distinct disease or medical condition; except that the following shall not constitute a new or additional Indication: (a) moving from one line of therapy to another within an Indication (*e.g.*, the use of a Licensed Product for the same disease or medical condition in a different line therapy after approval for a line of therapy); (b) use of a Licensed Product for the same disease or medical condition for different populations or population sub-types in the same line of therapy; (c) the use of a Licensed Product for the same disease or medical condition in different combinations or co-administration of therapies (*e.g.*, monotherapy vs. add-on or combination therapy with another agent in the same disease or medical condition); or (d) treatment of the same disease or medical condition with a Licensed Product in an expanded, modified, or additional patient population in the same line of therapy.

Section 1.57 "Initiation" means, with respect to a given Clinical Trial, the first dosing of the first human patient in such Clinical Trial. "Initiate" has a correlative meaning.

Section 1.58 "Invalidity Claim" has the meaning set forth in Section 7.4.

Section 1.59 "Know-How" means any tangible or intangible trade secrets, know-how, expertise, discoveries, inventions, information, data, or materials, including ideas, concepts, formulae, methods, procedures, designs, technologies, compositions, plans, applications, technical data, assays, manufacturing information or data, and all derivatives, modifications, and improvements of any of the foregoing.

Section 1.60 "Law" means any law, statute, rule, regulation, ordinance, common law, or other pronouncement having the effect of law, of any federal, national, multinational, state,

provincial, county, city, or other political subdivision, as from time to time enacted, repealed, or amended, including adverse event reporting requirements, guidance from the International Conference on Harmonization or other generally accepted conventions, the U.S. Federal Food, Drug, and Cosmetic Act and similar laws and regulations in countries outside the United States, and all other rules, regulations, and requirements of the FDA or any other applicable Regulatory Authority.

Section 1.61 "Licensed Compound" means any of the following: (a) Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as ISB 830, as further described on Schedule 1.61(a) ("ISB 830"); (b) Ichnos' proprietary OX40 antagonist monoclonal antibody referred to by Ichnos as ISB 830-X8, as further described on Schedule 1.61(b) ("X8"); (c) any backup or follow-on antibody to, or any improvement or modification of, either of the antibodies described in clause (a) or clause (b); and (d) any engineered or recombinant derivative of any antibody described in clause (a), (b), or (c), including, without limitation, an antigen binding fragment (e.g., Fab fragment), single chain antibody binding site, (e.g., scFv), human or humanized variant, monovalent, bivalent, polyvalent, monospecific, bispecific or multi-specific variant, and any antibody-drug conjugate or component of a cell based therapy such as CAR-T, of any antibody described in clause (a), (b), or (c).

Section 1.62 "Licensed Intellectual Property" means Licensed Know-How and Licensed Patents, collectively.

Section 1.63 "Licensed Know-How" means Know-How that is: (i) Controlled by Ichnos or, subject to Section 12.3(c), any of its Affiliates as of the Effective Date or during the Term; and (ii) necessary or reasonably useful for the Development, Manufacture, or Commercialization of any Licensed Compound or Licensed Product.

Section 1.64 "Licensed Patents" means Patents that: (i) are Controlled by Ichnos or, subject to Section 12.3(c), any of its Affiliates as of the Effective Date or during the Term; and (ii) Cover, or are necessary or reasonably useful for, the Exploitation of any Licensed Know-How or the Development, Manufacture, or Commercialization of any Licensed Compound or Licensed Product.

Section 1.65 "Licensed Product" means any pharmaceutical product that contains or comprises one or more Licensed Compounds as an active pharmaceutical ingredient, whether alone or in combination with one (1) or more other active ingredients, and in any form, formulation, dosage form and strength, and for any mode of delivery.

Section 1.66 "Licensed Product Documentation" means all INDs, Drug Approval Applications, and other regulatory applications or submissions submitted to any Regulatory Authority, Regulatory Approvals, pre-clinical and clinical data and information, regulatory materials, drug dossiers, master files (including Drug Master Files, as defined in 21 C.F.R. § 314.420 and any non-United States equivalents), and any other data, reports, records, regulatory correspondence, and other materials relating to Development or Regulatory Approval of any Licensed Product, or required to Manufacture, distribute, or sell any Licensed Product, including any information that relates to pharmacology, toxicology, chemistry, manufacturing, and controls data, batch records, safety, or efficacy, and any safety database.

Section 1.67 "Major European Market" means each of France, Germany, Italy, Spain, and the United Kingdom.

Section 1.68 "Manufacture" or "Manufacturing" means all activities associated with the production, manufacture, processing, filling, packaging, labeling, shipping, or storage of a drug substance or drug product, or any components thereof, including process and formulation development, process validation, stability testing, manufacturing scale-up, preclinical, clinical, and commercial manufacture, analytical methods development and validation, product characterization, quality assurance and quality control development, testing, and release.

Section 1.69 "Net Sales" means, with respect to any Licensed Product, the gross amounts invoiced by Astria or any of its Affiliates or Sublicensees (each, a "Selling Party") to Third Parties that are not Selling Parties for sales or other commercial dispositions of such Licensed Product, less the following deductions actually incurred, allowed, paid, accrued, or specifically allocated in the applicable Selling Party's financial statements and calculated in accordance with Accounting Standards:

(a) discounts (including trade, quantity, and cash discounts), cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any Third Party (including to Governmental Authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities (and other similar entities));

(b) credits or allowances, if any, on account of price adjustments, recalls, claims, damaged goods, rejections, or returns of items previously sold (including Licensed Products returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt; except that, if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid;

(c) rebates (or their equivalent), administrative fees, chargebacks, and retroactive price adjustments, and any other similar allowances granted by a Selling Party (including to Governmental Authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations (and other equivalent entities)) that effectively reduce the selling price or gross sales of the Licensed Product, normal and customary inventory management fees, and other *bona fide* service fees paid to distributors and wholesalers;

(d) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs incurred by a Selling Party in shipping Licensed Product to a Third Party; and

(e) import taxes, export taxes, excise taxes (including annual fees due under Section 9008 of the United States Patient Protection and Affordable Care Act of 2010 (Pub. L. No. 111-48) and other comparable Laws), sales tax, value-added taxes, consumption taxes, duties, or other taxes levied on, absorbed, determined, or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind) to the extent the Selling Party is not otherwise entitled to a credit or refund for such taxes, duties, or payments made.

There shall be no double counting in determining the foregoing deductions from gross amounts invoiced to calculate "Net Sales" hereunder. The calculations set forth in this definition shall be determined in accordance with Accounting Standards.

If non-monetary consideration is received by a Selling Party for any Licensed Product in a relevant country, Net Sales will be calculated based on the average price charged for such Licensed Product during the preceding royalty period, or, in the absence of such sales, the fair market value of the Licensed Product as determined by Astria in good faith.

Notwithstanding anything to the contrary in this definition, Net Sales will not include transfers of Licensed Products for use in Clinical Trials, non-clinical Development activities, or other Development activities with respect to Licensed Products, for *bona fide* charitable purposes, for compassionate use or named patient sales, or for Licensed Product samples, if provided at or below cost.

Net Sales shall be determined on, and only on, the first sale by a Selling Party to a non-Selling Party Third Party.

If a Licensed Product is sold as part of a Combination Product (as defined below), Net Sales will be the product of (i) Net Sales of the Combination Product calculated as above (i.e., calculated as for a non-Combination Product) and (ii) the fraction (A/(A+B)), where:

"A" is the gross invoice price in such country of the Licensed Product that is part of such Combination Product when sold without any other therapeutically active ingredients; and

"B" is the gross invoice price in such country of the other therapeutically active ingredients contained in the Combination Product.

If "A" or "B" cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price(s) in the above equation shall be determined by mutual agreement reached in good faith by the Parties prior to the end of the accounting period in question based on an equitable method of determining the same that takes into account, in the applicable country, variation in dosage units, and the relative fair market value of each therapeutically active ingredient in the Combination Product.

As used in this definition of "Net Sales," "Combination Product" means a Licensed Product that is sold for a single price with (a) one or more additional active ingredients (whether co-formulated or co-packaged) that are not Licensed Products or (b) any delivery device (*e.g.*, any autoinjector or on-body delivery device or system).

Section 1.70 "New Affiliates" has the meaning set forth in Section 1.20.

Section 1.71 "Non-Acting Party" has the meaning set forth in Section 6.6(a).

Section 1.72 "Out-of-Pocket Costs" means, with respect to certain activities hereunder, direct expenses paid or payable by either Party or any of its Affiliates to any Third Party (other than employees of such Party or any of its Affiliates) that are specifically identifiable and incurred

to conduct such activities hereunder and have been recorded in accordance with Accounting Standards.

Section 1.73 "Parent Entity" has the meaning set forth in Section 1.20.

Section 1.74 "Party" and "Parties" each has the meaning set forth in the Preamble to this Agreement.

Section 1.75 "Patent" means any: (a) patent or patent application anywhere in the world; (b) divisional, continuation, or continuation in-part of any such patent or patent application, or any other patent or patent application claiming priority, or entitled to claim priority, directly or indirectly to (i) any such patent or patent application or (ii) any patent or patent application from which such patent or patent application claims, or is entitled to claim, direct or indirect priority; or (c) patent issuing on any of the foregoing anywhere in the world, together with any registration, reissue, re-examination, patent of addition, renewal, patent term extension, supplemental protection certificate, or extension of any of the foregoing anywhere in the world.

Section 1.76 "Person" means any individual or any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, or other entity.

Section 1.77 "Phase I Clinical Trial" means a Clinical Trial of a product that would satisfy the requirements of 21 C.F.R. § 312.21(a) or its successor regulation, or any corresponding laws or regulations in an applicable country outside of the U.S. in the Territory, the principal purpose of which is a preliminary determination of safety, tolerability, and pharmacokinetics in study subjects where potential pharmacological activity may be determined.

Section 1.78 "Phase II Clinical Trial" means a Clinical Trial that would satisfy the requirements of 21 C.F.R. § 312.21(b) or its successor regulation, or any corresponding laws or regulations in an applicable country outside of the U.S. in the Territory, and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular Indication or Indications in a target patient population.

Section 1.79 "Phase III Clinical Trial" means a Clinical Trial of a product in any country that would satisfy the requirements of 21 C.F.R. § 312.21(c) or its successor regulation, or any corresponding laws or regulations in an applicable country outside of the U.S. in the Territory, and is intended to (a) establish that the product is safe and efficacious for its intended use, (b) define adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support Regulatory Approval for such product.

Section 1.80 "Phase IV Study" means a Clinical Trial of a product in any country that is (a) conducted to satisfy a requirement of a Regulatory Authority in order to maintain a Regulatory Approval or to satisfy a requirement or condition imposed by a Regulatory Authority in connection with the grant of a Regulatory Approval or (b) conducted voluntarily after Regulatory Approval of the product has been obtained for enhancing marketing or scientific knowledge of an approved Indication.

Section 1.81 "Prosecution" or "Prosecute" means the filing, preparation, prosecution, and maintenance of any Patent, including any pre-grant and any post-grant proceeding before any patent authority.

Section 1.82 "Receiving Party" has the meaning set forth in Section 1.27.

Section 1.83 "Regulatory Approval" means all approvals of each applicable Regulatory Authority necessary for the commercial marketing and sale of a product for a particular Indication in a country (including any required pricing or reimbursement approvals), such as an approved Biologics License Application (as more fully described in 21 C.F.R. § 601.20 or its successor regulation) or a similar approved application for Regulatory Approval to market a Licensed Product that is approved by a Regulatory Authority that is the foreign equivalent of the FDA, and all approved amendments and supplements thereto.

Section 1.84 "Regulatory Authority" means any federal, national, multinational, state, provincial, or local regulatory agency, department, bureau, or other governmental entity with authority over the testing, manufacture, use, storage, import, promotion, marketing, or sale (including pricing and reimbursement approval) of any pharmaceutical or biologic product in any country or territory.

Section 1.85 "Regulatory Exclusivity" means, with respect to any country or other jurisdiction in the Territory, any additional market protection, other than Patent protection, granted by a Regulatory Authority in such country or other jurisdiction which confers an exclusive Commercialization period during which Astria or its Affiliates or Sublicensees have the exclusive right to market and sell a Licensed Product in such country or other jurisdiction through a regulatory exclusivity right (*e.g.*, new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity).

Section 1.86 "Regulatory Interactions" means, with respect to any given Licensed Product: (a) monitoring and coordinating all regulatory actions, and preparing, submitting, and coordinating all communications and filings with, and submissions to, all Regulatory Authorities; with respect to the Development, Manufacture, or Commercialization of such Licensed Product and (b) interfacing, corresponding, and meeting with Regulatory Authorities with respect to such Licensed Product.

Section 1.87 "Royalty Term" has the meaning set forth in Section 6.3(b).

Section 1.88 "SEC" means the U.S. Securities and Exchange Commission.

Section 1.89 "Selling Party" has the meaning set forth in Section 1.69.

Section 1.90 "Sublicensee" means any Third Party to whom Astria or any of its Affiliates or any other Sublicensee grants a sublicense under the rights to Licensed Intellectual Property granted to Astria hereunder with respect to the Development, Manufacture, or Commercialization of Licensed Products in the Field; but excluding wholesalers, full-service distributors, or any other Third Party that purchases any Licensed Product in an arm's-length transaction, where such Third Party does not have a sublicense to Exploit any Licensed Product except for a limited sublicense

to the extent required to enable such Third Party to perform final packaging for such Licensed Product for local distribution.

Section 1.91 "Tax Action" has the meaning set forth in Section 6.6(a).

Section 1.92 "Term" has the meaning set forth in Section 11.1.

Section 1.93 "Territory" means worldwide.

Section 1.94 "Third Party" means any Person other than Ichnos and its Affiliates and Astria and its Affiliates.

Section 1.95 "Third Party Infringement" has the meaning set forth in Section 7.3(a).

Section 1.96 "United States" or "U.S." means the United States of America and all of its territories and possessions, including Puerto Rico.

Section 1.97 "Valid Claim" means: (a) a claim of any issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer, or otherwise; or (b) a claim of any patent application filed by a Person in good faith that has not been cancelled, withdrawn, or abandoned, nor been pending for more than [**] from the earliest filing date to which such patent application or claim is entitled.

Section 1.98 "X8" has the meaning set forth in Section 1.61.

Article II
Grant of Rights

Section 2.1 License Grant. Subject to the terms and conditions of this Agreement, Ichnos hereby grants to Astria an exclusive (even as to Ichnos and its Affiliates) right and license (with the right to grant sublicenses as set forth in Section 2.2), under the Licensed Intellectual Property, to Exploit the Licensed Compounds and Licensed Products in the Field in the Territory.

Section 2.2 Sublicense Rights. Astria shall have the right to grant sublicenses, through multiple tiers, within the scope of the license granted to Astria under Section 2.1 to any of its Affiliates or any Third Party. Any such sublicense granted by Astria shall be subject to the following:

(a) each sublicense granted hereunder shall be consistent with the requirements of this Agreement;

(b) except for sublicenses granted to Third Party subcontractors (*e.g.*, contract research organizations, contract manufacturers, distributors) in order for such subcontractors to provide services to Astria or any of its Affiliates or any Sublicensee, each sublicense to any Third Party must be granted pursuant to a written sublicense agreement, and, at Ichnos' request, Astria

shall provide Ichnos with a copy of any such sublicense agreement entered into under this Section 2.2 (which shall be Astria's Confidential Information); except that any such copy may be reasonably redacted to remove any confidential, proprietary, or competitively sensitive information, but such copy shall not be redacted to the extent that it impairs Ichnos' ability to ensure compliance with this Agreement; and

(c) Astria shall require each Sublicensee or Affiliate to whom Astria discloses any of Ichnos' Confidential Information to enter into a written agreement obligating such Sublicensee or Affiliate to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than are the obligations set forth in Article VIII.

(d) In the event that, within [**] after the Effective Date, Astria grants a sublicense under the Licensed Intellectual Property that grants the Sublicensee rights to Exploit Licensed Products containing or comprising ISB 830, then Astria shall pay to Ichnos a percentage of any upfront payments that Astria receives under such sublicense agreement, such percentage to be determined as follows:

(i) If such sublicense agreement is entered into within [**] after the Effective Date, such percentage shall be [**] percent ([**]%); or

(ii) If such sublicense agreement is entered into between [**] and [**] after the Effective Date, such percentage shall be [**] percent ([**]%).

(e) In the event that Astria grants a sublicense under the Licensed Intellectual Property that grants the Sublicensee rights to Exploit any Licensed Product, then Astria shall pay to Ichnos [**] percent ([**]%) of any milestone payment that Astria receives under such sublicense that is triggered by a milestone event that is not substantially similar to any milestone event set forth in Section 6.2 or Section 6.3.

Section 2.3 Affiliates and Sublicensees. Astria may exercise its rights and perform its obligations hereunder itself or through any of its Affiliates or Sublicensees. Astria shall be primarily liable for any failure by any of its Affiliates or Sublicensees to comply with all relevant restrictions, limitations, and obligations in this Agreement.

Section 2.4 No Implied Licenses or Rights. Each Party acknowledges that the licenses granted under this Agreement are limited to the scope expressly granted, and all other rights to Patents and Know-How licensed hereunder are expressly reserved to the Party granting the license to such Patents or Know-How. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party that are not expressly granted herein, whether by implication, estoppel, or otherwise. Without limiting the foregoing, notwithstanding anything to the contrary in this Agreement (including the definitions of "Combination Product" and "Licensed Product"), each Party hereby acknowledges and agrees that neither Party grants to the other Party any rights under any Patents or Know-How to Exploit any active ingredient that is not a Licensed Compound.

Section 2.5 Section 365(n) of the Bankruptcy Code. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of

rights to "intellectual property" as defined in Section 101 of such Code. Each Party, as licensee, may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, if a Party elects to retain its rights as a licensee under any Bankruptcy Code, such Party shall be entitled to complete access to any technology licensed to it hereunder and all embodiments of such technology. Such embodiments of the technology shall be delivered to the licensee Party not later than: (a) the commencement of bankruptcy proceedings against the licensor, upon written request, unless the licensor elects to perform its obligations under the Agreement, or (b) if not delivered under clause (a), upon the rejection of this Agreement by or on behalf of the licensor, upon written request. Any agreements supplemental hereto will be deemed to be "agreements supplementary to" this Agreement for purposes of Section 365(n) of the Bankruptcy Code.

Article III
Exclusivity

Section 3.1 Exclusivity. Ichnos covenants and agrees, solely on behalf of itself and its Affiliates, that Ichnos and its Affiliates shall not (except in the conduct of activities pursuant to this Agreement), alone or with, for, or through any Third Party, (a) Develop, Commercialize, or otherwise Exploit any product that directly modulates (including through regulation, antagonizing, targeting inhibition, or otherwise) OX40 receptor (CD134) or (b) (sub)license (including granting any option, covenant not to sue, or other like right thereto), authorize, appoint, or otherwise seek to or enable, whether directly or indirectly, any Third Party to conduct any of the activities described in clause (a).

Section 3.2 Exceptions.

(a) Change of Control. If a Change of Control occurs with respect to Ichnos, the Acquirer and any New Affiliates shall be permitted (i) to continue to conduct any ongoing activities and (ii) to initiate new activities (whether planned before the occurrence of the Change of Control or thereafter) where any such activities would otherwise cause the Acquirer or the New Affiliates to violate Section 3.1 (an "Acquirer Program"), and such initiation or continuation will not constitute a violation of Section 3.1, as long as (A) Ichnos and the Collaboration Affiliates implement and enforce, and cause the Acquirer and applicable New Affiliates to implement and enforce, firewalls with respect to such Acquirer Program as of the completion of such Change of Control (in the event of (i)) or the initiation of the Acquirer Program (in the event of (ii)) for the duration of the Term, (B) no technology or intellectual property rights of Ichnos or any Collaboration Affiliate (including any Licensed Patents or Licensed Know-How) is used in such Acquirer Program, and (C) no Confidential Information of Astria is used in such Acquirer Program.

(b) Acquired Competitive Programs. Without limiting Section 3.2(a), the restrictions set forth in Section 3.1 shall not prevent Ichnos or any of its Affiliates from merging or consolidating with, or otherwise acquiring, a Third Party that is then engaged in activities that would otherwise constitute a breach of Section 3.1 by Ichnos or its Affiliates (a "Competitive Program"), as long as, within [**] after the date of such merger, consolidation, or acquisition, Ichnos notifies Astria that it intends to either (A) terminate, or cause its relevant Affiliate to terminate, the Competitive Program or (B) divest, or cause its relevant Affiliate to divest, whether by license or otherwise, the Competitive Program, and:

(i) if Ichnos notifies Astria that it intends to terminate, or cause its relevant Affiliate to terminate, such Competitive Program, Ichnos or its relevant Affiliate, (A) terminates such Competitive Program as quickly as possible, and in any event within [**] (unless Applicable Law requires a longer termination period) after Ichnos delivers such notice to Astria and (B) confirms to Astria by written attestation that such termination has been completed within such time period; or

(ii) if Ichnos notifies Astria that it intends to divest such Competitive Program, Ichnos or its relevant Affiliate (A) uses all reasonable efforts to effect such divestiture as quickly as possible, and in any event within [**] after Ichnos delivers such notice to Astria, and (B) confirms to Astria by written attestation that such divestiture has been completed within such time period.

Article IV
Technology Transfer; Support

Section 4.1 Tech Transfer.

(a) Within a reasonable period of time following the Effective Date, Ichnos, at its cost and expense, shall obtain for Astria [**].

(b) Ichnos and Astria agree to enter into a quality agreement governing the relevant ongoing activities set forth in this Agreement. In addition, as soon as reasonably practicable, and in any event within [**] following the Effective Date, Ichnos shall (i) at Astria's request, either (A) novate or otherwise transfer to Astria the development and manufacturing agreements to which Ichnos is a party that relate to any Licensed Compound or Licensed Product or (B) assist Astria to enter into agreements with the counterparties to such development and manufacturing agreements that will provide Astria with substantially equivalent rights as those granted to Ichnos in such agreements, in each case with respect to the Licensed Compounds and Licensed Products, (ii) at Astria's request, use reasonable efforts to assist Astria in establishing a commercial relationship with the counterparties to the agreements described in clause (i), and (iii) transfer to Astria tangible or electronic copies of all Licensed Know-How that are in Ichnos' possession and Control and that relate to the Licensed Compounds or Licensed Products.

(c) Ichnos will also, at the request of Astria, transfer some or all of the existing drug substance or drug product that is in Ichnos' possession and Control at the costs set forth in Schedule 4.1, plus any shipping and storage costs that are pre-agreed upon by the Parties.

Section 4.2 Support. At Astria's reasonable request, Ichnos shall use reasonable efforts to provide reasonable assistance, including making its personnel reasonably available for meetings or teleconferences to answer questions and provide technical support to Astria, (a) for a period of [**] following the Effective Date, with respect to the Know-How and materials transferred pursuant to Section 4.1 and (b) during the Term with respect to (i) Regulatory Interactions with respect to the Licensed Products and (ii) Prosecution of the Licensed Patents. Ichnos shall provide [**] of such assistance [**] Astria will reimburse Ichnos for each hour that any Ichnos employee spends in providing such assistance at a rate of [**] United States Dollars ($[**]) per hour within [**] after receipt of any undisputed invoice therefor.

Section 4.3 Out-of-Pocket Costs. Astria will reimburse Ichnos for all reasonable Out-of-Pocket Costs incurred by Ichnos in performing any technology transfer or support activities pursuant to Section 4.1(b) or Section 4.2 within [**] after receipt of any undisputed invoice therefor.

Article V
Exploitation

Section 5.1 General. As between the Parties, Astria shall have the sole right and responsibility, in its sole discretion and at its sole expense, for all aspects of the Development, Manufacture, and Commercialization of Licensed Compounds and Licensed Products.

Section 5.2 Diligence. Astria shall, itself or with or through any of its Affiliates or Sublicensees, use Commercially Reasonable Efforts to (a) Develop and obtain Regulatory Approval for at least one (1) Licensed Product in the United States and the Major European Markets and Japan and (b) following receipt of Regulatory Approval for a Licensed Product in the United States or any Major European Market, to Commercialize at least one (1) Licensed Product in the United States and such countries in the Major European Markets and Japan where Regulatory Approval has been obtained.

Section 5.3 Progress Reports.

(a) Non-Binding Estimated Timeline. Schedule 5.3 includes a non-binding estimate of the anticipated timeline of Astria's Development of the first Licensed Product through [**].

(b) Development Progress Reports. During the period beginning on the Effective Date and ending on the date of the First Commercial Sale of a Licensed Product, Astria shall provide Ichnos with a written report (which may be in the form of slides) every [**] that provides a summary of Astria's and its Affiliates' and Sublicensees' significant activities related to Development of the Licensed Compounds and Licensed Products during the previous [**] period. At the request of Ichnos, Ichnos and Astria shall have a virtual or in person meeting no more than [**] (or, during any period in which Astria has an active Directly Competitive Program, no more than [**]) at which Astria will provide a summary of significant activities related to Development of the Licensed Compounds and Licensed Products during the previous [**] (or, as applicable, [**]) period.

(c) Commercialization Progress Reports. During the period beginning [**] prior to submission of the first Drug Approval Application for a Licensed Product and ending on the date on which Astria provides Ichnos with the first royalty report for a Licensed Product pursuant to Section 6.3(e), Astria shall provide Ichnos with a written report every [**] that provides a summary of Astria's and its Affiliates' and Sublicensees' significant activities related to Commercialization of Licensed Products during the previous [**] period.

Section 5.4 Documentation and Regulatory Matters.

(a) Licensed Product Documentation. Ichnos shall, as soon as practicable (and, in any event, within [**] after the Effective Date), transfer to Astria, and assign to Astria ownership

of (and Ichnos hereby assigns to Ichnos ownership of), any and all Licensed Product Documentation for each Licensed Product in the Territory, to the extent in Ichnos' Control, and thereafter Astria (or its designee) shall file and hold title to all Licensed Product Documentation, including Regulatory Approvals and supplements thereto, relating to any Licensed Product in the Territory. Prior to completion of such transfer, Ichnos must: (a) provide to Astria electronic copies of all written communication with Regulatory Authorities regarding any Licensed Product within [**] after receipt thereof; and (b) facilitate that Astria is present at, or has approved in writing, any Regulatory Interactions. At Astria's reasonable request, Ichnos shall provide to each applicable Regulatory Authority a written statement implementing or confirming the assignments described in this Section 5.4.

(b) Regulatory Interactions. As of and after the date upon which the transfer described in Section 5.4(a) is effected, Astria shall have sole responsibility in the Territory for all Regulatory Interactions with respect to each Licensed Product.

Article VI
Financial Provisions

Section 6.1 Upfront Fee. In partial consideration of the rights and licenses granted by Ichnos to Astria under this Agreement, within [**] after receipt of an invoice therefor (which invoice will be provided on or after the Effective Date), Astria shall pay to Ichnos a one-time, non-refundable, non-creditable upfront amount equal to Fifteen Million U.S. Dollars ($15,000,000).

Section 6.2 Milestone Payments.

(a) Development and Regulatory Milestones. Astria shall pay Ichnos the following one-time amounts after the first achievement by or on behalf of Astria or its Affiliates or Sublicensees of the corresponding development and regulatory milestone events set forth below with respect to the first applicable Licensed Product to achieve such milestone event.

Milestones	**Payment (in US Dollars)**		
	First Indication	**Second Indication**	**Third Indication**
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]

	Payment (in US Dollars)		
Milestones	**First Indication**	**Second Indication**	**Third Indication**
[**]	[**]	[**]	[**]

(i) Astria shall notify Ichnos within [**] after becoming aware of the achievement of any milestone set forth in the table above in this Section 6.2(a) by Astria or any of its Affiliates or Sublicensees and shall pay Ichnos the corresponding milestone payment within [**] after receipt of an invoice therefor.

(ii) For clarity, the milestone payments set forth in the table above in this Section 6.2(a) (to the extent payable) shall be paid only once for the first Licensed Product to achieve the appliable milestone for the applicable listed Indication. In no event would Astria owe Ichnos more than [**] U.S. Dollars ($[**]) in milestone payments under this Section 6.2(a).

(iii) If a milestone event in row [**] or [**] of the table set forth in above in this Section 6.2(a) is achieved with respect to a given Indication before achievement of the milestone event in row [**] of such table for such Indication, then such skipped milestone will be deemed to have been achieved with respect to such Indication upon the achievement of such subsequent milestone with respect to such Indication, and Astria shall pay to Ichnos the milestone payment corresponding to such skipped milestone within [**] after such achievement.

(b) Commercial Milestones. Astria shall notify Ichnos within [**] after the end of the Calendar Year in which any sales milestone event set forth below is first achieved and shall pay Ichnos the corresponding one-time milestone payment within [**] after receipt of an invoice therefor. In no event would Astria owe Ichnos more than Two Hundred Fifteen Million U.S. Dollars ($215,000,000) in milestone payments under this Section 6.2(b).

Milestones	**Payment (in US Dollars)**
First time worldwide Annual Net Sales of all Licensed Products, in aggregate, meet or exceed $[**]	[**]
First time worldwide Annual Net Sales of all Licensed Products, in aggregate, meet or exceed $[**]	[**]
First time worldwide Annual Net Sales of all Licensed Products, in aggregate, meet or exceed $[**]	[**]

Section 6.3 Royalty Payments.

(a) Royalty Rate. Subject to the remainder of this Section 6.3, Astria shall pay to Ichnos royalties on the Annual Net Sales of all Licensed Products as set forth below:

Annual Net Sales	Royalty Rate
Portion of Annual Net Sales of all Licensed Products by all Selling Parties, in the aggregate, up to and including [**] U.S. Dollars ($[**]).	[**]%
Portion of Annual Net Sales of all Licensed Products by all Selling Parties, in the aggregate, greater than [**] U.S. Dollars ($[**]) up to and including [**] U.S. Dollars ($[**]).	[**]%
Portion of Annual Net Sales of all Licensed Products by all Selling Parties, in the aggregate, greater than [**] U.S. Dollars ($[**]).	[**]%

Each royalty rate set forth in the table above will apply only to that portion of Annual Net Sales of Licensed Products during a given Calendar Year that falls within the indicated portion. For example, if Annual Net Sales of Licensed Products by all Selling Parties were $[**], then the royalties payable with respect to such Annual Net Sales would be:

[**].

(b) Royalty Term. Royalties payable under this Section 6.3 shall be paid by Astria on a Licensed Product-by-Licensed Product and country-by-country basis from the date of First Commercial Sale of such Licensed Product in such country until the latest of (i) expiration of the last to expire Valid Claim of the Licensed Patents Covering the composition of matter of such Licensed Product in such country, (ii) expiration of the last to expire Regulatory Exclusivity with respect to such Licensed Product in such country, and (iii) twelve (12) years following the date of First Commercial Sale of such Licensed Product in such country (each such term with respect to a Licensed Product and a country, a "Royalty Term").

(c) Royalty Reduction.

(i) On a Licensed Product-by-Licensed Product, country-by-country, and Calendar Quarter-by-Calendar Quarter basis, subject to Section 6.3(c)(iv), during any Calendar Quarter in which such Licensed Product is not Covered by a Valid Claim of a Licensed Patent in such country, the royalty rate with respect to such Licensed Product in such country for such Calendar Quarter will be reduced to [**] percent ([**]%) of the applicable rate set forth in Section 6.3(a).

(ii) On a Licensed Product-by-Licensed Product basis, subject to Section 6.3(c)(iv), Astria may deduct [**] percent ([**]%) of any Deductible Third Party Payments paid by Astria or any of its Affiliates with respect to such Licensed Product from the royalties otherwise owed to Ichnos pursuant to Section 6.3(a).

(iii) If, on a Licensed Product-by-Licensed Product, country-by-country and Calendar Quarter-by-Calendar Quarter basis, there is Biosimilar Competition with respect to such Licensed Product in such country during such Calendar Quarter, then, subject to Section

6.3(c)(iv), the royalty rate with respect to such Licensed Product in such country for such Calendar Quarter will be reduced to [**] percent ([**]%) of the applicable rate set forth in Section 6.3.

(iv) In no event shall the royalty reductions described in this Section 6.3(c), alone or together, reduce the royalties payable by Astria for a given Licensed Product in a given Calendar Quarter to less than [**] percent ([**]%) of the amounts otherwise payable by Astria for such Licensed Product in such Calendar Quarter pursuant to Section 6.3. Astria may carry over and apply any such royalty reductions that are accrued in a Calendar Quarter and are not deducted in such Calendar Quarter due to the limitation set forth in the first sentence of this Section 6.3(c)(iv) to any subsequent Calendar Quarter(s) and shall begin applying such reductions to such royalties as soon as practicable and continue applying such reductions on a Calendar Quarter basis thereafter until fully deducted, in all cases subject to the limitation set forth in the first sentence of this Section 6.3(c)(iv).

(d) Expiration of Royalty Term. Upon the expiration of the Royalty Term with respect to a Licensed Product in a country, the license granted by Ichnos to Astria pursuant to Section 2.1 shall be deemed to be fully paid-up, irrevocable, and perpetual with respect to such Licensed Product in such country.

(e) Royalty Reports; Payments. Within [**] following the end of each Calendar Quarter in which a royalty payment accrues, Astria shall (i) [**] and (ii) make the royalty payments owed to Ichnos hereunder in accordance with such royalty report in arrears.

Section 6.4 Financial Records. Astria shall keep, and shall require its Affiliates and Sublicensees to keep, complete and accurate books and records in accordance with Accounting Standards concerning payments owed under this Agreement. Astria shall keep, and shall require its Affiliates and Sublicensees to keep, such books and records for at least [**] following the end of the Calendar Year to which they pertain. Such books of accounts shall be kept at the principal place of business of the financial personnel with responsibility for preparing and maintaining such records. Such records shall be in sufficient detail to support calculations of royalties due to Ichnos under this Agreement.

Section 6.5 Audits.

(a) Audit Team. Ichnos may, upon request and at its expense (except as provided for herein), cause an internationally recognized independent accounting firm selected by Ichnos (except one to whom Astria has a reasonable objection) (the "Audit Team") to audit during ordinary business hours the books and records of Astria and the correctness of any payment made or required to be made, and any report underlying such payment (or lack thereof), pursuant to the terms of this Agreement. Prior to commencing its work pursuant to this Agreement, the Audit Team shall enter into a confidentiality agreement with Astria obligating the Audit Team to be bound by obligations of confidentiality and restrictions on use of Astria's confidential information that are no less restrictive than are the obligations set forth in Article VIII.

(b) Limitations. In respect of each audit of Astria's books and records: (i) Astria may be audited [**] per Calendar Year, (ii) no records for any given Calendar Year may be audited more than [**] (but Astria's records shall still be made available if such records impact another

financial year which is being audited), and (iii) Ichnos shall only be entitled to audit books and records of Astria from the [**] Calendar Years prior to the Calendar Year in which the audit request is made.

(c) Audit Notice. In order to initiate an audit for a particular Calendar Year, Ichnos must provide written notice to Astria. Ichnos shall provide Astria with notice of one or more proposed dates of the audit not less than [**] prior to the first proposed date. Astria will reasonably accommodate the scheduling of such audit. Astria shall provide such Audit Team(s) with full and complete access to the applicable books and records and otherwise reasonably cooperate with such audit.

(d) Payments. If an audit shows any underpayment or overpayment by Astria, that underpayment or overpayment shall be reported to Ichnos and (i) Astria shall remit such underpayment (together with interest at the rate set forth in Section 6.9) to Ichnos and (ii) Ichnos shall reimburse such overpayment to Astria, each within [**] after receiving the audit report. Further, if an audit for an annual period shows an underpayment by Astria for that period in excess of [**] percent ([**]%) of the amounts properly determined, Astria shall reimburse Ichnos for its reasonable Out-of-Pocket Costs in connection with such audit, which reimbursement shall be made within [**] after receiving appropriate invoices and other support for such audit-related costs.

Section 6.6 Tax Matters.

(a) Withholding Taxes. Except as expressly set forth in this Section 6.6, each Party shall pay any and all taxes levied on account of all payments it receives under this Agreement. Each Party shall provide such information and documentation to the other Party as are reasonably requested by such other Party to determine if any withholding taxes apply to any payments to be made by such other Party under this Agreement and to establish qualification for a reduced withholding rate or an exemption from such withholding tax under an applicable bilateral income tax treaty or relevant statutory provision. If a Party believes that it is required to withhold taxes on a payment to the other Party, the paying Party shall notify the other Party of such determination no less than [**] prior to making such payment. To the extent that Applicable Laws require that taxes be withheld with respect to any payments to be made by a Party to the other Party under this Agreement, the paying Party shall: (i) deduct those taxes from the remittable payment, (ii) pay the taxes to the proper taxing authority, and (iii) promptly send evidence of the obligation together with proof of tax payment to the other Party on a reasonable and timely basis following such tax payment. Each Party agrees to cooperate with the other Party in claiming refunds, reductions, or exemptions from such deductions or withholdings under any relevant agreement or treaty that is in effect. Notwithstanding anything to the contrary in this Agreement, in the event a Party redomiciles or assigns its rights or obligations under this Agreement in accordance with Section 12.3 (each, a "Tax Action," and such Party, the "Acting Party"), and, as a result of such Tax Action, the amount of tax required to be withheld under this Section 6.6(a) in respect of a payment to the other Party (the "Non-Acting Party") is greater than the amount of such tax that would have been required to have been withheld absent such Tax Action, then any such amount payable to the Non-Acting Party shall be adjusted to take into account such withholding taxes as may be necessary so that, after making all required withholdings or credits, the Non-Acting Party receives an amount equal to the sum it would have received, taking into account applicable tax rates imposed on such income and any tax credits available as a result of the

withholding or credits, had no such Tax Action occurred (but in no case shall any payment under this Agreement be an amount less than the remittable payment due without regard to this Section 6.6). The obligation to adjust payments pursuant to the preceding sentence shall not apply, however, to the extent such increased withholding tax (A) would not have been imposed but for a Tax Action taken by the Party receiving the payment subject to withholding under this Section 6.6(a) or (B) is attributable to the failure by the Non-Acting Party to comply with the requirements of this Section 6.6(a). For purposes of this Section 6.6(a), a "redomiciliation" shall include a reincorporation or other action resulting in a change in tax residence of the applicable Party or its assignee.

(b) Tax Documentation. Each Party has provided a properly completed and duly executed IRS Form W-9 or applicable Form W-8 to the other Party. Each Party shall provide to the other Party, at the time or times reasonably requested by such other Party or as required by Applicable Law, such properly completed and duly executed documentation (for example, IRS Forms W-8 or W-9) as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes, and the applicable payment shall be made without (or at a reduced rate of) withholding to the extent permitted by such documentation, as reasonably determined by the paying Party.

Section 6.7 Foreign Derived Intangible Income Deduction. Each Party shall use commercially reasonable efforts to provide, and to cause its Affiliates, subcontractors, (sub)licensees, customers, and applicable Third Parties to provide, any information and documentation reasonably requested by the other Party to obtain the benefits of Section 250 of the Internal Revenue Code of 1986, as amended and the applicable Treasury Regulations, including information required to demonstrate the extent to which the Licensed Products will be sold, consumed, used, or manufactured outside the United States.

Section 6.8 Currency Exchange. Unless otherwise expressly stated in this Agreement, all amounts specified in, and all payments made under, this Agreement shall be in United States Dollars. If any currency conversion shall be required in connection with the calculation of amounts payable under this Agreement, such conversion shall be performed in a manner consistent with the paying Party's normal practices used to prepare its audited financial statements for internal and external reporting purposes.

Section 6.9 Late Payments. Any payments that are not paid on or before the date such payments are due under this Agreement shall bear interest at an annual rate equal to the lesser of (a) the "prime rate" as reported by The Wall Street Journal, plus [**] percent ([**]%), or (b) the highest rate permitted by Applicable Law; in each case calculated on the number of days such payment is delinquent, compounded monthly; except that, with respect to any disputed payments, no interest payment shall be due until such dispute is resolved and the interest which shall be payable thereon shall be based on the finally-resolved amount of such payment, calculated from the original date on which the disputed payment was due through the date on which payment is actually made.

Section 6.10 Blocked Payments. In the event that, by reason of Applicable Law in any country, it becomes impossible or illegal for a Party (or any of its Affiliates or (sub)licensees) to transfer, or have transferred on its behalf, payments owed to the other Party hereunder, such paying

Party will promptly notify the other Party of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of such other Party in a recognized banking institution designated by such other Party or, if none is designated by such other Party within a period of [**], in a recognized banking institution selected by the paying Party or its Affiliate or its (sub)licensee, as the case may be, and identified in a written notice given to such other Party.

Section 6.11 Prohibitions on Payments. When, in any country in the Territory, Applicable Law prohibits both the transmittal and the deposit of royalties on sales in such country, royalty payments due on Net Sales shall be suspended for as long as such prohibition is in effect and, as soon as such prohibition ceases to be in effect, all royalties that the paying Party would have been under an obligation to transmit or deposit but for the prohibition shall forthwith be deposited or transmitted, to the extent allowable. The Parties shall cooperate in good faith to overcome, to the extent reasonably possible, any prohibition described in this Section 6.11 within a reasonable period of time.

Article VII
Intellectual Property

Section 7.1 Ownership of Know-How and Patents. As between the Parties, Ichnos will retain all right, title, and interest in and to all Licensed Intellectual Property, except to the extent that any such rights are expressly licensed by Ichnos to Astria under this Agreement, and Astria will retain all right, title, and interest in and to all Patents and Know-How owned or controlled by Astria. With respect to any invention, whether or not patentable, that is conceived or discovered by or on behalf of any Party or any of its respective Affiliates, whether solely or jointly with the other Party, any Affiliate of either Party, or any Third Party, in the course of activities under this Agreement, ownership shall follow inventorship, as determined in accordance with the rules of inventorship under United States patent Laws.

Section 7.2 Prosecution of Patents.

(a) Sole and First Prosecution Rights. As between the Parties, Astria will have the first right (but not the obligation) to Prosecute each Licensed Patent at Astria's sole expense. Ichnos shall as promptly as practicable (but in no event later than [**] after the Effective Date) transition all Prosecution responsibilities to Astria with respect to each Licensed Patent, including execution of such documents as may be necessary to effect such transition. In furtherance of the foregoing, Ichnos will instruct its patent counsel to transition all Prosecution documents relating to the Licensed Patents to Astria's patent counsel, and will otherwise provide reasonable assistance to Astria and cooperate with Astria to effectuate such transition. After such transition, Astria shall (i) keep Ichnos informed as to material developments with respect to the Prosecution of the Licensed Patents, including by providing copies of all substantive office actions or any other substantive documents in connection with the Licensed Patents that Astria receives from any patent office, and (ii) provide Ichnos with a reasonable opportunity to comment substantively on the Prosecution of the Licensed Patents prior to taking material actions (including the filing of initial applications) with respect to the Licensed Patents, and will consider in good faith any comments made, and actions recommended, by Ichnos with respect thereto, as long as Ichnos does so promptly and consistently with any applicable filing deadlines.

(b) Step-In Right. If Astria decides not to Prosecute any Licensed Patent in any country in the Territory, or if Astria intends to allow any such Patent to lapse or become abandoned without having first filed a substitute, it shall notify Ichnos of, and consult with Ichnos regarding, such decision or intention at least [**] prior to the date upon which the subject matter of such Patent shall become unpatentable or shall lapse or become abandoned, and Ichnos shall thereupon have the right (but not the obligation) to assume the Prosecution thereof at Ichnos' own expense with counsel of its choice. Astria shall provide reasonable assistance to Ichnos, and shall cooperate with Ichnos, in connection with the transition of Prosecution responsibilities under this Section 7.2(b), including execution of such documents as may be necessary to effect such transition. Following such transition for a given Patent, Ichnos shall (i) keep Astria informed as to material developments with respect to the Prosecution of such Patent, including by providing copies of all substantive office actions or any other substantive documents in connection with such Patent that Ichnos receives from any patent office, and (ii) provide Astria with a reasonable opportunity to comment substantively on the Prosecution of such Patent prior to taking material actions (including the filing of initial applications) with respect to such Patent, and will consider in good faith any comments made, and actions recommended, by Astria with respect thereto, as long as Astria does so promptly and consistently with any applicable filing deadlines.

Section 7.3 Third Party Infringement.

(a) Notice. Each Party shall immediately provide the other Party with written notice reasonably detailing any (i) known or alleged infringement of any Licensed Patent, or known or alleged misappropriation of any Licensed Know-How, by any Third Party in a manner that is, or could reasonably be expected to be, competitive with any Licensed Product, or (ii) declaratory judgment or similar action alleging invalidity, unenforceability, or non-infringement of any Licensed Patent that could reasonably be expected to have a material effect on the Patent protection of any Licensed Product (collectively "Third Party Infringement").

(b) First Right to Initiate Actions. Astria shall have the initial right, but not the obligation, to initiate a suit or take other appropriate action that Astria believes is reasonably required to enforce or protect any Licensed Patent against any Third Party Infringement. Astria shall give Ichnos advance notice of Astria's intent to file any such suit or take any such action and the reasons therefor, and shall provide Ichnos with an opportunity to make suggestions and comments regarding such suit or action. Thereafter, Astria shall keep Ichnos reasonably informed regarding the status of any such suit or action.

(c) Step-in Right. If Astria fails to initiate a suit or take such other appropriate action under Section 7.3(b) above with respect to any Third Party Infringement in a reasonable period of time prior to any deadline on which initiation of a suit or other appropriate action is required to avoid limiting or compromising any remedies (including monetary relief and stay of regulatory approval) that may be available against the applicable alleged Third Party infringer, then Ichnos may, in its discretion, provide Astria with written notice of its intent to initiate a suit or take other appropriate action to combat such Third Party Infringement. If Ichnos provides such notice, then Ichnos shall have the right, but not the obligation, to initiate a suit or take other appropriate action that it believes is reasonably required to protect the applicable Licensed Patent from such Third Party Infringement. Ichnos shall give Astria advance notice of its intent to file any such suit or take any such action and the reasons therefor and shall provide Astria with an

opportunity to make suggestions and comments regarding such suit or action, which Ichnos shall consider in good faith. Thereafter, Ichnos shall keep Astria reasonably informed regarding the status of such suit or action.

(d) Conduct of Action; Costs. The Party initiating any suit under this Section 7.3 shall have the sole and exclusive right to select counsel for such suit; except that such counsel must be reasonably acceptable to the other Party. If required under Applicable Law in order for such Party to initiate or maintain such suit, the other Party shall join as a party to the suit. If requested by the Party initiating suit, the other Party shall provide reasonable assistance to the Party initiating suit in connection therewith, and the initiating Party shall reimburse the other Party for all reasonable Out-of-Pocket Costs (including its reasonable outside counsel expenses) incurred in rendering such assistance. The Party initiating suit shall assume and pay all of its own Out-of-Pocket Costs incurred in connection with any litigation or proceedings described in this Section 7.3, including the fees and expenses of the counsel selected by it. The other Party shall have the right to participate and be represented in any such suit by its own counsel at its own expense.

(e) Recoveries. Any recovery obtained as a result of any proceeding described in this Section 7.3 or from any counterclaim or similar claim asserted in a proceeding described in Section 7.4, by settlement or otherwise, shall be applied in the following order of priority:

(i) first, the Parties shall be reimbursed for all previously unreimbursed Out-of-Pocket Costs in connection with such proceeding; and

(ii) second, any remainder [**].

Section 7.4 Claimed Invalidity. If any Third Party at any time asserts any claim that any issued Licensed Patent is invalid or otherwise unenforceable, or if any such Patent is the subject of any pre-grant proceeding or post-grant proceeding (*e.g.*, *inter partes* review, post grant review, European opposition proceeding) (each, an "Invalidity Claim"), then Astria shall have the first right (but not the obligation) to control the defense and settlement of such Invalidity Claim; except that, if such Invalidity Claim is brought in an infringement action brought by Ichnos pursuant to Section 7.3(c), then Ichnos shall have the right to control the defense and settlement of such Invalidity Claim.

Section 7.5 Patent Term Extensions. Astria will have the sole and exclusive right to select the appropriate Patents for filing to obtain patent term extensions, including supplementary protection certificates and any other extensions that are now available or become available in the future, based on Regulatory Approvals for Licensed Products in the Field in the Territory. Ichnos will cooperate with Astria in gaining any such patent term extensions with respect to any Licensed Patent, including by signing all necessary papers.

Article VIII
Confidentiality

Section 8.1 General. Each Receiving Party shall (a) maintain in confidence the Confidential Information of the Disclosing Party using not less than the efforts such Receiving Party uses to maintain in confidence its own proprietary information of similar kind and value, but in no event less than a reasonable degree of effort, (b) not disclose such Confidential Information

to any of its Affiliates or any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (c) not use such Confidential Information for any purpose except to perform the Receiving Party's obligations, or exercise the Receiving Party's rights, under this Agreement.

Section 8.2 Permitted Disclosure. The Receiving Party may provide the Disclosing Party's Confidential Information:

(a) to the Receiving Party's Affiliates, and its and their respective employees, directors, officers, consultants, (sub)contractors, and advisors (including attorneys and accountants), who (i) have a need to know such Confidential Information in order to perform the Receiving Party's obligations, or exercise the Receiving Party's rights, under this Agreement and (ii) have an obligation to treat such information and materials as confidential under obligations of confidentiality and non-use no less protective than are those set forth in this Article VIII;

(b) to Regulatory Authorities in order to seek or obtain approval to conduct Clinical Trials, or to gain Regulatory Approval, with respect to any Licensed Product, as contemplated by this Agreement;

(c) to patent offices in order to seek or obtain Patents as contemplated by this Agreement;

(d) to any of its actual or potential *bona fide* investors, merger partners, acquirers, lenders or other financing sources, collaboration partners, or (sub)licensees, and their respective attorneys, consultants, and advisors, as may be necessary or useful in connection with their evaluation of such actual or potential investment, merger, acquisition, financing, collaboration, or (sub)license, as long as such Third Party agrees to be bound by reasonable obligations of confidentiality and non-use with respect to such Confidential Information; and

(e) if such disclosure is required by judicial order or Applicable Law (including the rules and regulations of the SEC or any securities exchange on which securities issued by such Party or any of such Party's Affiliate are traded) or to defend or prosecute litigation or arbitration, as long as, prior to such disclosure, to the extent permitted by Applicable Law, the Receiving Party promptly notifies the Disclosing Party of such requirement, cooperates with the Disclosing Party to take whatever action the Disclosing Party may deem appropriate to protect the confidentiality of the information, and furnishes only that portion of the Disclosing Party's Confidential Information that the Receiving Party is legally required to furnish.

Section 8.3 Publicity; Terms of this Agreement.

(a) Initial Press Release. Following the Effective Date, Astria may issue a press release announcing the execution of this Agreement (the "Astria Initial Press Release"). At a date and time approved by Astria, Ichnos may issue a press release approved by Astria in writing announcing the execution of this Agreement (the "Ichnos Initial Press Release").

(b) Public Announcements by Astria. In addition to the Astria Initial Press Release, (i) Astria may file a copy and description of this Agreement with the SEC or any securities exchange on which securities issued by Astria or any of its Affiliates are traded and (ii) Astria may

issue press releases regarding this Agreement in accordance with Astria's internal policies. If Astria intends to make reference to Ichnos in any press release other than the Astria Initial Press Release, Astria shall provide Ichnos with a copy of such draft press release at least [**] prior to its intended publication for Ichnos' review. Ichnos may provide Astria with suggested modifications to such draft press release, and Astria shall consider Ichnos' suggestions with respect to such press release in good faith. Notwithstanding anything to the contrary in the foregoing, nothing in this Section 8.3(b) shall restrict Astria's right to make any public disclosure, including in any press release or SEC filing, of any information that is substantially consistent with information that has previously approved by Licensor and been made publicly available.

(c) Public Announcements by Ichnos. Except for the Ichnos Initial Press Release, Ichnos may not issue any press releases or make any public announcements regarding this Agreement, any activities contemplated by this Agreement, or any Licensed Compound or Licensed Product except as approved at least [**] in advance in writing by Astria (such approval not to be unreasonably withheld, conditioned, or delayed).

Section 8.4 Term. All obligations under Section 8.1, Section 8.2, and Section 8.5 shall survive termination or expiration of this Agreement and shall expire [**] following termination or expiration of this Agreement.

Section 8.5 Return of Confidential Information.

(a) Obligations to Return or Destroy. Upon the expiration or termination of this Agreement, the Receiving Party shall return to the Disclosing Party or destroy (at the Disclosing Party's election) all of the Disclosing Party's Confidential Information (and all copies and reproductions thereof) in the Receiving Party's possession or control, except to the extent required to be maintained by Regulatory Authorities or an administrative or court order (but any such copies may only be used or disclosed as required by such Regulatory Authorities or administrative or court order). In addition, the Receiving Party shall destroy:

(i) any notes, reports, or other documents prepared by the Receiving Party that contain Confidential Information of the Disclosing Party; and

(ii) any Confidential Information of the Disclosing Party (and all copies and reproductions thereof) that is in electronic form or cannot otherwise be returned to the Disclosing Party.

(b) Electronic Back-Up Media. Nothing in this Section 8.5 shall require the alteration, modification, deletion, or destruction of archival tapes or other electronic back-up media made in the ordinary course of business, but the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article VIII with respect to any Confidential Information contained in such archival tapes or other electronic back-up media indefinitely.

(c) Retained Copies. Notwithstanding the foregoing in this Section 8.5:

(i) the Receiving Party's legal counsel may retain one copy of the Disclosing Party's Confidential Information solely for the purpose of determining the Receiving Party's continuing obligations under this Article VIII; and

(ii) the Receiving Party may retain the Disclosing Party's Confidential Information and its own notes, reports, and other documents:

(A) to the extent reasonably required (1) to exercise the rights and licenses of the Receiving Party expressly surviving expiration or termination of this Agreement; or (2) to perform the obligations of the Receiving Party expressly surviving expiration or termination of this Agreement; or

(B) to the extent it is impracticable to return or destroy such Confidential Information without incurring disproportionate cost.

Notwithstanding the return or destruction of the Disclosing Party's (and its Affiliates') Confidential Information, the Receiving Party shall continue to be bound by its obligations of confidentiality and other obligations under this Article VIII.

Section 8.6 Vicarious Responsibility. If the Receiving Party discloses any of the Disclosing Party's Confidential Information to any of the Receiving Party's Affiliates, or any of its or their respective employees, directors, officers, consultants, subcontractors, advisors (including attorneys and accountants), investors, merger partners, acquirers, or licensees (or any of their respective attorneys, consultants, or advisors), then the Receiving Party shall be responsible for any action or omission by any such disclosee that would breach this Article VIII if such action or omission were undertaken or not undertaken by the Receiving Party.

Article IX
Representations and Warranties

Section 9.1 Mutual Representations. Each of Ichnos and Astria represents and warrants to the other Party, as of the Effective Date, as follows:

(a) Authority. Such Party is duly organized, validly existing, and in good standing under the Laws of the jurisdiction of its formation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) Consents. All necessary consents, approvals, and authorizations of all Governmental Authorities and other Persons required to be obtained by it as of the Effective Date in connection with the execution, delivery, and performance of this Agreement have been obtained.

(c) No Conflict. The execution and delivery of this Agreement, the performance of such Party's obligations under this Agreement, and the licenses granted pursuant to this Agreement (i) do not and will not conflict with or violate any requirement of any Applicable Laws existing as of the Effective Date and (ii) do not and will not conflict with, violate, breach, or constitute a default under any agreement or any provision thereof, oral or written, to which such Party is a party or by which such Party or any of its Affiliates is bound.

(d) Enforceability. This Agreement has been duly executed and delivered on behalf of such Party and is a legal and valid obligation binding upon it and is enforceable in accordance with its terms, subject to applicable bankruptcy, insolvency, moratorium, and other similar Laws affecting creditors' rights generally and by general principles of equity.

Section 9.2 Additional Astria Representations. Astria represents and warrants to Astria, as of the Effective Date, as follows:

(a) Astria has the financial resources to make the upfront payment set forth in Section 6.1 and anticipates it will have or be able to obtain the ability and resources, including financial resources, to carry out its other obligations under this Agreement.

(b) There are no actions, suits, proceedings, or arbitrations pending or threatened in writing against Astria that would adversely impact its activities under this Agreement.

Section 9.3 Additional Ichnos Representations. Ichnos represents and warrants to Astria, as of the Effective Date, as follows:

(a) Ichnos has all rights, authorizations, and consents necessary to grant all rights and licenses it purports to grant to Astria under this Agreement.

(b) Ichnos is the sole and exclusive legal and beneficial owner of the entire right, title, and interest in and to the Licensed Intellectual Property.

(c) Ichnos has Control over all Patents and Know-How owned by it or its Affiliates that are necessary or reasonably useful for the Exploitation of Licensed Products for the treatment or prevention of diseases in humans.

(d) Ichnos has obtained from all inventors of any invention claimed in any Licensed Patent valid assignments of all of such inventors' rights in the Licensed Patents to Ichnos, or Ichnos otherwise holds all such rights by operation of Law. Ichnos has obtained from each of its current and former employees, consultants and contractors written agreements containing obligations of confidentiality and non-use with respect to the Licensed Intellectual Property. No inventor (whether employee, contractor, or consultant) of any invention within the Licensed Intellectual Property retains any rights to such inventions that would (i) prevent or conflict with the rights and licenses granted under or otherwise contemplated by this Agreement or (ii) require the payment of royalties or other consideration for their contribution to any such invention.

(e) Ichnos has not used any Know-How in the Development, Manufacture, or Commercialization of any Licensed Compound or Licensed Product that is encumbered by any contractual right of, or obligation to, any Third Party that conflicts or interferes with any of the rights or licenses granted or to be granted to Astria hereunder.

(f) Ichnos has not granted any right or license to any Third Party under any Licensed Intellectual Property that conflicts with or limits the scope of the rights or licenses granted to Astria hereunder.

(g) There are no claims, litigations, suits, actions, disputes, arbitrations, or legal, administrative, or other proceedings or governmental investigations pending or threatened against Ichnos, and Ichnos is not a party to any judgment or settlement relating to, any Licensed Compound or Licensed Product.

(h) To Ichnos' knowledge, the practice of the Licensed Intellectual Property as contemplated under this Agreement has not, does not, and will not (i) infringe any claim of any Patent of any Third Party (without regard to actual or alleged infringement under 35 USC §271(e)(1) and comparable provisions under Applicable Law outside the United States, including any safe harbor, research exemption, government or executive declaration of urgent public health need, or any similar right available at law or in equity that otherwise exempts actual or alleged infringing activity) or (ii) misappropriate any Know-How of any Third Party.

(i) Ichnos has not received any claim, allegation, threat, or other notice from any Third Party that the Development, Manufacture, or Commercialization of any Licensed Compound or Licensed Product (i) has infringed, infringes, or would infringe, any claim of any Patent of any Third Party (without regard to actual or alleged infringement under 35 USC §271(e)(1) and comparable provisions under Applicable Law outside the United States, including any safe harbor, research exemption, government or executive declaration of urgent public health need, or any similar right available at law or in equity that otherwise exempts actual or alleged infringing activity) or (ii) has misappropriated, misappropriates, or would misappropriate any Know-How of any Third Party.

(j) Each issued Licensed Patent was, and each pending Licensed Patent is being, diligently prosecuted in accordance with all Applicable Laws and otherwise in compliance with all applicable duties of candor and disclosure to the applicable patent office(s). Each Licensed Patent has been filed, prosecuted, and maintained consistent with commercially reasonable patent prosecution practice. All applicable fees have been paid with respect to the Licensed Patents on or before the due date for payment.

(k) None of the Licensed Patents is subject to any pending or threatened opposition, re-examination, derivation, interference, *inter partes* review, post grant review, covered business methods review, or litigation proceeding.

(l) The inventions claimed in or Covered by the Licensed Patents (i) were not invented in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof or any Governmental Authority in any other country, (ii) are not "subject inventions" as that term is described in 35 U.S.C. Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act or any similar Law in any country outside of the United States.

(m) Neither Ichnos nor any of its Affiliates has granted any lien or security interest on any of the Licensed Intellectual Property, and such intellectual property is free and clear of any mortgage, pledge, claim, security interest, covenant, easement, encumbrance, lien, or charge of any kind, in each case that would conflict or limit any of the rights granted to Astria hereunder.

(n) Schedule 9.2(n) contains a complete and accurate list of all Patents Controlled by Ichnos or any its Affiliates as of the Effective Date that are included in the Patents licensed hereunder, indicating any co-owner(s), if applicable. Except as set forth on Schedule 9.2(n), neither Ichnos nor any of its Affiliates owns or Controls any Patent that is necessary or, to Ichnos' reasonable belief as of the Effective Date, reasonably useful to Exploit any Licensed Product.

(o) All Licensed Know-How that derives value from not being known by Third Parties (including the existence of X8) has been kept confidential or has been disclosed to Third Parties only under commercially reasonable confidentiality obligations.

(p) Ichnos has not brought or threatened any claim against any Third Party alleging infringement of any Licensed Patent, nor, to Ichnos' knowledge, is any third party infringing or preparing or threatening to infringe any Licensed Patent.

(q) Ichnos and its Affiliates have conducted, and, to Ichnos' knowledge, their respective contractors and consultants have conducted, all Development of each Licensed Compound and Licensed Product in accordance in all material respects with Applicable Law.

(r) To Ichnos' knowledge, there is no material safety or toxicity issue with respect to ISB 830 and Ichnos is not aware of any fact or information that would reasonably be expected to materially adversely affect Astria's ability to Exploit ISB 830 as contemplated by this Agreement.

(s) Ichnos has completely and accurately responded to all of Astria's diligence questions and requests and has provided to Astria, prior to the Effective Date, true, correct, and complete copies of all material data and information in Ichnos' or any of its Affiliates' control regarding the quality, efficacy, or safety of any Licensed Compound or Licensed Product, and all quality, efficacy, and safety data and information provided or otherwise made available to Astria is true, correct and complete in all material respects. All information, documents, and materials provided or otherwise made available in writing by or on behalf of Ichnos or any of its Affiliates to Astria on or prior to the Effective Date in contemplation of this Agreement were and are true, correct, and complete in all material respects, and such information, documents, and materials do not (i) contain any untrue statement of a material fact or (ii) omit any fact that would cause the statements or facts or information contained therein, in light of the circumstances under which they were made, to be misleading in any material respect.

Section 9.4 Ichnos Covenant. During the Term, Ichnos and its Affiliates will not assign, transfer, convey, encumber, license, or dispose of any Licensed Intellectual Property, or disclose to any Third Party any Ichnos Confidential Information relating to any Licensed Compound or Licensed Product, except in connection with a permitted assignment of this Agreement pursuant to Section 12.3.

Section 9.5 Disclaimer. Except as otherwise expressly set forth in this Agreement, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY THAT ANY PATENTS ARE VALID OR ENFORCEABLE, AND EXPRESSLY DISCLAIMS ALL

IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT. Without limiting the generality of the foregoing, each Party disclaims any warranties with regards to (a) the success of any study or test commenced under this Agreement; (b) the safety or usefulness for any purpose of any technology or materials, including any Licensed Product; or (c) the validity, enforceability, or non-infringement of any intellectual property rights or technology it provides or licenses to the other Party under this Agreement.

Article X
Indemnification; Limitation of Liability

Section 10.1 By Astria. Astria agrees, at Astria's cost and expense, to defend, indemnify, and hold harmless Ichnos and its Affiliates and each of their respective directors, officers, employees, and agents (collectively, the "Ichnos Indemnified Parties") from and against any Damages arising out of any Claim to the extent relating to:

(a) any breach by Astria of this Agreement;

(b) any negligence, willful misconduct, or violation of Law of Astria or any of its Affiliates or Sublicensees in connection with Astria's performance of its obligations or exercise of its rights under this Agreement; or

(c) any Development, Manufacture, or Commercialization of any Licensed Product by or on behalf of Astria or any of its Affiliates or Sublicensees;

in each case ((a)-(c)), except to the extent that Ichnos has an indemnification obligation pursuant to Section 10.2 for such Damages, as to which Damages each Party shall indemnify the other Party to the extent of such Party's respective fault for such Damages.

Section 10.2 By Ichnos. Ichnos agrees, at Ichnos' cost and expense, to defend, indemnify, and hold harmless Astria and its Affiliates and each of their respective directors, officers, employees, and agents (the "Astria Indemnified Parties") from and against any Damages arising out of any Claim to the extent relating to:

(a) any breach by Ichnos of this Agreement;

(b) any negligence, willful misconduct, or violation of Law of Ichnos or any of its Affiliates or (sub)licensees in connection with Ichnos' performance of its obligations or exercise of its rights under this Agreement; or

(c) the Exploitation of any Licensed Compound or Licensed Product by or on behalf of Ichnos or any of its Affiliates or Sublicensees after the effective date of termination of this Agreement if Ichnos exercises its rights pursuant to Section 11.3(b).

in each case ((a)-(c)), except to the extent that Astria has an indemnification obligation pursuant to Section 10.1 for such Damages, as to which Damages each Party shall indemnify the other Party to the extent of such Party's fault for such Damages.

Section 10.3 Indemnification Procedures.

(a) General. Promptly after the receipt by a Person seeking indemnification under this Article X (the "Indemnitee") of notice of any pending or threatened Claim for which the Indemnitee intends to seek indemnification under this Article X, such Indemnitee shall promptly provide notice thereof to the Party from whom indemnification is sought (the "Indemnitor"), which notice shall include a reasonable identification of the alleged facts giving rise to such Claim. Any failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement, except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice. The Indemnitor shall have the right to participate in, and, to the extent the Indemnitor so desires, to control the defense and settlement of the indemnified Claim with counsel selected by the Indemnitor. However, notwithstanding the foregoing, the Indemnitee shall have the right to participate in, but not control, the defense of any indemnified Claim, and request separate counsel, with the fees and expenses to be paid by the Indemnitee, unless (a) representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other parties represented by such counsel in such proceedings or (b) the Indemnitor has failed to assume the defense of the applicable Claim, in which case ((a) or (b)), such fees and expenses shall be paid by the Indemnitor. The Indemnitee shall, and shall cause each of its Affiliates and its and their respective directors, officers, employees, agents, successors, and assigns, as applicable, to, cooperate in the defense of any indemnified Claim and shall furnish such records, information, and testimony, provide such witnesses, and attend such conferences, discovery proceedings, hearings, trials, and appeals, and otherwise provide reasonable access to such indemnitees and other employees and agents of the Indemnitee, in each case as may be reasonably requested in connection therewith. The Indemnitor shall reimburse the Indemnitee for its reasonable and verifiable out-of-pocket expenses in connection therewith. The Indemnitor may not settle any Claim, and the Indemnitee shall not be responsible for or be bound by any settlement of a Claim that imposes an obligation on it, without the prior written consent of the Indemnitee (which consent shall not be unreasonably withheld, conditioned, or delayed), unless such settlement or compromise (i) fully releases the Indemnitee without any liability, loss, cost, or obligation, (ii) admits no liability, wrongdoing, or other admission against interest on the part of the Indemnitee, and (iii) would not have an adverse effect on the Indemnitee's interests (including any rights under this Agreement or the scope or enforceability of the intellectual property licensed hereunder).

(b) No Acknowledgment. The assumption of the defense of a Claim by the Indemnitor shall not be construed as an acknowledgment that the Indemnitor is liable to indemnify the Indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnitor of any defenses it may assert against the Indemnitee's claim for indemnification.

Section 10.4 Limitation of Liability. EXCEPT WITH RESPECT TO A BREACH OF ARTICLE VIII, OR A PARTY'S LIABILITY PURSUANT TO SECTION 10.1 OR SECTION 10.2, NEITHER PARTY SHALL BE LIABLE FOR ANY SPECIAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE, OR OTHER INDIRECT OR REMOTE DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA, OR LOSS OF USE DAMAGES ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE EXERCISE OF ITS RIGHTS HEREUNDER, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STRICT

LIABILITY, OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSS.

Article XI
Term and Termination

Section 11.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated pursuant to Section 11.2, shall remain in effect until it expires (the "Term") as follows:

(a) on a Licensed Product-by-Licensed Product and country-by-country basis, this Agreement shall expire on the date of the expiration of the Royalty Term with respect to such Licensed Product in such country; and

(b) this Agreement shall expire in its entirety upon the expiration of all Royalty Terms with respect to all Licensed Products in all countries in the Territory.

Section 11.2 Termination.

(a) Termination for Convenience. Astria shall have the right to terminate this Agreement in its entirety for convenience upon ninety (90) days' prior written notice to Ichnos.

(b) Termination for Material Breach.

(i) Termination by Either Party for Breach. This Agreement may be terminated, in its entirety, by either Party for the material breach of this Agreement by the other Party, if the breaching Party has not cured such material breach within [**] after the date of written notice to the breaching Party of such breach (or [**], in the case of Astria's payment obligations under this Agreement) (the "Cure Period"), which notice shall describe such material breach in reasonable detail and shall state the non-breaching Party's intention to terminate this Agreement pursuant to this Section 11.2(b)(i) [**].

(ii) Disagreement as to Material Breach. If the Parties reasonably and in good faith disagree as to whether there has been a material breach of this Agreement, then: (A) the Party that disputes that there has been a material breach may contest the allegation by referring such matter, within [**] following such notice of alleged material breach, for resolution to the Executive Officers, who shall meet promptly to discuss the matter, and determine, within [**] following referral of such matter, whether or not there has been a material breach of this Agreement; (B) [**]; (C) [**]; and (D) [**].

(iii) Failure to Resolve. If the Executive Officers are unable to resolve a dispute within such [**] period after it is referred to them, the matter will be resolved as provided in Section 12.1(b).

(c) Termination for Insolvency. To the extent permitted by Law, this Agreement may be terminated by either Ichnos or Astria upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings with respect to, or upon an assignment of a substantial portion of the assets for the benefit of creditors by, the other Party;

except that, in the event of any involuntary bankruptcy or receivership proceeding, such right to terminate shall only become effective if the non-terminating Party consents to the involuntary bankruptcy or receivership or such proceeding is not dismissed within [**] after the filing thereof.

Section 11.3 Effects of Termination.

(a) Upon any termination of this Agreement, the following shall apply (except with respect to any license, Licensed Product, or country with respect to which Astria's license has become irrevocable pursuant to Section 6.3(d)):

(i) Termination of Licenses. All licenses granted by Ichnos to Astria under Section 2.1 shall terminate.

(ii) Right to Sell. If Astria or any of its Affiliates or Sublicensees possesses any inventory of any Licensed Product, has started the Manufacture of any Licensed Product, or has accepted any order for any Licensed Product, Astria and its Affiliates and Sublicensees shall have the right, for up to [**] following the effective date of termination of this Agreement, to sell their inventories thereof, complete the Manufacture thereof, and Commercialize such fully-Manufactured Licensed Products, in order to fulfill such accepted orders or distribute such fully-Manufactured Licensed Products, subject to the obligation of Astria to pay Ichnos any and all related milestone and royalty payments as provided in this Agreement.

(iii) Termination of Clinical Trials. If any Clinical Trial of any Licensed Product is being conducted at the time of the termination of this Agreement, each Party hereby agrees to reasonably cooperate in the completion or winding down of such Clinical Trial in consultation with the appropriate Regulatory Authorities and any applicable institutional review board(s).

(b) Reversion License.

(i) If Ichnos terminates this Agreement pursuant to Section 11.2(b), then, upon the written request of Ichnos within [**] after the effective date of such termination, [**] (collectively, ((A) and (B)), the "Astria Foreground Intellectual Property").

(ii) If Astria terminates this Agreement pursuant to Section 11.2(a) or if Ichnos terminates this Agreement pursuant to Section 11.2(c), then, upon the written request of Ichnos within [**] after the effective date of such termination, [**].

Section 11.4 Survival. Upon any termination or expiration of this Agreement, unless otherwise specified in this Agreement and except for any rights or obligations that have accrued prior to the effective date of termination or expiration, all rights and obligations of each Party under this Agreement shall terminate, except that Article I, Section 2.1 (solely upon expiration as set forth in Section 6.3(d)), Section 2.5, Section 6.3(d), Section 6.4, Section 6.5 (for the time periods specified therein), Section 6.6 through Section 6.11, Section 7.1, Section 7.3 (solely with respect to Third Party Infringement occurring during the Term), Article VIII, Section 9.5, Article X, Section 11.3 through Section 11.5, and Article XII shall survive any such termination or expiration of this Agreement.

Section 11.5 Other Relief. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including the Parties' ability to receive legal damages or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

Article XII
Miscellaneous

Section 12.1 Dispute Resolution.

(a) The Parties agree that any dispute arising with respect to the interpretation, enforcement, termination, or invalidity of this Agreement (each, a "Dispute") shall first be presented to the Parties' respective Executive Officers for resolution. If the Parties are unable to resolve a given Dispute pursuant to this Section 12.1(a) after discussions between the Executive Officers within [**] after referring such Dispute to the Executive Officers, either Party may, at its sole discretion, seek resolution of such matter in accordance with Section 12.1(b).

(b) Subject to Section 12.1(c), all disputes arising out of or in connection with this Agreement that are not resolved in accordance with Section 12.1(a) will be finally settled under the Rules of Arbitration of the American Arbitration Association (the "Rules") by three (3) arbitrators appointed in accordance with the Rules. The language of the arbitration will be English. The place of arbitration will be New York, New York. The arbitrators will award to the prevailing Party, if any, as determined by the arbitrator(s), its reasonable attorneys' fees and costs. Judgment on an award may be entered in any court having jurisdiction thereof. The Parties will maintain the confidential nature of the arbitration proceeding and the award, including the hearing, except as may be necessary to prepare for or conduct the arbitration hearing on the merits, or except as may be necessary in connection with a court application for a preliminary remedy, a judicial challenge to an award or its enforcement, or unless otherwise required by Law.

(c) Unless otherwise agreed by the Parties, a dispute between the Parties relating to the validity or enforceability of any Patent will not be subject to arbitration, but will instead be submitted to a court or patent office of competent jurisdiction in the relevant country or jurisdiction in which such Patent was issued or, if not issued, in which the underlying patent application was filed.

Section 12.2 Governing Law. This Agreement and all questions regarding its validity or interpretation, or the performance or breach of this Agreement, shall be governed by and construed and enforced in accordance with the laws of the State of New York, without reference to conflicts of laws principles thereof that may dictate application of the laws of any other jurisdiction.

Section 12.3 Assignment.

(a) Generally. Neither this Agreement nor any of the rights, interests, or obligations hereunder shall be assigned by either Party (whether by operation of law or otherwise) without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without the other Party's written consent, assign this Agreement in its entirety to (i) an Affiliate of such Party or (ii) a Third Party that acquires, by or otherwise in connection with, merger, sale of assets, or otherwise, all or substantially all of the business of the assigning Party to

which the subject matter of this Agreement relates, as long as the assignee agrees in writing to assume all of the assigning Party's obligations under this Agreement. The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned.

(b) All Other Assignments Null and Void. The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators, and permitted assigns of the Parties. Any purported assignment in violation of this Section 12.3 will be null and void *ab initio*.

(c) Change of Control. Notwithstanding anything to the contrary in this Agreement, if either Party undergoes a Change of Control, then any technology or intellectual property rights owned, licensed, or otherwise controlled by the Acquirer of such Party or any New Affiliate shall not be included in the technology and intellectual property rights licensed to the other Party hereunder to the extent held by such Acquirer or any New Affiliate prior to such transaction, or to the extent such technology or intellectual property rights are developed by such Acquirer or any New Affiliate outside the scope of activities conducted hereunder and without use of or reference to (i) any technology or intellectual property rights of Ichnos or any Collaboration Affiliate (including any Licensed Patents or Licensed Know-How) or (ii) any Confidential Information of the other Party.

Section 12.4 Force Majeure. If the performance of any part of this Agreement by a Party is prevented, restricted, interfered with, or delayed by a Force Majeure Event, such Party shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference, or delay. However, the affected Party shall use its commercially reasonable efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed.

Section 12.5 Notices. Unless otherwise agreed by the Parties or specified in this Agreement, all notices required or permitted to be given under this Agreement shall be in writing and shall be sufficient if: (a) personally delivered; (b) sent by registered or certified mail (return receipt requested and postage prepaid); or (c) sent by express courier service providing evidence of receipt and postage prepaid where applicable, in each case to the address for a Party set forth below, or such other address for a Party as may be specified in writing by like notice:

To Ichnos:	To Astria:
Ichnos Sciences Inc. One World Trade Center - 76th Floor, Suite D New York, NY 10007 USA	Astria Therapeutics, Inc. 75 State Street, Suite 1400 Boston, MA 02109 Attn: CEO and CLO

With a copy, which shall not constitute notice, to:	With a copy, which shall not constitute notice, to:
Ichnos Sciences SA Chemin de la Combeta 5 - La Chaux-de-Fonds Neuchâtel 2300, Switzerland	WilmerHale 60 State Street Boston, MA 02109 Attention: Sarah Tegan Hogan Telephone: (617) 526-6706 Facsimile: (617) 526-5000

Any such notices shall be effective upon receipt by the Party to whom it is addressed.

Section 12.6 Waiver. Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party's rights at a later time to thereafter enforce such provision. No waiver by any Party of any condition or term in any one or more instances shall be construed as a further or continuing waiver of such condition or term or of another condition or term.

Section 12.7 Severability. If any provision of this Agreement should be invalid, illegal, or unenforceable in any jurisdiction, the Parties shall negotiate in good faith a valid, legal, and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions of this Agreement shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. If the Parties cannot agree upon a substitute provision, the invalid, illegal, or unenforceable provision of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid, illegal, or unenforceable provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without the invalid, illegal, or unenforceable provision.

Section 12.8 Entire Agreement. This Agreement (including the Exhibits and Schedules attached hereto) constitutes the entire agreement between the Parties relating to its subject matter, and supersedes all prior and contemporaneous agreements, representations, or understandings, either written or oral, between the Parties with respect to such subject matter, including the Confidentiality Agreement. There are no covenants, promises, agreements, warranties, representations, conditions, or understandings, either oral or written, between the Parties with respect to such subject matter other than as set forth herein.

Section 12.9 Modification. No modification, amendment, or addition to this Agreement, or any provision hereof, shall be effective unless reduced to writing and signed by a duly authorized representative of each Party. No provision of this Agreement shall be varied, contradicted, or explained by any oral agreement, course of dealing or performance, or any other matter not set forth in an agreement in writing and signed by a duly authorized representative of each Party.

Section 12.10 Independent Contractors; No Intended Third Party Beneficiaries. Nothing contained in this Agreement is intended or shall be deemed or construed to create any relationship of employer and employee, agent and principal, partnership, or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of, or in the name of, the other Party, nor to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder.

Section 12.11 Interpretation; Construction. The captions to the several Articles and Sections of this Agreement are included only for convenience of reference and shall not in any way affect the construction of, or be taken into consideration in interpreting, this Agreement. In this Agreement, unless the context requires otherwise, (a) the words "including," "include," "includes," "such as" and "*e.g.*" shall be deemed to be followed by the phrase "without limitation" or like expression, whether or not followed by the same; (b) references to the singular shall include the plural and vice versa; (c) references to masculine, feminine, and neuter pronouns and expressions shall be interchangeable; (d) the words "herein" or "hereunder" relate to this Agreement; (e) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or" unless preceded by the word "either" or other language indicating the subjects of the conjunction are, or are intended to be, mutually exclusive; (f) the word "will" shall be construed to have the same meaning and effect as the word "shall"; (g) all references to "dollars" or "$" herein shall mean U.S. Dollars; and (h) a capitalized term not defined herein but reflecting a different part of speech from that of a capitalized term which is defined herein shall be interpreted in a correlative manner. Each Party represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will apply against the Party which drafted such terms and provisions.

Section 12.12 Counterparts. This Agreement may be executed in two (2) counterparts, each of which shall be deemed an original, and both of which together shall constitute one and the same instrument. Any such counterpart, to the extent delivered by means of a fax machine or by .pdf, .tif, .gif, .jpeg or similar attachment to electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original executed counterpart and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. No Party shall raise the use of Electronic Delivery to deliver a signature or the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery as a claim or defense with respect to the formation of a contract, and each Party forever waives any such claim or defense, except to the extent that such claim or defense relates to lack of authenticity.

Section 12.13 Equitable Relief. Notwithstanding anything to the contrary herein, the Parties shall be entitled to seek equitable relief, including injunction and specific performance, as a remedy for any breach of this Agreement. Such remedies shall not be deemed to be the exclusive remedies for a breach of this Agreement but shall be in addition to all other remedies available at law or equity.

Section 12.14 Further Assurances. Each Party shall execute, acknowledge, and deliver such further instruments, and do all such other acts, as may be necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement. Without limiting the foregoing, at Astria's request (and without limiting Ichnos' liability under Section 9.3(c)) Ichnos shall, within [**], obtain from each inventor of any invention claimed in any Licensed Patent a valid assignment of all of such inventors' rights in the Licensed Patents to Ichnos.

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Execution Date.

ICHNOS SCIENCES SA

By: /s/ Roberto Giovaninni
Name: Roberto Giovaninni
Title: Chief Process and Manufacturing Officer

By: /s/ Dean Thomas
Name: Dean Thomas
Title: General Counsel

ICHNOS SCIENCES INC.

By: /s/ Michael D. Price
Name: Michael D. Price
Title: Chief Financial Officer

ASTRIA THERAPEUTICS, INC.

By: /s/ Jill C. Milne
Name: Jill C. Milne
Title: Chief Executive Officer and President

[Signature Page to License Agreement]

Schedule 4.1
Drug Substance and [**] Drug Product Cost

Material	Quantity	Cost ($)
Bulk Drug substance	[**]	[**]
[**] Drug Product vials	[**]	[**]

Total quantities available as of the Effective Date:

Bulk Drug substance:

[**]

[**] Drug Product:

[**]

SUBLEASE AGREEMENT

This SUBLEASE AGREEMENT (this "Sublease") is made as of the 3rd day of January 2024 (the "Effective Date") between **Duck Creek Technologies LLC,** a Delaware limited liability company ("Sublessor") with an address of 22 Boston Wharf Road, Boston, Massachusetts 02110 and **Astria Therapeutics, Inc.,** a Delaware corporation ("Sublessee"), with an address of 75 State Street, Suite 1400, Boston, Massachusetts 02109.

RECITALS:

WHEREAS, pursuant to that certain Lease dated as of August 7, 2017 (the **"Master Lease")** by and between Sublessor, as tenant, and MEPT Seaport 13 Stillings LLC, as landlord (the **"Master Lessor"),** Sublessor has leased, in part, from Master Lessor a portion of the building consisting of approximately 30,110 square feet of space located on the tenth (10th) floor having a street address of 22 Boston Wharf Road, Boston, Massachusetts (the **"Subleased Premises");**

WHEREAS, Sublessee desires to sublease from Sublessor, and Sublessor desires to sublease to Sublessee, the entirety of the Subleased Premises upon the terms and conditions set forth in this Sublease.

AGREEMENT:

In consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and legal sufficiency of which are acknowledged, Sublessor and Sublessee agree as follows:

1. Sublease.

1.1 Term. Sublessor demises and subleases to Sublessee, and Sublessee hires and subleases from Sublessor, the Subleased Premises, together with all appurtenances applicable thereto pursuant to the Master Lease for a term (the "Sublease Term") commencing on the Sublease Commencement Date (as defined in Paragraph 1.2 below) and ending on November 30, 2028 (the "Termination Date"), unless sooner terminated pursuant to any provision hereof.

1.2 Sublease Commencement Date. The Sublease Commencement Date shall be the later of: (i) June 1, 2024 or (ii) the date that Master Lessor has granted its Consent (as defined in Paragraph 14.11 of this Sublease) to this Sublease. Promptly after the determination of the Sublease Commencement Date, if requested by either party, Sublessor and Sublessee shall enter into a commencement letter agreement detailing the actual date of the Sublease Commencement Date. Sublessee shall have access to and exclusive use of the Subleased Premises as of the Sublease Commencement Date. Sublessor shall provide Sublessee with appropriate access credentials (e.g. key, key card, etc.) to enable Sublessee to access and use the Subleased Premises beginning June 1, 2024.

1.3 Use. The Sublessee shall use and occupy the Subleased Premises only for the Permitted Use in accordance with the provisions of the Master Lease.

1.4 Delivery. Sublessee acknowledges and agrees that it has had the opportunity to inspect and familiarize itself with the Subleased Premises and has done so. Sublessee's taking possession of the Subleased Premises shall be conclusive evidence by Sublessee that the Subleased Premises were in good order and satisfactory condition when Sublessee took possession. The Subleased Premises shall be delivered to Sublessee on the Sublease Commencement Date. Sublessor shall

remove all of its personal property and equipment from the Subleased Premises along with the forty (40) cubicles located adjacent to the kitchen/café area, and shall deliver the Subleased Premises, broom clean but otherwise in "AS IS, WHERE IS" condition, without any obligation on the part of Sublessor to prepare or make improvements to the Subleased Premises for Sublessee's occupancy. Sublessee acknowledges that neither Sublessor nor Sublessor's agents have made any representation or warranty as to the condition of the Subleased Premises or the suitability of the Subleased Premises for the conduct of Sublessee's business.

1.5 Security Deposit. $391,430.01 (three (3) months of Fixed Rent).

2. Incorporation of the Master Lease.

2.1 Compliance with Master Lease. Except as expressly otherwise provided in this Sublease, Sublessee shall timely and fully comply with all of the provisions of the Master Lease that are to be observed or performed during the Sublease Term by Sublessor, as tenant under the Master Lease, with respect to the Subleased Premises, except as expressly provided otherwise by this Sublease; provided, the amount of any base rental for the Subleased Premises ("Fixed Rent") and any other amounts due hereunder to be paid by Sublessee shall be governed by the terms of this Sublease. Notwithstanding any other provision of this Sublease, Sublessee shall not, by any act or omission, cause Sublessor to be in violation of or in default under the Master Lease, or do or permit, any act that is in violation of this Sublease or the Master Lease.

2.2 Incorporation of Master Lease. Insofar as the provisions of the Master Lease do not conflict with specific provisions of this Sublease, such provisions (except for the Excluded Provisions listed below) are incorporated by this reference into this Sublease as fully as if completely restated herein. Subject to the preceding sentence, Sublessee shall be bound by all the provisions of the Master Lease pertaining to the Subleased Premises and shall perform all of the obligations and responsibilities that Sublessor is obligated to perform pursuant to the Master Lease pertaining to the Subleased Premises from and after the Sublease Commencement Date. Therefore, for the purposes of this Sublease, wherever in the Master Lease the words "Premises" or similar words are used, they shall mean the Subleased Premises, whenever in the Master Lease, the word "Landlord" is used, it shall mean Sublessor, and wherever in the Master Lease the word "Tenant" is used, it shall mean Sublessee, provided, however, the word "Landlord" shall mean (i) Master Lessor, not Sublessor, with respect to any provisions in the Master Lease relating to Master Lessor's representations, warranties or obligations relating to the compliance of the Subleased Premises (or portions thereof) or any portion of the Building with any laws, or any service, repair, restoration, replacement, maintenance or alteration obligations on the part of Master Lessor; any provisions relating to Master Lessor's obligation to maintain insurance; any provisions relating to Master Lessor's indemnification obligations; any provisions relating to Master Lessor's representations, warranties or obligations relating to the existence of hazardous materials on, at, in, under or about the Subleased Premises; any remedial work or other obligations on the part of Master Lessor relating thereto.

2.3 Time Periods. Except in the event of a default, in which event the time periods provided in Paragraph 7.2 hereof shall govern, with respect to any time periods provided in the Master Lease: (a) in any instance where Master Lessor under the Master Lease has a certain time period in which to notify Sublessor of some decision by Master Lessor that Master Lessor will or will not take some action, Sublessor shall have an additional five (5) business day period after receiving such notice in which to notify Sublessee; and (b) in any instance where Sublessor, as tenant under the Master Lease, has a certain time period in which to notify Master Lessor under the Master Lease of some decision by Sublessor that Sublessor will or will not take some action, Sublessee must notify

Sublessor at least five (5) business days prior to the end of the period granted in the Master Lease of any decision by Sublessee that Sublessee will or will not take some action.

2.4 Subject to Master Lease. This Sublease is expressly subject and subordinate to the Master Lease, and to the rights of Master Lessor thereunder, and Sublessee shall under no circumstances have any greater rights than does Sublessor under the Master Lease, and no provision of this Sublease shall be construed in a manner that would constitute a breach of the Master Lease. Without limiting the generality of the foregoing, in the event of the termination or cancellation of the Master Lease for any reason, this Sublease shall automatically be deemed terminated effective as of the same day of such cancellation or termination of the Master Lease, and neither Sublessor nor Sublessee shall have any liability or obligation to the other as a result thereof; provided, however, that if the Master Lease terminates as a result of a default or breach by Sublessor or Sublessee under this Sublease or the Master Lease, then the defaulting party shall be liable to the non-defaulting party for the damage suffered as a result of such termination and the defaulting party shall indemnify, exonerate and hold the non-defaulting party harmless from and against any and all loss, cost, damage and liability (including without limitation reasonable attorneys' fees) incurred by the non-defaulting party by reason of any breach by the defaulting party of its obligations, covenants and/or undertakings under this Sublease and/or the Master Lease or failure to perform any obligations under this Sublease. Sublessor hereby covenants that it shall not, by its omission or act, do or permit anything to be done which would cause a default under the Master Lease, and Sublessor hereby agrees that it shall not voluntarily terminate the Master Lease (except for any termination rights granted to Sublessor as a result of a casualty or eminent domain).

2.5 Approval of Master Lease; Amendments to Master Lease. Sublessee represents that it has read and is familiar with all of the provisions of the Master Lease as redacted and attached hereto. Sublessor shall not amend or modify any term of the Master Lease in any manner that would materially and adversely affect Sublessee's rights under this Sublease without the prior consent of Sublessee which shall not be unreasonably withheld, delayed or conditioned.

2.6 Services. Notwithstanding anything in this Sublease to the contrary, Sublessee acknowledges and agrees that Sublessor shall not be obligated to furnish to Sublessee any services of any nature whatsoever (including, without limitation, the furnishing of heat, electrical energy, air conditioning, loading dock, elevator service, cleaning, window washing, and rubbish removal services, or security services). Insofar as Master Lessor is obligated to furnish any services to the Subleased Premises, to repair or rebuild the same, to perform any other act whatsoever with respect to the Subleased Premises, or to perform any obligation or satisfy any condition under the Master Lease, Sublessee expressly acknowledges that Sublessor does not undertake the performance or observance of such obligations, but is only obligated, upon receipt of written notice from Sublessee, to use commercially reasonable efforts to obtain Master Lessor's performance for Sublessee's benefit and without obligating itself to institute legal action or incur any expense.

2.7 Consent of Master Lessor. Wherever Sublessor's consent is required under this Sublease, the consent of Master Lessor shall also be required (to the extent set forth in the Master Lease). Whenever Master Lessor's consent is required under the Master Lease, the consent of Sublessor shall also be required, which consent by Sublessor shall not be unreasonably withheld where Master Lessor consents thereto.

2.8 Master Lessor's Representations and Warranties. Sublessor shall have no liability or obligation to Sublessee based upon any representation or warranty made by Master Lessor to Sublessor under the Master Lease or based upon any act or omission of Master Lessor or its agents, employees, or contractors.

2.9 Sublessor's Representations. Sublessor represents to Sublessee as follows: (i) the Master Lease, a redacted copy of which is attached hereto as Exhibit A, constitutes the entire agreement between Master Lessor and Sublessor relating to the lease of the Premises, has not been otherwise amended and is in force and effect; (ii) no default or breach by Sublessor or, to the best knowledge of Sublessor, by Master Lessor exists under the Master Lease; (iii) no event has occurred that, with the passage of time, the giving of notice, or both, otherwise would constitute a default or breach by Sublessor, or to the best of Sublessor's knowledge, the Master Lessor under the Master Lease; (iv) Sublessor shall promptly pay when due all rents due and accruing to Master Lessor under the Master Lease, and perform its obligations under the Master Lease except to the extent required to be performed by Sublessee hereunder; and (v) subject to receipt of Master Lessor's written consent hereto, Sublessor has the right and power to execute and deliver this Sublease and to perform its obligations hereunder.

3. Inapplicability of Certain Provisions of Master Lease. The following Sections or provisions of the Master Lease (the "Excluded Provisions") are NOT incorporated into this Sublease and do not form a part of this Sublease except to the extent that they contain defined terms which are used herein: (a) any provisions that are superseded by or in direct conflict with the provisions hereof; (b) any provision granting Sublessor any rights or options to extend or renew the term, or granting Sublessor any expansion options or right of first refusals or first offers, including without limitation, the provisions of Section 2.1.2 and 2.2.2 of the Master Lease; (c) any redacted provisions; and (d) the following sections of the Master Lease: 2.1.3(a) through (h) (regarding creation of the Rooftop Deck), 2.2.3 (regarding the determination of Fair Market Rent for Extension Option), 2.3 (regarding initial buildout plans), 2.4 (regarding Landlord's work), 2.5 (regarding initial Tenant Improvements), 3.4 (regarding additional rent), 4.27 — third sentence only (regarding limitation of liability), Exhibit C (regarding listing of plans and specification for Tenant Improvements), and Exhibit H (regarding Landlord's Base Building Work).

4. Rent.

4.1 Fixed Rent.

4.1.1 Commencing on: September 1, 2024 (the "Sublease Rent Commencement Date"), and continuing through the Termination Date, Sublessee shall pay to Sublessor for the Subleased Premises annual base rental ("Fixed Rent") as follows:

Sublease Term	Annual Fixed Rent	Monthly Fixed Rent	Fixed Rent/SF
September 1, 2024 - August 31, 2025	$1,565,720.00	$130,476.67	$52.00/SF
September 1, 2025 - August 31, 2026	$1,597,034.40	$133,086.20	$53.04/SF
September 1, 2026 - August 31, 2027	$1,628,951.00	$135,745.91	$54.10/SF
September 1, 2027 - August 31, 2028	$1,661,469.80	$138,455.81	$55.18/SF

September 1, 2028 - November 30, 2028	$423,722.97 *	$141,240.99	$56.29/SF

*Prorated; Three-month period of remainder of the Sublease Term.

(Fixed Rent and any other amounts due hereunder, including the electricity charges set forth herein, are sometimes referred to herein as "Rent").

4.1.2 Monthly installments of Fixed Rent will be due and payable on or before the first day of each succeeding calendar month during the Sublease Term to the address set forth in Paragraph 4.1.1 above; provided, however, that the first monthly installment of Fixed Rent shall be due and payable upon the execution of this Sublease by Sublessee.

4.2 No Setoff. All Rent shall be payable without any setoff or deduction, and without notice or demand.

5. Additional Rent.

5.1 Operating Costs and Property Taxes. Sublessee shall not be responsible for the payment of any Operating Costs or Property Taxes as set forth in Section 3.4 the Master Lease. Sublessee's Fixed Rent shall be deemed to include said additional rent from the Master Lease.

5.2 Utilities. Beginning on the Sublease Commencement Date, Sublessee shall pay for all electricity and other utilities consumed in and/or services which are to serve the Subleased Premises as provided by Section 3.5 of the Master Lease. In addition, if due to Sublessee's particular manner of use or occupancy of the Premises, there is any surcharge, or supplemental cost or expense charged by Master Lessor or if Sublessee requests any additional services or utilities to the Subleased Premises for which an additional charge is imposed by Master Lessor, Sublessee shall promptly pay such amount to Master Lessor (provided, however, that if Master Lessor requires Sublessor to pay for any such services for the benefit of Sublessee, then Sublessee shall reimburse Sublessor for such costs within thirty (30) days after Sublessee's receipt of an invoice therefor from Sublessor).

6. Insurance and Indemnity.

6.1 Insurance. Sublessee shall carry all of the insurance policies required to be carried by Sublessor under the Master Lease and shall name Master Lessor and Sublessor and any other parties required pursuant to the Master Lease as additional insureds on all such policies. Prior to the earlier to occur of the Sublease Commencement Date or Sublessee's entry to or occupancy of the Subleased Premises, and at least thirty (30) days prior to each policy's expiration date, Sublessee shall deliver to Sublessor evidence satisfactory to Sublessor of maintenance of insurance coverage with respect to the Subleased Premises as required under the Master Lease. Without limiting the foregoing, the insurance provisions set forth in the Master Lease are incorporated herein by reference, it being the intention of the parties, and Sublessee hereby agreeing, that Sublessee shall be bound by such insurance provisions as the tenant under the Master Lease, and that such insurance obligations shall extend to both Master Lessor and Sublessor. In addition, the waiver of subrogation and release provisions of the Master Lease shall apply to the relationship between Sublessor and Sublessee, and be binding upon and enforceable as between Sublessor and Sublessee and each party

hereby confirms the same and agrees to obtain the necessary waiver of subrogation endorsements from their respective insurers in order to comply with the provisions hereof.

6.2 Indemnification and Waiver. Sublessor's indemnity obligations set forth in Section 4.12 of and elsewhere in the Master Lease are hereby applicable to and binding upon Sublessee, and Sublessee's indemnity obligations hereunder and therein shall run to both Sublessor and Master Lessor. Master Lessor's indemnity obligations set forth in Section 4.12_of and elsewhere in the Master Lease are hereby applicable to and binding upon Sublessor. The obligations set forth in this Paragraph shall survive the expiration or sooner termination of this Sublease.

7. Default.

7.1 Default and Enforcement. The rights of Sublessor and Sublessee to enforce the provisions of this Sublease, defaults under this Sublease, and termination of this Sublease shall be governed by the applicable default and remedy provisions of the Master Lease as if Sublessor and Sublessee were landlord and tenant thereunder, respectively.

7.2 Cure Periods. The parties acknowledge that a failure to perform by Sublessee under this Sublease may place Sublessor in default of its obligations under the Master Lease. Therefore, the parties agree that the period afforded Sublessee to cure a monetary default under this Sublease shall be two (2) days less than that provided to Sublessor under the Master Lease, if any, and the period afforded Sublessee to cure a non-monetary default under this Sublease shall be five (5) days less than that provided to Sublessor under the Master Lease, if any.

7.3 Notices. Whenever Sublessor has an obligation to perform any act or to give any notice to Master Lessor under the Master Lease, and such obligation is assumed by Sublessee in this Sublease, then Sublessee shall perform such act or give such notice at least two (2) days before the due date specified in the Master Lease.

8. Assignment and Sublease. Sublessee shall not assign this Sublease or sublease all or any portion of the Subleased Premises other than in accordance with the terms and conditions set forth in Section 4.16 of the Master Lease. In the event that Sublessor and Master Lessor consent to any assignment or sublet by Sublessee, then Sublessee shall reimburse (i) Master Lessor as provided in the Master Lease and (ii) Sublessor for its reasonable attorneys' fees incurred in the review of the applicable documentation, regardless of whether such consent is ultimately granted. No permitted assignment or sublease shall release Sublessee from liability under this Sublease. The consent of Sublessor to any one assignment or sublease shall not be deemed to be Sublessor's consent to any other or further assignment or sublease.

9. Alterations. Notwithstanding any provisions of the Master Lease to the contrary, Sublessee shall not make any alterations, additions, improvements or other changes in or to the Subleased Premises except as provided in the Master Lease, including, without limitation, the provisions of Section 4.4 thereof. Any Alterations (as defined by the Master Lease) done by or on behalf of Sublessee to the Subleased Premises shall be effected in conformance with all applicable laws, rules, ordinances and regulations and shall be subject to all of the terms and conditions of this Sublease and the Master Lease. Without limiting any of the terms hereof or of the Master Lease or the Sublease and except as hereafter provided, Sublessor shall not be required to approve or consent to any Alterations unless Master Lessor agrees in writing that Sublessor shall have no obligation to remove such Alterations at the expiration of earlier termination of the Sublease Term.

10. **Access by Sublessor.** Sublessor may enter the Subleased Premises at reasonable times to examine the Subleased Premises or to make any repairs or replacements Sublessor may deem necessary. Sublessor's entry into the Subleased Premises shall be upon reasonable prior notice to Sublessee (except in cases of emergency where no notice is required), in each case in accordance with Sublessee's reasonable policies and procedures, including confidentiality terms if applicable. In addition, in the event that Master Lessor requires Sublessor to remove any alterations or equipment from the Subleased Premises which is not the responsibility of Sublessee to remove pursuant to the terms of this Sublease, then Sublessor shall have access to the Subleased Premises prior to the Termination Date as may be reasonably necessary for Sublessor to complete such removal. Sublessor shall use reasonable efforts to minimize any disruption to Sublessee's business operations in connection with such access. Notwithstanding anything to the contrary in this Sublease, upon the expiration of the Sublease Term, Sublessee shall not be obligated to remove any alterations, installations, additions, or improvements in or about the Subleased Premises made prior to the Sublease Commencement Date.

11. **Signage. Subject to** the reasonable approval of Sublessor and Master Lessor which shall not be unreasonably withheld, and compliance with any applicable provisions of the Master Lease, Sublessee shall have the right to Sublessor's existing signage space available at the Subleased Premises. On or before the Sublease Commencement Date, Sublessor shall remove Sublessor's existing signage, if any, at the Subleased Premises in accordance with the terms of the Master Lease.

12. **Hazardous Materials.** Notwithstanding anything contained in the Master Lease to the contrary, Sublessee shall not use, store or dispose of any Hazardous Materials in connection with its use and occupancy of the Subleased Premises except with the prior written consent of the Sublessor and the Master Lessor, which may be withheld in their sole discretion. Sublessor represents to Sublessee that as of the date of this Sublease, to the best knowledge of Sublessor, there are no Hazardous Materials in the Subleased Premises.

13. **Holdover in Subleased Premises.** If Sublessee fails to surrender the Subleased Premises in the condition required in this Sublease on the Termination Date (or earlier pursuant to the terms of this Sublease), Sublessee shall pay rent for the Subleased Premises at a monthly rate equal to one hundred fifty (150%) percent of the rate of Fixed Rent hereunder, the cost of electricity and all other utilities supplied to the Subleased Premises, and all other charges provided hereunder. During such holdover period, Sublessee shall be subject to every other applicable term, covenant and agreement contained herein. Nothing contained in this Paragraph 13 shall be construed as consent by Sublessor or Master Lessor to any holding over by Sublessee, and Sublessor expressly reserves the right to require Sublessee to surrender possession of the Subleased Premises to Sublessor as provided in this Sublease. If Sublessee fails to timely surrender the Subleased Premises to Sublessor, in addition to any other liabilities to Sublessor accruing therefrom, Sublessee shall protect, defend, indemnify and hold Sublessor harmless from all loss, costs (including reasonable attorneys' fees) and liability resulting from Sublessee's holding over, including, without limitation, any claims made by Master Lessor and any succeeding subtenant or licensee. Nothing set forth in this Paragraph 13 shall negate Sublessee's obligation to vacate the Subleased Premises on the Termination Date (or earlier pursuant to the terms of this Sublease), and Sublessee's failure to do so shall entitle Sublessor to exercise all of the rights and remedies set forth in the Master Lease and this Sublease.

14. **Miscellaneous.**

14.1 Waiver. Waiver of one breach of a term, condition, or covenant of this Sublease by either party hereto shall be limited to the particular instance and shall not be deemed to waive future breaches of the same or other terms, conditions, or covenants.

14.2 Joint and Several. If Sublessee consists of more than one person or entity, the obligations of such parties under this Sublease shall be joint and several.

14.3 Entire Agreement; Amendments. This Sublease, including the exhibits and addenda, if any, embodies the entire agreement between the parties with relation to the transaction contemplated hereby, and this Sublease supersedes and cancels any and all previous negotiations, arrangements, brochures, agreements, letters of intent, and understandings, if any, between Sublessor and Sublessee, or displayed by Sublessor's brokers or agents or Sublessor with respect to the subject matter of this Sublease or the Subleased Premises. There are no representations between Sublessor and Sublessee other than those contained in this Sublease. Any amendment or modification of this Sublease must be in writing and signed by Sublessor and Sublessee (and with the consent of Master Lessor).

14.4 Survival of Indemnities and Covenants. Any and all indemnities of each of Sublessor and Sublessee and any and all covenants of each of Sublessor and Sublessee not fully performed on the date of the expiration or termination of this Sublease shall survive such expiration or termination.

14.5 Sublessor's Default. It is the express understanding and agreement of the parties and it is a condition of Sublessor's agreement to execute this Sublease that, Sublessor shall not be in default under this Sublease unless Sublessor fails to perform obligations required of Sublessor within thirty (30) days after written notice by Sublessee to Sublessor, specifying wherein Sublessor has failed to perform such obligation; provided, however, that if the nature of Sublessor's obligation is such that more than thirty (30) days are required for its cure, then Sublessor shall not be in default if Sublessor commences performance within such thirty (30) day period and thereafter diligently pursues the same to completion. Except to the extent Sublessor has any such right under the Master Lease, in no event shall Sublessee have the right to terminate this Sublease or to any abatement of or offset from the rent or other charges payable by Sublessee under this Sublease as a result of Sublessor's default, and Sublessee's remedies shall be limited to an independent action for damages, specific performance and/or an injunction. Sublessee hereby waives its right to recover consequential damages (including, but not limited to, lost profits) or punitive damages arising out of a Sublessor default. Sublessor hereby waives its right to recover consequential damages (including, but not limited to, lost profits) or punitive damages arising out of a Sublessee default except in the event of Sublessee's wrongful refusal to relinquish possession of the Subleased Premises for a period of more than fifteen (15) days. This Sublease and the obligations of each of Sublessor and Sublessee hereunder shall not be affected or impaired because such party is unable to fulfill any of its obligations hereunder or is delayed in doing so, if such inability or delay is caused by reason of force majeure, and the time for Sublessor's and Sublessee's performance, as applicable, shall be extended for the period of any such delay.

14.6 Litigation Costs. If any legal action is filed to enforce this Sublease, or any part thereof, the prevailing party shall be entitled to recover reasonable attorneys' fees and costs of the action.

14.7 Notices. All notices, demands and requests given pursuant to this Sublease and other communications related to this Sublease shall be given in accordance with the terms of the Master Lease to the following addresses:

To Sublessor:	Duck Creek Technologies. 100 Summer Street Boston, MA 02110 ATTN: Teresa M. Kim, CFO
With a copy to:	Burns & Levinson LLP 125 High Street Boston, MA 02110 Attn: Michael D. MacClary, Esq.
To Sublessee:	Astria Therapeutics, Inc. 75 State Street, Suite 1400 Boston, MA 02109 ATTN: Legal With a copy via email to Legal@Astriatx.com
With a copy to:	Langer & McLaughlin, LLP 535 Boylston Street, 3rf Floor Boston, MA 02116 Attn: Astria Leasing Matters

Each party shall promptly deliver to the other party copies of all notices, requests, or demands which relate to the Subleased Premises or the use or occupancy thereof after receipt of same from the Master Lessor.

14.8 Successors and Assigns. This Sublease shall inure to the benefit of, and be binding upon, the parties hereto and their respective successors and permitted assigns.

14.9 Multiple Counterparts. This Sublease may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same instrument.

14.10 Surrender of Subleased Premises. Upon the Termination Date or upon earlier expiration of the Sublease as provided herein, Sublessee shall surrender the Subleased Premises in the condition required by the Master Lease. Prior to the expiration of the Sublease Term or the earlier expiration of the Sublease, Sublessee shall, at its sole cost and expense, (a) remove Sublessee's trade fixtures, furniture, equipment, improvements, alterations as required by Paragraph 9 of this Sublease, signage, cabling, wiring, fixtures and other personal property from the Subleased Premises, (b) repair any damage resulting from such removal. Any of Sublessee's equipment or personal property which shall remain in the Subleased Premises for more than ten (10) days after the expiration or termination of the term of this Sublease or earlier expiration of the Sublease shall be deemed conclusively to have been abandoned, and either may be retained by Sublessor as its property or may be disposed of in such manner as Sublessor may see fit, at Sublessee's sole cost and expense.

14.11 Conditions. This Sublease shall not be effective unless and until it has been signed by Sublessee and Sublessor, and Master Lessor's form of consent to this Sublease has been executed and delivered by Master Lessor ("Consent"). Following execution by Master Lessor, the Consent shall be attached hereto as **Exhibit B.** If Master Lessor does not consent to this Sublease, this Sublease will not become effective, and neither party shall have any obligation or liability to the other. Notwithstanding anything to the contrary in this Sublease, if the Consent is not obtained

within fifteen (15) Business Days after the mutual execution and delivery of this Sublease, then Sublessee shall have the right to terminate this Sublease effective upon written notice to Sublessor at any time prior to Sublessee's receipt of the Consent.

14.12 Sublessor's Exercise of Rights During Damage or Destruction. Sublessee acknowledges and agrees that if the Master Lease gives Sublessor any right to terminate the Master Lease, including, without limitation, in the event of the partial or total damage, destruction, or condemnation of the Subleased Premises or the Building or property of which the Subleased Premises are a part, then the exercise of such right by Sublessor shall not constitute a default or breach hereunder. In addition, in the event any taking by eminent domain or damage by fire or other casualty affects the Subleased Premises, Sublessee shall be entitled to exercise, if applicable, any termination rights afforded the Sublessor under the Master Lease, subject to the provisions set forth therein. Sublessor shall have no obligation to repair or restore the Building, all or any portion of the Premises under the Master Lease, including without limitation, the Subleased Premises or to compensate Sublessee in the event of a fire or other casualty or a taking by way of eminent domain which affects the Building or the Subleased Premises. To the extent Sublessor's rent is abated under the Master Lease for the Premises pursuant to provisions thereof, Sublessee's Fixed Rent (and any Additional Rent, to the extent abated for Sublessor) hereunder shall also be abated for the same period. Notwithstanding anything to contrary herein, in the event Master Lessor rebuilds the Subleased Premises following a casualty, Sublessee shall not be required to repair or restore any alterations, installations, additions, or improvements in or about the Subleased Premises made prior to the Sublease Commencement Date.

14.13 Capitalized Terms. All terms used herein with initial capital letters that are not specifically defined herein shall have the same meanings attributed to those terms in the Master Lease as the case may be, provided that the same are not in conflict with the terms and provisions of this Sublease.

14.14 No Recording. Neither party shall record this Sublease or any notice of this Sublease.

15. **Security Deposit.** On the Execution Date, Sublessee shall deposit with Sublessor the Security Deposit in the amount specified in Section 1.5 in United States dollars, as security for the full and faithful performance of every provision of this Sublease to be performed by Sublessee. If Sublessee Defaults with respect to any provision of this Sublease, including but not limited to the provisions relating to the payment of Fixed Rent or Additional Rent, Sublessor may use, apply or retain all or any part of the Security Deposit for the payment of Fixed Rent or Additional Rent or any other amount which Sublessor may spend or become obligated to spend by reason of Sublessee's Default, to repair damages to any part of the Premises, to clean the Premises or to compensate Sublessor for any other loss or damage which Sublessor may suffer by reason of Sublessee's Default. Sublessor shall not be required to keep the Security Deposit separate from its general funds, and Sublessee shall not be entitled to interest on the Security Deposit. If Sublessee shall fully and faithfully perform every provision of this Sublease to be performed by it, the Security Deposit or any balance thereof shall be returned to Sublessee within thirty (30) days following the Termination Date or such earlier termination of this Sublease.

16 **Brokers.** Sublessor and Sublessee represent and warrant that Perry CRE, Inc. and JLL ("Brokers") are the only brokers involved in the procurement, negotiation, and execution of this Sublease. Brokers' commission shall be paid by Sublessor pursuant to a separate commission agreement. Neither party dealt with any other broker or finder (other than Brokers) in connection with the consummation of this Sublease and each party agrees to indemnify, hold and save the other party

harmless from and against any and all claims for brokerage commissions or finder's fees arising out of either of their acts in connection with this Sublease.

17. **Quiet Enjoyment.** Provided Sublessee is not in default beyond applicable notice and cure periods hereunder, Sublessee shall have the quiet enjoyment of the Subleased Premises during the Sublease Term without interference by Sublessor or anyone claiming by, through or under Sublessor, subject however to all terms and conditions of this Sublease and the Master Lease as incorporated herein.

18. **Prohibited Persons.** Each of Sublessor and Sublessee hereby represents and warrants to the other that it is not: (a) in violation of any Anti-Terrorism Law; (b) conducting any business or engaging in any transaction or dealing with any Prohibited Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Prohibited Person; (c) dealing in, or otherwise engaging in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224; (d) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate any of the prohibitions set forth in any Anti-Terrorism Law; or (e) a Prohibited Person, nor are any of its partners, members, managers, officers or directors a Prohibited Person. As used herein, "Anti-Terrorism Law" is defined as any law relating to terrorism, anti-terrorism, money laundering or anti-money laundering activities, including, without limitation, Executive Order No. 13224 and Title 3 of the USA Patriot Act. As used herein, "Executive Order No. 13224" is defined as Executive Order No. 13224 on Terrorist Financing effective September 24, 2001, and relating to "Blocking Property and Prohibiting Transactions With Persons Who Commit, or Support Terrorism". As used herein, "Prohibited Person" is defined as (i) a person or entity that is listed in the Annex to Executive Order 13224; (ii) a person or entity with whom Sublessee or Sublessor, as applicable, is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law; or (iii) a person or entity that is named as a "specially designated national and blocked person" on the most current list published by the U.S. Treasury Department Office of Foreign Assets Control at its official website, http://www.treas.gov/ofac/t11sdn.pdf or at any replacement website or other official publication of such list. As used herein, "USA Patriot Act" is defined as the "Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001" (Public Law 107-56), as may have been or may hereafter be amended.

19. **Furniture.** In consideration of the payment of Fixed Rent by Sublessee to Sublessor, and without any additional consideration, Sublessor hereby grants to Sublessee the right to use or dispose of the furniture currently in the Subleased Premises and more particularly described on Exhibit C attached hereto (the "Furniture"). Sublessor shall remove the items laid out in the LOI prior to the Sublease Commencement Date. Sublessee acknowledges and agrees that the Furniture is provided in "as-is" condition without any warranty, implied or express, of any kind whatsoever. Sublessor shall deliver a bill of sale for good and valuable consideration of less than One Hundred Dollars ($100.00) on the Termination Date conveying title to the Furniture to Sublessee. Sublessee shall be responsible for removing from the Subleased Premises so much of the Furniture as may be required to be so removed pursuant to the Master Lease.

EXECUTED as of the Effective Date.

SUBLESSOR:

Duck Creek Technologies, LLC

DocuSigned by:
By: /s/ Chris Stone
Name: Chris Stone
Title: Chief Legal Officer
Duly Authorized

SUBLESSEE:

Astria Therapeutics, Inc.,

DocuSigned by:
By: /s/ Jill Milne
Name: Jill Milne
Title: CEO
Duly Authorized

EXHIBIT A

MASTER LEASE

[SEE ATTACHED]

GROSS LEASE
(w/Base Amounts)

THIS LEASE (this "Lease") is made as of August 7th, 2017 (the "Effective Date"), by and between

"Landlord" MEPT Seaport 13 Stillings LLC, a Delaware limited liability company

and

"Tenant" Duck Creek Technologies LLC, a Delaware limited liability company.

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LISTING OF EXHIBITS

SECTION **1: DEFINITIONS**

Access Laws: The Americans With Disabilities Act of 1990 (including the Americans with Disabilities Act Accessibility Guidelines for Building and Facilities) and all other Governmental Requirements relating to the foregoing.

Additional Rent: Defined in paragraph captioned "Additional Rent".

Affiliate: An entity controlling, controlled by, or under common control with Tenant (control being defined as ownership of more than fifty percent (50%) of the beneficial ownership and voting control of the entity in question).

Base Amount Allocable to the Premises: Defined in paragraph captioned "Additional Rent".

Base Rent: The monthly amount of Base Rent and the portion of the Lease Term during which such monthly amount of Base Rent is payable shall be determined from the following table. For convenience and ease of reference, the annual rental rate for the computation of Base Rent and the annual Base Rent are also set forth in tabular form with the annual Base Rent equaling the monthly Base Rent installment multiplied by twelve. In the case of any conflict or inconsistency between the monthly Base Rent installment and the other illustrative figures set forth in tabular form or in any computations utilizing such figures, the monthly Base Rent installment so specified shall be controlling and conclusive.

Applicable Portion of Lease Term	Rate Per/Rentable Sq. Ft./ Annum	Annual Base Rent	Monthly Base Rent Installment (Annual ÷ 12)
Commencement Date through the date immediately preceding the Rent Commencement Date	[redacted]	[redacted]	[redacted]
Months 1 through 12	[redacted]	[redacted]	[redacted]
Months 13 through 24	[redacted]	[redacted]	[redacted]
Months 25 through 36	[redacted]	[redacted]	[redacted]
Months 37 through 48	[redacted]	[redacted]	[redacted]
Months 49 through 60	[redacted]	[redacted]	[redacted]
Months 61 through 72	[redacted]	[redacted]	[redacted]
Months 73 through 84	[redacted]	[redacted]	[redacted]
Months 85 through 96	[redacted]	[redacted]	[redacted]
Months 97 through 108	[redacted]	[redacted]	[redacted]
Months 109 through 120	[redacted]	[redacted]	[redacted]

Notwithstanding the foregoing, Landlord shall abate all Base Rent applicable to the Premises for the period beginning on the Commencement Date and ending on the date immediately preceding the Rent Commencement Date (the "Abatement Period"). Although Landlord shall abate Base Rent payable for the Abatement Period, Tenant acknowledges and agrees that Tenant shall be liable for all Additional Rent payable during such period. For purposes of the above rent schedule, Month 1 begins on the first day of the first full month of the Lease Term beginning on or after the Rent Commencement Date. If the Rent Commencement Date is a date other than the first day of a calendar month, Base Rent for the period from the Rent Commencement Date through the end of the calendar month in which the Rent Commencement Date occurs shall be at the same rate as months 1 through 12, but shall be prorated as provided in Paragraph 3.2 hereof.

Brokers: Tenant and Landlord were both represented in this transaction by CB Richard Ellis — N.E. Partners, LP, a licensed real estate broker.

Building: The building located on the Land at 22 Boston Wharf Road, Boston, Massachusetts, containing approximately 123,977 rentable square feet.

Business Day: Calendar days, except for Saturdays and Sundays and holidays when banks are closed in Boston, Massachusetts.

Claims: An individual and collective reference to any and all claims, demands, damages, injuries, losses, liens, liabilities, penalties, fines, lawsuits, actions, other proceedings and expenses (including attorneys' fees and expenses incurred in connection with the proceeding whether at trial or on appeal).

Commencement Date: The date of Substantial Completion of Landlord's Base Building Work and Landlord's receipt of a certificate of occupancy for the Building, provided, however, if Landlord is unable to obtain such certificate of occupancy for the Building prior to the substantial completion of the Tenant Improvements then the Commencement Date shall be deemed to have occurred on the date of Substantial Completion of Landlord's Base Building Work.

Deck Allowance: The maximum amount, if any, to be contributed by Landlord to reimburse Tenant for Deck Costs (as defined in Paragraph 2.1.3(a) hereof), which maximum shall not exceed [redacted] per rentable square foot of the Premises).

ERISA: The Employee Retirement Income Security Act of 1974, as now or hereafter amended, and the regulations promulgated under it.

Estimated Operating Costs Allocable to the Premises: Defined in paragraph captioned "Additional Rent".

Events of Default: One **or** more of those events or states of facts defined in the paragraph captioned "Events of Default".

Fair Market Rent: The prevailing base rent and additional rent (including provisions for escalations, subsequent increases, market concessions and incentives such as tenant improvements and free rent periods, and other adjustments) for new leases or lease renewals (as applicable) of a comparable term then currently being negotiated or executed for comparable space located in the Building and for new leases or lease renewals (as applicable) then being negotiated or executed for comparable space located elsewhere in similar first class office buildings located **in** the Seaport District of Boston, Massachusetts (the "Comparable Properties"), in either case considering the relative age, condition and location of the Building and the Comparable Properties, the relative condition of the Building's and Comparable Properties' systems, the relative condition of the Premises and such comparable space, concessions being offered in the Building and in Comparable Properties, amenities available in the Building and in Comparable Properties, and other relevant factors.

Governmental Agency: The United States of America, the state in which the Land is located, any county, city, district, municipality or other governmental subdivision, court or agency or quasi-governmental agency having jurisdiction over the Land and any board, agency or authority associated with any such governmental entity, including the fire department having jurisdiction over the Land.

Governmental Requirements: Any and all statutes, ordinances, codes, laws, rules, regulations, orders and directives of any Governmental Agency as now or later amended.

Green Agency Ratings: Any one or more of the following ratings, as same may be in effect or amended or supplemented from time to time: The U.S. EPA's Energy Star® rating and/or Design to Earn Energy Star, the Green Building Initiative's Green Globes ™ for Continual Improvement of Existing Buildings (Green Globes™-CIEB), the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system, LEED EBOM (existing buildings operations and maintenance) and any applicable substitute third party or governmental mandated rating systems.

Hazardous Substance(s): Asbestos, PCBs, petroleum or petroleum-based chemicals or substances, urea formaldehyde or any chemical, material, element, compound, solution, mixture, sub-stance or other matter of any kind whatsoever which is now or later defined, classified, listed, designated or regulated as hazardous, toxic or radioactive by any Governmental Agency.

Land: The land upon which the Building is located in Boston, Suffolk County, Commonwealth of Massachusetts.

Landlord: The limited liability company named on the first page of this Lease, or its successors and assigns as provided in paragraph captioned "Assignment by Landlord".

Landlord's Agents: The managers, officers and employees of Landlord and the consultants and advisors to the Landlord and employees of the foregoing.

Landlord's Base Building Work: The base building work described on Exhibit H attached hereto. A rendering of the Building lobby that is included in the Landlord's Base Building Work is attached as Exhibit K, provided that the parties hereto acknowledge and agree that Exhibit K is merely a rendering and that Landlord's plans and specification for the Building lobby that are included in the Landlord's Base Building Work shall control.

Lease Memorandum: Defined in paragraph entitled "Lease Memorandum".

Lease Security Deposit: The letter of credit delivered by Tenant to Landlord as described in the paragraph entitled "Security Provisions."

Lease Term: Commencing on the Commencement Date and ending on the last day of that calendar month which is one hundred twenty (120) months after the Rent Commencement Date, provided that, if the Rent Commencement Date is the first day of a calendar month, the Lease Term shall end on the date immediately preceding the date which is ten (10) years after the Rent Commencement Date.

Lender: Defined in paragraph entitled "Landlord's Default".

Manager: CB Richard Ellis - N.E. Partners, LP, or its replacement as specified by written notice from Landlord to Tenant.

Manager's Address: 101 Seaport Blvd., Boston, Massachusetts 02210, which address may be changed by written notice from Landlord to Tenant.

Operating Costs: Defined in paragraph captioned "Additional Rent".

Operating Costs Allocable to the Premises: Defined in paragraph captioned "Additional Rent".

Original Tenant: Duck Creek Technologies LLC, a Delaware limited liability company.

Permitted Transferee: An Affiliate to which Tenant has either assigned its interest in this Lease or sublet all or any portion of the Premises subject to and in accordance with the terms and provisions of Paragraph 4.16.8 hereof.

Permitted Use: General business office uses, so long as such use is consistent with Governmental Requirements and with first-class buildings of the same or similar use as the Building located in the metropolitan area in which the Building is located.

Plans and Specifications: (a) Those certain plans and specifications for the Tenant Improvements, if any, as listed in Exhibit C and any modifications to them approved in writing by Landlord and Tenant; or (b) if Exhibit C does not include a listing of such plans and specifications, then such plans and specifications shall be prepared by Tenant (the "Preparing Party") and delivered to Landlord (the "Receiving Party") and approved by Landlord and Tenant as set forth in the paragraph entitled "Plans and Specifications".

Prepaid Rent: [redacted], to be applied toward Base Rent for the first full calendar month of the Lease Term or to the first month in which full rent is due.

Premises: The portion of the Building comprising the entire 10th floor of the Building, depicted on the plan attached as Exhibit B and agreed by Landlord and Tenant for all purposes under this Lease to consist of approximately thirty thousand one hundred ten (30,110) rentable square feet. The number of rentable square feet of the Premises recited above shall be final, conclusive and controlling for all purposes of this Lease.

Prime Rate: Defined in paragraph captioned "Default Rate".

Property Taxes: (a) Any form of ad valorem real or personal property tax or assessment imposed by any Governmental Agency on the Land, Building, related improvements or any personal property owned by Landlord associated with such Land, Building or improvements; (b) any other form of tax or assessment, license fee, license tax, tax or excise on rent or any other levy, charge, expense or imposition made or required by any Governmental Agency on any interest of Landlord in such Land, Building, related improvements or personal property; (c) any fee for services charged by any Governmental Agency for any services such as fire protection, street, sidewalk and road maintenance, refuse collection, school systems or other services provided or formerly provided to property owners and residents within the general area of the Land; (d) any governmental impositions allocable to or measured by the area of any or all of such Land, Building, related improvements or personal property or the amount of any base rent, additional rent or other sums payable under any lease for any or all of such Land, Building, related improvements or personal property; (e) any gross receipts or other excise tax allocable to, measured by or a function of any one or more of the matters referred to in clause (d); (f) any impositions by any Governmental Agency on any transaction evidenced by a lease of any or all of

such Land, Building, related improvements or personal property or charge with respect to any document to which Landlord is a party creating or transferring an interest or an estate in any or all of such Land, Building, related improvements or personal property; (g) any increase in any of the foregoing based upon construction of improvements or change of ownership of any or all of such Land, Building, related improvements or personal property, and (h) tax consultant fees and expenses and costs of appeals of any Property Taxes. Property Taxes shall not include taxes on Landlord's net income nor any inheritance, estate, succession, transfer, gift, franchise or capital stock tax.

Punch List Work: Minor items of repair, correction, adjustment or completion as such phrase is commonly understood in the construction industry in the metropolitan area in which the Land is located.

Rent Commencement Date: The date which is six (6) months after the Commencement Date, provided, however, if Tenant is unable to obtain a temporary or permanent certificate of occupancy for the Premises upon the substantial completion of the Tenant Improvements solely as a result of an issue with the Landlord's Base Building Work, then the Rent Commencement Date shall be the later of (a) the date which is six (6) months after the Commencement Date, and (b) the date such issue with the Landlord's Base Building Work has been corrected.

Rooftop Access Allowance: The maximum amount, if any, to be contributed by Landlord to reimburse Tenant for Rooftop Deck Access Costs (as defined in paragraph 2.1.3(b) hereof), which maximum shall not exceed [redacted]).

Rooftop Deck Area: The area on the roof of the Building shown on Exhibit G attached hereto.

Restrictions: Any covenants, conditions and restrictions applicable to the Land [which are recorded with the Suffolk County Registry of Deeds.

Rent Payment Address: 22 Boston Wharf Road, BLDG ID: 3521, PO Box 209265, Austin, TX 78720-926.

Space Plan Allowance: The maximum amount, if any, to be contributed by Landlord to reimburse Tenant for the preparation of Tenant's Space Plan for the Premises, which maximum shall not exceed [redacted]) (which amount is calculated based upon [redacted] per rentable square foot of the Premises).

Substantial Completion: The date that the Landlord's Base Building Work has been completed substantially in accordance with Exhibit H, subject to Punch List Work. While a certificate of occupancy is not required for substantial completion of the Landlord's Base Building Work to have occurred, the issuance of a temporary or permanent certificate of occupancy for the Building by the proper governmental authority shall *be* conclusive evidence that substantial completion has occurred of the Landlord's Base Building Work. Notwithstanding the above, the Landlord's Base Building Work shall be considered substantially complete even though (a) there remains to be completed Punch List Work, the lack of which will not materially interfere with Tenant's construction of the Tenant Improvements including, without limitation, minor or insubstantial details of construction, decoration or mechanical adjustment, or (b) there is a delay in substantial completion due to Tenant's failure to meet its obligations under this Lease or "Tenant Delay" as such term is defined in this Lease. Without limiting the foregoing, if the Landlord or its general contractor is delayed in substantially completing the Landlord's Base Building Work as a result of the occurrence of Tenant Delay, then for purposes of determining the Commencement Date, the date of substantial completion shall be deemed to be the date that the Landlord's Base Building Work would have been substantially completed absent any Tenant Delay. In addition, notwithstanding the definition of the Commencement Date, if the Landlord is delayed in obtaining a certificate of occupancy for the Building as a result of the occurrence of Tenant Delay, then the Commencement Date shall be deemed to be the date that the Landlord's Base Building Work has been, or would have been, completed absent any Tenant Delay.

Telecommunication Facilities: Equipment, facilities, apparatus and other materials utilized for the purpose of electronic telecommunication, including cable, switches, wires, conduit and sleeves.

Telecommunication Services: Services associated with electronic telecommunications, whether in a wired or wireless mode. Basic voice telephone services are included within this definition.

Tenant: The person or entity(ies) named on the first page of this Lease.

Tenant Alterations: Defined in paragraph captioned "Tenant Alterations".

Tenant Delay: Any delay in the completion of construction of Landlord's Base Building Work resulting from (i) Tenant's failure to comply with the provisions of this Lease, including without limitation, Tenant's failure to meet any time deadlines established herein, (ii) any delay in the Substantial Completion of Landlord's Base Building Work caused by Tenant's early entry into the Premises and work on the Tenant Improvements pursuant to Paragraph 2.4.2 hereof prior to the Substantial Completion of Landlord's Base Building Work, (iii) any other delay arising from the act or omission of Tenant or Tenant's Agents, and/or (iv) the occurrence of any other act, omission, failure, or event which this Lease describes as "Tenant Delay.

Tenant Improvement Allowance: The maximum amount, if any, to be contributed by Landlord to reimburse Tenant for Tenant Improvement Costs (as defined in paragraph 2.5.1 hereof), which maximum shall not exceed [redacted] (calculated based upon [redacted] per rentable square foot of the Premises).

Tenant Improvements: Those alterations or improvements to the Premises as appear and are depicted in the Plans and Specifications.

Tenant's Agents: Any and all officers, partners, contractors, subcontractors, consultants, licensees, agents, concessionaires, subtenants, servants, employees, customers, guests, invitees or visitors of Tenant.

Tenant's Pro Rata Share: is 30,110/123,977 = twenty-four and twenty-nine one-hundredths percent (24.29%), which shall be final, conclusive and controlling during the Lease Term for all purposes of this Lease.

Year: A calendar year commencing January 1 and ending December 31 or that portion of the calendar year within the Lease Term.

SECTION 2: PREMISES AND TERM

2.1 Lease of Premises.

2.1.1 Initial Premises. Landlord leases the Premises to Tenant, and Tenant leases the Premises from Landlord, upon the terms and conditions set forth in this Lease.

2.1.2 Right of First Offer.

(a) While this Lease is in full force and effect, provided that all amounts then due and payable under this Lease have been paid in full and no Event of Default has occurred during the Lease Term and further provided that the Original Tenant is itself occupying the entire Premises then demised to Tenant, in each case both as of the date of the Acceptance Notice and the Offer Space Inclusion Date (each as defined below), in the event that any rentable space in the Building which is contiguous to the Premises then leased by Tenant hereunder ("Potential Expansion Space") shall become available (or is anticipated to become available) for lease as a result of the expiration or termination of any lease now existing or hereafter entered into, Landlord shall first offer such Potential Expansion Space to Tenant at the Landlord's then current asking rates for the Building, including any market concessions then being offered by Landlord, by written notice (a "ROFO Notice") on an "AS IS" basis as of the date of the Offer Space Inclusion Date for the balance of the Lease Term, subject to any renewal rights of then current tenants. The date on which Landlord delivers possession of any Potential Expansion Space to Tenant in connection with Tenant's exercise of the right of first offer is referred to herein as the "Offer Space Inclusion Date". If any Potential Expansion Space is available as of the date hereof, Landlord shall have no obligation to offer such space-to Tenant pursuant to the right of first offer until after the expiration or termination of any lease of such space hereafter entered into by Landlord (including any extensions thereof). Notwithstanding the foregoing or anything herein to the contrary, any exercise by Tenant of the right of first offer shall be conditioned upon Landlord's approval of Tenant's financial condition based upon Landlord's standard underwriting criteria and a review of Tenant's then current financial statements.

(b) The leasing of Potential Expansion Space pursuant to the right of first offer shall be on the same terms, covenants and conditions as provided for herein with respect to the Premises except (i) Base Rent and escalations for Operating Costs and Property Taxes shall be at the Landlord's then asking rates for the Building as set forth in Paragraph 2.1.2(a) above, and (ii) Landlord shall have no obligation to prepare, refurbish or construct the Potential Expansion Space or any part thereof or otherwise provide any amount of improvement allowance in respect of the Potential Expansion Space, except for the improvement allowance (if any) set forth in the applicable ROFO Notice. The ROFO Notice shall include

the anticipated availability date (the "Anticipated Availability Date") for the Potential Expansion Space. Tenant shall have fifteen (15) Business Days from the ROFO Notice within which to accept Landlord's offer in writing to lease all (but not less than all) of the offered Potential Expansion Space. If Tenant has not accepted Landlord's offer set forth in any ROFO Notice in writing (an "Acceptance Notice") within said fifteen (15) Business Day time period and/or has not executed an amendment to this Lease satisfactory to Landlord in its reasonable discretion (a "ROFO Amendment") within ten (10) days after Landlord's delivery of same to Tenant (in each case time being of the essence), then such right of first offer shall expire as to such Potential Expansion Space and be of no further force or effect, and the Landlord shall be free to lease all or any portion of the applicable Potential Expansion Space to any third party at any time thereafter on the same terms and conditions as offered to Tenant or on such other terms and conditions as Landlord shall determine.

(c) Notwithstanding the foregoing or anything herein to the contrary, if less than three {3) years were to remain on the Lease Term as of the Anticipated Availability Date for any Potential Expansion Space offered to Tenant, Tenant may not exercise such right of first offer unless the Extension Option (as defined in subparagraph 2.2.2 hereof) is still available to Tenant and Tenant exercises such Extension Option (provided that, at Landlord's option, the Fair Market Rent for the Extension Period for both the then existing Premises and the Potential Expansion shall not be determined prior to the date which is twelve (12) months prior to the then expiration date of the Lease Term).

(d) If Tenant timely accepts Landlord's ROFO Notice to lease any Potential Expansion Space and Landlord is unable to deliver possession of the Potential Expansion Space to Tenant for any reason beyond Landlord's reasonable control on or before the Anticipated Availability Date as set forth in the ROFO Notice, the applicable Potential Expansion Space shall become part of the Premises leased hereunder on the date on which Landlord is able to so deliver possession and Landlord shall have no liability to Tenant therefor and this Lease shall not in any way be impaired. In such case, the date on which Landlord is able to so deliver possession shall be the Offer Space Inclusion Date.

(e) If the Tenant does not accept, or is deemed not to have accepted, Landlord's offer set forth in any ROFO Notice for certain Potential Expansion Space, Landlord shall not offer to lease the Potential Expansion Space set forth in the applicable ROFO Notice to a third party for an annual rental rate that is less than ninety percent (90%) of the annual rental rate offered to Tenant for such Potential Expansion Space. If Landlord desires to offer to lease such Potential Expansion Space at an annual rental rate of less than ninety percent (90%) of the annual rental rate offered to Tenant in the ROFO Notice, Landlord must provide Tenant with a second ROFO Notice with such revised rental rate and the process set forth above in this subparagraph 2.1.2 shall repeat.

2.1.3 Rooftop Deck.

(a) Subject to Tenant obtaining any and all necessary governmental permits, approvals and licenses and the terms and conditions set forth herein, (i) Tenant shall have, as appurtenant to the Premises, the right at Tenant's sole cost and expense to construct an open air deck on the roof of the Building in the Rooftop Deck Area (the "Rooftop Deck") and access thereto, and (ii) upon the completion of any such Rooftop Deck, Tenant shall have the exclusive right to use the Rooftop Deck during the Lease Term. All costs and expenses, including all hard and soft costs such as and without limitation, all labor and materials, architectural, engineering, project management, and permitting fees incurred by Tenant for the Rooftop Deck (excluding Rooftop Deck Access Costs, as defined in paragraph 2.1.3(b) below) are hereinafter collectively referred to as the "Deck Costs"). Landlord shall cooperate with Tenant's efforts to obtain any necessary governmental approvals for the construction and use of the Rooftop Deck, provided that Landlord shall not he required to incur any out-of-pocket expense in connection therewith.

(b) Prior to the date of this Lease, Landlord and Landlord's architect have established and framed a location for the potential addition of an elevator or lift for access to the Rooftop Deck. The cost of any such elevator or lift and improvements necessary to access the Rooftop Deck shall be paid by Tenant, provided that Landlord shall grant an allowance to Tenant in an amount equal to the Rooftop Access Allowance (as defined in Section 1.1 hereof) to be used solely to reimburse the Tenant for the costs associated with such access (collectively, the "Rooftop Deck Access Costs"), including any necessary additional elevator lift, framed structural steel, demolition of concrete and access hallways and doors (collectively, the "Access Work"). For avoidance of doubt, no portion of the Rooftop Access Allowance may be used to pay for the costs and expenses of any Tenant Improvements other than Rooftop Deck Access Costs unless Tenant elects not to construct the Rooftop Deck and so notifies

Landlord in writing, in which event the Rooftop Access Allowance will be included as part of the Tenant Improvement Allowance.

(c) Landlord shall grant an allowance to Tenant in an amount equal to the Deck Allowance (as defined in Section 1.1 hereof) to be used solely to reimburse the Tenant for the Deck Costs, provided that no more than fifteen percent (15%) of the Deck Allowance may be used for soft costs. For avoidance of doubt, no portion of the Deck Allowance may be used to pay for any furniture or equipment or to pay for the costs and expenses of any work on the Rooftop Deck not included in the Plans and Specifications, and Tenant shall be responsible, at its sole cost and expense, for all such costs and expenses.

(d) The installation of the Rooftop Deck and Access Work shall constitute Tenant Improvements and, as such, shall be subject to all terms hereof applicable thereto, except that Tenant shall not be permitted to use any of the Tenant Improvement Allowance for any costs related to the Rooftop Deck or Access Work, including, without limitation, the cost of designing, fabricating, installing, maintaining or removing the Rooftop Deck or Access Work.

(e) If Tenant elects to construct the Rooftop Deck in accordance with the terms hereof, the Plans and Specifications to be submitted by Tenant to Landlord for approval by Landlord pursuant to Paragraph 2.3 hereof shall include the Rooftop Deck and Access Work and shall be subject to all of the terms thereof.

(f) Without in any way limiting the scope or terms of Paragraph 2.1.3(a) hereof, Tenant shall be solely responsible for the design and construction of the Rooftop Deck and Access Work. Without limiting the foregoing, Tenant hereby acknowledges that (i) Tenant shall be solely responsible for compliance of the Rooftop Deck with Access Laws and any other laws governing accessibility of the Rooftop Deck by persons with disabilities, and (ii) Tenant shall be solely responsible for the cost of any modifications required to the Building in order to comply with Access Laws and any other laws governing accessibility of the Rooftop Deck by persons with disabilities. Notwithstanding Landlord's review and approval of Tenant's Plans and Specifications for the Rooftop Deck and Access Work, Landlord shall have no liability to Tenant or to any other person for errors or omissions in such Plans and Specifications or in the construction of the Rooftop Deck or Access Work (Landlord's review and approval of the such plans and specifications being for Landlord's own purposes). Tenant shall indemnify, defend, protect and hold Landlord and Landlord's Agents harmless from all Claims which arise in any way, directly or indirectly from or in connection with the design, construction and/or use of the Rooftop Deck and Access Work, including without limitation, claims arising from the work of Tenant's architect, engineer, contractor, employees or agents.

(g) Subject to the terms and conditions hereof, provided that all Tenant Allowance Conditions (as defined in Paragraph 2.5.6) hereof have been satisfied, the Rooftop Access Allowance shall be available in a single draw (the "Rooftop Access Allowance Advance") upon the completion of the Rooftop Deck and Access Work, to reimburse Tenant for Rooftop Deck Access Costs incurred and paid by Tenant in the following manner. In the event that Tenant elects not to construct the Rooftop Deck and so notifies Landlord in writing, the Rooftop Access Allowance will be included as part of the Tenant Improvement Allowance. At least twenty (20) Business Days before the date upon which the Tenant desires the Rooftop Access Allowance Advance, the Tenant shall submit an itemized requisition (an "Access Requisition") on a form acceptable to the Landlord in its reasonable discretion, stating the amount of the Rooftop Access Allowance Advance, the items(s) to be reimbursed from the proceeds thereof, and the date upon which the advance is desired. Landlord's obligation to make the Rooftop Access Allowance Advance shall be subject to Tenant's satisfaction of each and all of the following conditions: (1) to the extent required by Governmental Requirements, Tenant shall have submitted to Landlord an issued and effective certificate of occupancy or approved inspection for the Rooftop Deck and Access Work for the Permitted Rooftop Deck Use and a certification signed by Tenant's architect certifying that the Rooftop Deck and the Access Work have been completed in accordance with Plans and Specifications approved by the Landlord and attaching thereto executed final waivers or releases of liens from Tenant's general contractor and each of Tenant's subcontractors and suppliers in connection with the Rooftop Deck and Access Work in such form as Landlord may reasonably require, plus a certificate of Tenant's general contractor identifying each contractor, subcontractor and supplier who performed labor and/or supplied materials for the Rooftop Deck and Access Work, (2) Tenant shall have furnished Landlord with copies of third party invoices and evidence of payment of same, for all work and services performed and materials delivered in connection with the Rooftop Deck and Access Work, and (3) at the time of the Rooftop Access Allowance Advance is to be made there shall exist no event which is, or solely with the passage

of time and/or giving of notice would be, an Event of Default. Subject to satisfaction of all of the foregoing conditions, Landlord shall pay to Tenant, within twenty (20) Business Days after receipt by Landlord of a written request therefore from Tenant in accordance with the foregoing, the lesser of (a) the full amount of the Rooftop Access Allowance, if the aggregate sum of the paid invoices for Access Work from contractors submitted pursuant to (2) above equals or exceeds the full amount of the Rooftop Access Allowance, or (b) the aggregate sum of the paid invoices for Access Work from contractors submitted pursuant to (2) above, if said aggregate sum is less than the full amount of the Rooftop Access Allowance. Tenant shall not be entitled to any credit, trade off or cash payment for any unused portion of the Rooftop Access Allowance, and the Landlord shall have no obligation to Tenant with respect to any such unused portion of the Rooftop Access Allowance. Further, notwithstanding anything herein to the contrary, in the event that Tenant has not completed the Rooftop Deck and Access Work and satisfied all of the conditions for payment of the Rooftop Access Allowance on or before the date which is eighteen (18) months after the Commencement Date, the Rooftop Access Allowance shall be deemed forfeited and Landlord shall have no further obligation to make the Rooftop Access Allowance Advance.

(h) Subject to the terms and conditions hereof, provided that all Tenant Allowance Conditions (as defined in Paragraph 2.5.6) hereof have been satisfied, the Deck Allowance shall be available in a single draw (the "Deck Allowance Advance") upon the completion of the Rooftop Deck and Access Work, to reimburse Tenant for Deck Costs incurred and paid by Tenant in the following manner. At least twenty (20) Business Days before the date upon which the Tenant desires the Deck Allowance Advance, the Tenant shall submit an itemized requisition (a "Deck Requisition") on a form acceptable to the Landlord in its reasonable discretion, stating the amount of the Deck Allowance Advance, the items(s) to be reimbursed from the proceeds thereof, and the date upon which the advance is desired. Landlord's obligation to make the Deck Allowance Advance shall be subject to Tenant's satisfaction of each and all of the following conditions: (1) to the extent required by Governmental Requirements, Tenant shall have submitted to Landlord an issued and effective certificate of occupancy or approved inspection for the Rooftop Deck and Access Work for the Permitted Rooftop Deck Use and a certification signed by Tenant's architect certifying that the Rooftop Deck and the Access Work have been completed in accordance with Plans and Specifications approved by the Landlord and attaching thereto executed final waivers or releases of liens from Tenant's general contractor and each of Tenant's subcontractors and suppliers in connection with the Rooftop Deck and Access Work in such form as Landlord may reasonably require, plus a certificate of Tenant's general contractor identifying each contractor, subcontractor and supplier who performed labor and/or supplied materials for the Rooftop Deck and Access Work, (2) Tenant shall have furnished Landlord with copies of third party invoices and evidence of payment of same, for all work and services performed and materials delivered in connection with the Rooftop Deck and Access Work, and (3) at the time of the Deck Allowance Advance is to be made there shall exist no event which is, or solely with the passage of time and/or giving of notice would be, an Event of Default. Subject to satisfaction of all of the foregoing conditions, Landlord shall pay to Tenant, within twenty (20) Business Days after receipt by Landlord of a written request therefore from Tenant in accordance with the foregoing, the lesser of (a) the full amount of the Deck Allowance, if the aggregate sum of the paid invoices for the Rooftop Deck from contractors submitted pursuant to (2) above equals or exceeds the full amount of the Deck Allowance, or (b) the aggregate sum of the paid invoices for the Rooftop Deck from contractors submitted pursuant to (2) above, if said aggregate sum is less than the full amount of the Deck Allowance. Tenant shall not be entitled to any credit, trade off or cash payment for any unused portion of the Deck Allowance, and the Landlord shall have no obligation to Tenant with respect to any such unused portion of the Deck Allowance, except that Tenant may apply any unused portion of the Deck Allowance to the Tenant Improvement Costs. Further, notwithstanding anything herein to the contrary, in the event that Tenant has not completed the Rooftop Deck and Access Work and satisfied all of the conditions for payment of the Deck Allowance on or before the date which is eighteen (18) months after the Commencement Date, the Deck Allowance shall be deemed forfeited and Landlord shall have no further obligation to make the Rooftop Access Allowance Advance.

(i) Tenant's use of the Rooftop Deck shall be subject to compliance with all applicable Governmental Requirements (including, without limitation, all fire and safety codes and the ADA), the non-compliance with which shall be Tenant's responsibility. At all times during the Lease Term, Tenant shall maintain in full force and effect all necessary permits, approvals and licenses from the City of Boston and the Commonwealth of Massachusetts for Tenant's use and operation of the Rooftop Deck.

(j) Notwithstanding anything herein to the contrary, Tenant shall not have no right to sublet, license or otherwise permit the use of the Rooftop Deck by anyone other than Tenant's employees, invitees, subtenants and assigns (it being agreed that Tenant's subtenants and assignees shall have the right to use the Rooftop Deck only in connection with a bona fide sublease or assignment of the indoor portion of the Premises).

(k) Tenant shall have the right to use the Rooftop Deck solely for the following purposes: (i) enjoying outdoor views, (ii) lunch seating for Tenant's employees, (iii) gatherings and functions for Tenant's employees, customers and vendors, and (iv) limited storage of furniture to be used on the Rooftop Deck provided that such furniture is properly secured to prevent damage and injury to the building and persons in the event of wind or other storms and is kept in a reasonably neat and orderly condition (collectively, the "Permitted Rooftop Deck Use").

(l) The following restrictions shall apply at all times to Tenant's use of the Rooftop Deck: (i) no music or other entertainment (live or recorded, amplified or acoustic) shall be played on the Rooftop Deck at or above a volume at which such music can be heard by any Building tenant at any time, (ii) no more than the maximum number of occupants permitted by applicable governmental laws, ordinances, orders, rules, regulations and other restrictions shall be present on the Rooftop Deck, and (iii) no liquids, odors or smoke shall migrate into neighboring Buildings or into the premises of other Building tenants.

(m) No smoking shall be permitted on the Rooftop Deck or any portion of the roof of the Building by Tenant's employees, agents, contractors or invitees. Tenant shall enforce a no-smoking policy on the Rooftop Deck and the roof of the Building by any employees, agents, contractors or invitees of Tenant. Tenant further acknowledges and agrees to monitor use of the Rooftop Deck and the roof of the Building to prevent smoking from occurring, and Tenant shall post a clearly visible notice at the entrance to the Rooftop Deck that smoking is not permitted on the Rooftop Deck or otherwise on the roof of the Building.

(n) In the event that Landlord, on at least two (2) separate occasions receives a good-faith complaint from any Building tenant regarding the volume of music, conversations or other noise emanating from the Rooftop Deck or conduct or activities conducted on the Rooftop Deck being unreasonably loud (each such complaint, a "Complaint"), Landlord shall have the right to require Tenant, at Tenant's sole cost expense, to implement on the Rooftop Deck such sound mitigation measures as may be reasonably designated by Landlord or its consultant. In the event that, from and after Tenant's implementation of the foregoing sound mitigation measures or Tenant's notice of any Complaint relating to Tenant's conduct or activities on the Rooftop Deck, Landlord receives two (2) additional Complaints, Landlord shall have the right to impose additional reasonable restrictions and measures with regard to the Rooftop Deck until such time as Tenant shall have returned to compliance with the terms, conditions, rules and regulations set forth herein. Within ten (10) days after Landlord's demand therefor, Tenant shall reimburse Landlord for all costs incurred by Landlord in investigating Complaints and verifying Tenant's compliance with this paragraph, including, without limitation, the costs of any third-party consultants retained by Landlord.

(o) Tenant shall not utilize, place or store on the Rooftop Deck any heating, cooking or open flame appliances, equipment or devices. In no event shall Tenant utilize any propane heaters on the Rooftop Deck.

(p) Tenant shall be solely responsible for providing for the orderly control of its employees, agents, contractors and invitees when using the Rooftop Deck. Tenant assumes full responsibility for the security and protection of its employees, agents, contractors and invitees on the Rooftop Deck. Tenant shall be responsible for implementing security measures and access control for the Rooftop Deck.

(q) Tenant shall not place any items of furniture or equipment on the Rooftop Deck (collectively, the "Rooftop Deck Personal Property") without first receiving Landlord's written permission, which permission shall not be unreasonably withheld, conditioned or delayed. In no event shall Tenant place any items on the Rooftop Deck that are otherwise prohibited herein. Landlord shall have the right to reasonably determine the permissible location of the Rooftop Deck Personal Property on the Rooftop Deck. Tenant shall be responsible for securing the Rooftop Deck Personal Property when the same is not in use, and for the removal and storage thereof during windy conditions, inclement weather and extended periods of non-use. Tenant's use of the Rooftop Deck Personal Property shall be solely at Tenant's risk, and Landlord shall have no responsibility for damage, vandalism, or theft thereof.

(r) Whenever deemed necessary by Landlord in order to conduct maintenance, repairs, alterations or installations to the Building, upon one (1) Business Days' notice to Tenant (or immediately

in case of emergency), Tenant shall cease temporarily the use of the Rooftop Deck and shall, at Tenant's sole expense, remove the Rooftop Deck Personal Property from the Rooftop Deck and, if necessary to accommodate the nature and extent of such maintenance, repairs, alterations or installations, store the same either at the Building (in which event Tenant shall pay Landlord's then-standard rental charge for storage space) or offsite (i.e., at a site other than the Building). Landlord shall use reasonable efforts to (i) minimize interference with Tenant's use and enjoyment of the Rooftop Deck during any such maintenance, repairs, alterations or installations to the Building, and (ii) diligently complete any such maintenance, repairs, alterations or installations to the Building.

(s) Tenant shall not use the Rooftop Deck for storage purposes of any kind, including, without limitation, storage of the Rooftop Deck Personal Property during extended periods of non-use. In no event shall the Rooftop Deck be used for overnight sleeping.

(t) Tenant shall insure the Rooftop Deck and its use of the Rooftop Deck under Paragraph 4.13 of this Lease as if the Rooftop Deck was part of the Premises, and Tenant shall indemnify and hold harmless Landlord for Tenant's use of the Rooftop Deck under Paragraph 4.12 of this Lease as if the Rooftop Deck was part of the Premises.

(u) Tenant shall keep the Rooftop Deck reasonably clean and in good condition and repair at all times. Tenant shall store its garbage (so-called "wet" and "dry"), trash and other refuse generated on the Rooftop Deck in proper containers and shall remove the same with a frequency sufficient to prevent odors and/or vermin. Landlord, in its reasonable discretion, shall have the right to require Tenant, at Tenant's sole cost and expense, to contract for and utilize a pest extermination service in order to eradicate any vermin outbreak (or to control any ongoing vermin issues) attributable to Tenant's use of the Rooftop Deck.

(v) Tenant shall be responsible for ensuring that its agents, employees, contractors and invitees do not access the roof area of the Building beyond the Rooftop Deck for any reason without the prior written consent of Landlord in each instance.

(w) In the event that, as a result of the acts or omissions of Tenant or its employees, agents, contractors or invitees, the City of Boston or any governmental agency shall impose a monetary penalty or charge or ban on use with respect to the Rooftop Deck and/or Tenant's use thereof or shall require attendance at a hearing with respect to the Rooftop Deck and/or Tenant's use thereof, Tenant shall be solely responsible for any such penalty, charge or ban and Tenant shall otherwise abide by any decision of the City of Boston or any governmental agency.

(x) Landlord shall have the right to impose additional rules and regulations regarding Tenant's use of, and access to, the Rooftop Deck, which rules and regulations shall be issued in good faith and consistent with those which would be issued by other institutional owners of first class office buildings of comparable size, age, quality in the Seaport area, taking into account the reasonable interests of other Building tenants as well as Tenant's reasonable rights under this Lease.

2.2 Lease Term.

2.2.1 Initial Lease Term. The Lease Term shall be for the period stated in the definition of that term, unless earlier terminated as provided in this Lease.

2.2.2 Option to Extend. While this Lease is in full force and effect, provided that no Event of Default has occurred at any time during the Lease Term, and further provided that the Original Tenant has not assigned this Lease nor sublet more than seven thousand five hundred (7,500) rentable square feet of the Premises then demised to Tenant under this Lease (excluding transfers to Permitted Transferees), in each case both as of the time of option exercise and as of the commencement of the herein additional term, Tenant shall have the right or option (the "Extension Option") to extend the original term of this Lease for one (1) period of five (5) years (the "Option Period"). Such extension of the original term shall be on the same terms and covenants as provided for in the original term except that (a) Tenant shall have no further option to extend the Lease Term, (b) Base Rent for the Option Period shall be one hundred percent (100%) of the then Fair Market Rent for the Premises as determined in accordance with subparagraph 2.2.3, and (c) Landlord shall have no obligation to prepare, refurbish or construct the Premises or any part thereof prior to the commencement of the Option Period or otherwise provide any amount of improvement allowance in respect of the Premises. Any exercise of such Extension Option by Tenant as provided herein shall be irrevocable. If the Fair Market Rent has not been determined as of the commencement date of the Option Period, Tenant initially shall pay Base Rent plus escalations for the extended term at the Fair Market Rent designated by Landlord, with a retroactive adjustment to be made within ten (10) Business Days after the determination of Fair Market Rent. Notice (the "Option Notice") of

Tenant's intention to exercise the Extension Option must be given to Landlord, in writing, at least twelve (12) months prior to the then current expiration of the Lease Term (time being of the essence) or the Extension Option shall lapse and be of no further force or effect. If Tenant exercises the Extension Option, after the determination of the Fair Market Rent for the Premises as herein provided, the Landlord and Tenant shall execute an amendment to this Lease confirming same.

2.2.3 **Determination of Fair Market Rent for Extension Option.** If Tenant exercises the Extension Option as provided above, Landlord and Tenant shall have a period of twenty (20) days after Landlord's receipt of the Option Notice to agree upon the Fair Market Rent for the Premises. If Landlord and Tenant fail to reach agreement on the Fair Market Rent for the Premises, then the Fair Market Rent for the Premises shall be determined by three (3) licensed commercial real estate brokers, one of whom shall be named by Landlord, one of whom shall be named by Tenant, and the third of whom shall be selected by the brokers chosen by Landlord and Tenant. All such brokers shall be independent and none of the brokers nor their firms shall have been employed by Landlord (with respect to the Building), Tenant or their affiliates for the immediately preceding five (5) years. Furthermore, each such broker shall be a commercial real estate broker licensed in Massachusetts, specializing in office leasing in the so-called "Seaport District" of Boston, with not less than ten (10) years' experience in appraising comparable commercial properties in such market and recognized as reputable within the local real estate industry (each such broker being defined herein for purposes of this paragraph as a "Qualified Broker"). The parties each agree to select their Qualified Broker within ten (10) days after the expiration of the aforesaid twenty (20) day period. The third Qualified Broker shall be selected by the first two Qualified Brokers within ten (10) days after the first two (2) Qualified Brokers have been selected. If a party fails to timely select a Qualified Broker, the determination of the Fair Market Rent for the Premises shall be made by the Qualified Broker selected by the other party. Within fifteen (15) days after the third Qualified Broker has been selected, all of the Qualified Brokers shall meet to attempt to agree upon the Fair Market Rent for the Premises. If the Qualified Brokers are unable to reach agreement, all Qualified Brokers shall, within fifteen (15) days after the expiration of the preceding fifteen (15) day period, arrange to simultaneously submit to Landlord and Tenant in writing the Fair Market Rent for the Premises he or she deems appropriate (each such Qualified Broker's determination of Fair Market Rent for purposes of this paragraph being referred to herein as an "Appraisal"). If none of the Appraisals varies from the mean of the other two (2) Appraisals by more than ten percent (10%), the mean of the determinations of all three (3) Appraisals shall be the Fair Market Rent for the Premises. If, on the other hand, any single Appraisal varies from the mean of the other two (2) Appraisals by more than ten percent (10%), the mean of the two (2) Appraisals which are closest shall be the Fair Market Rent for the Premises. The Fair Market Rent for the Premises determined in accordance with this subparagraph 2.2.3 shall be final and binding on Landlord and Tenant. Each of the parties to this Lease shall pay the costs of the services of the Qualified Broker selected by that party, and the cost of the services of the third Qualified Broker shall be divided equally between Landlord and Tenant.

2.3 **Plans and Specifications/Selection of Tenant's General Contractor.**

2.3.1 If there are no Plans and Specifications attached as Exhibit C, then Tenant shall retain a licensed architect of its choice, subject to Landlord's prior written approval, to prepare the Plans and Specifications for the Tenant Improvements. The plans and specifications shall be subject to Landlord's approval, which approval shall not be unreasonably delayed, provided that such Plans and Specifications comply with the requirements of this paragraph 2.3. Tenant acknowledges that Landlord is seeking LEED certification for the core and shell of the Building and in connection therewith Tenant acknowledges and agrees that the Tenant Improvements must be designed consistent with the Mandatory Tenant LEED Design, Construction and performance Requirements set forth on Exhibit A attached hereto. In addition to, and without limiting, the foregoing, Tenant is encouraged **to** use reasonable efforts to (a) design the Tenant Improvements consistent with the Landlord's sustainability practices and certain Green Agency Ratings (as determined by Landlord), specifically the SMACNA "IAQ Guidelines for Occupied Buildings under Construction" 1995, Chapter 3, (b) engage a third party LEED or Green Globe Accredited Professional or similarly qualified professional with respect to the design and construction of the Tenant Improvements, and (c) seek and maintain LEED for Commercial Interiors certification with respect to the Tenant Improvements and to register the Premises with the U. S. Green Building Council prior to completion of the Plans and Specifications.

2.3.2 Within ten (10) days following the date of execution of the Lease by Tenant, Tenant shall cause its architect to furnish to Landlord for Landlord's approval space plans sufficient to convey the

architectural design of the Premises, including, without limitation, the location of doors, partitions, kitchenettes and bathrooms (including an estimate of the number and type of plumbing fixtures), and, to the extent then known, the location of heavy floor loads and other special requirements (collectively, the "Space Plan"). If required by Landlord, Tenant's architect shall consult with Landlord's engineer in preparing the Space Plan, and incorporate such engineer's requirements into the Space Plan. The fees of such engineer and any other out-of-pocket expenses incurred by Landlord in connection with Landlord's review of Tenant's Space Plan and Plans and Specifications and the inspection of the Tenant Improvements, which collectively shall not exceed [redacted] shall be Tenant Improvement Costs (as hereafter defined) and reimbursed by Tenant to Landlord. If Landlord shall reasonably disapprove of any portion of the Space Plan within five (5) Business Days after Landlord's receipt thereof, Landlord shall advise Tenant of the reasons therefor and shall notify Tenant of the revisions-to the Space Plan that are reasonably required by Landlord for the purpose of obtaining approval. If Landlord fails for any reason to approve or disapprove Tenant's Space Plan within five (5) Business Days after Landlord's receipt thereof, Landlord shall be deemed to have disapproved such Space Plan and such deemed disapproval shall in no event be considered or deemed unreasonable. Tenant shall within seven (7) days submit to Landlord, for Landlord's reasonable approval, a redesign of the Space Plan, incorporating the revisions required by Landlord. The foregoing process shall be repeated until Landlord has approved Tenant's Space Plan.

2.3.3 Tenant shall cause its architect to prepare from Tenant's approved Space Plan, complete Plans and Specifications within sixty (60) days after Landlord approves the Space Plan. The Plans and Specifications shall (a) be compatible with the Building shell and with the design, construction and equipment of the Building; (b) comply with all Governmental Requirements; (c) comply with all applicable insurance regulations; and (d) be consistent with the approved Space Plan. Tenant shall submit the Plans and Specifications for Landlord's Approval in the same manner as provided in Subparagraph 2.3.2 above for approval by Landlord of Tenant's Space Plan.

2.3.4 Landlord shall grant an allowance to Tenant in an amount up to the Tenant Space Plan Allowance (as defined in Section 1 hereof) to be used solely to reimburse the Tenant for the cost (the "Space Plan Costs") of the preparation of Tenant's Space Plan. Payment by Landlord of any portion of the Tenant Space Plan Allowance shall be subject to satisfaction of each and all of the following conditions: (1) Tenant shall have furnished Landlord with copies of third party invoices and evidence of payment of same for all Space Plan Costs, (2) Tenant shall have furnished Landlord with copes of Tenant's final approved Space Plan, and (3) Tenant shall not be in default of any term or condition of this Lease. Subject to satisfaction of all of the foregoing conditions, Landlord shall pay to Tenant, within thirty (30) days after receipt by Landlord of a written request therefore from Tenant in accordance with the foregoing, the lesser of (a) the full amount of the Tenant Space Plan Allowance, if the aggregate sum of the paid invoices submitted pursuant to (1) above equals or exceeds the full amount of the Tenant Space Plan Allowance, or (b) the aggregate sum of the paid invoices submitted pursuant to (1) above, if said aggregate sum is less than the full amount of the Tenant Space Plan Allowance. Tenant shall not be entitled to any credit, trade off or cash payment for any unused portion of the Tenant Space Plan Allowance, and the Landlord shall have no obligation to Tenant with respect to any such unused portion of the Tenant Space Plan Allowance.

2.3.5 Unless Tenant agrees to use Consigli Construction ("Consigli") as its general contractor for the construction of the Tenant Improvements, Tenant shall obtain bids (each a "Bid" and collectively the "Bids") for the Tenant Improvements (including buildout, general conditions and overhead profits) from Consigli and two (2) general contractors that are mutually acceptable to Landlord and Tenant (collectively, the "Approved Contractors"), provided that in all events the general contractor engaged by Tenant and all of its subcontractors of any tier shall: (i) be parties to, and bound by, a collective bargaining agreement with a labor organization affiliated with the Building and Construction Trades Council of the AFL-CIO and (ii) employ only members of such organization to perform work within their respective jurisdictions). Such contractors also shall comply with all requirements in Paragraph 4.5 of this Lease. Upon receipt of such Bids, Tenant shall promptly (x) provide a copy of each such Bid to Landlord, and (y) review such Bids and obtain any revisions thereto that are necessary to cause each Bid to include all of the same work and be based upon all of the same plans and specifications. At the conclusion of such process, if Consigli's Bid does not exceed the average of the two (2) lowest Bids or if Consigli agrees to reduce its bid to the average of the two (2) lowest Bids, then Tenant agrees to use Consigli as its general contractor for the Tenant Improvements. If Consigli's bid is higher than the average of the two

(2) lowest Bids and Consigli will not agree to reduce its bid to the average of the two (2) lowest Bids, then Tenant may select one of the other Approved Contractors to construct the Tenant Improvements.

2.4 Landlord's Base Building Work/Commencement Date/Early Entry.

2.4.1 Landlord shall complete the Landlord's Base Building Work at Landlord's sole cost and expense and obtain a certificate of occupancy for the Building (but not as to the Premises). Landlord shall deliver possession of the Premises to the Tenant on the Commencement Date. Tenant acknowledges that the Premises shall be delivered in a "shell" condition with only Landlord's Base Building Work completed and that Landlord shall have no obligation to build out the Premises for Tenant's use. Tenant further acknowledges that, except for the completion of Landlord's Base Building Work, the Premises shall be delivered to Tenant in AS IS condition and that no representations as to the condition of the Premises have been made by Landlord, provided that the base building systems which serve the Premises, including electrical and life safety systems and new rooftop HVAC units shall be delivered in good working order. The taking of possession by Tenant shall establish that the Premises are in good and satisfactory condition when possession was so taken and the Commencement Date shall occur as provided in the definition of that term. In no event shall Tenant's refusal or failure to take possession of the Premises delay or postpone the occurrence of the Commencement Date.

2.4.2 Tenant acknowledges that Landlord's general contractor for Landlord's Base Building Work is Consigli. In the event that Tenant engages Consigli as Tenant's general contractor for the Tenant Improvements, if the Commencement Date has not occurred prior to October 1, 2017 Tenant shall be permitted entry into the Premises on or about October 1, 2017 solely for the limited purpose of having Consigli begin construction of the Tenant Improvements in a manner coordinated with Consigli's completion of the Landlord's Base Building Work, but any such entry prior to the Commencement Date shall be at the Tenant's sole risk and subject to all of the terms and conditions of this Lease, except the obligation to pay Base Rent and escalations for Property Taxes and Operating Expenses.

2.5 Tenant Improvements.

2.5.1 Upon receipt of possession of the Premises and the selection of the general contractor for the Tenant Improvements, each in accordance with Paragraph 2.3 hereof, the Tenant shall prepare the Premises for Tenant's occupancy and complete the Tenant Improvements (including low voltage cabling) in accordance with the Plans and Specifications and at the Tenant's sole cost and expense (all such costs and expenses, including all hard and soft costs such as and without limitation, all labor and materials, architectural, engineering, permitting, project management, and space planning fees are hereinafter collectively referred to as the "Tenant Improvement Costs", provided that Tenant Improvement Costs shall not include Access Costs or Deck Costs). Tenant shall make no changes to the Plans and Specifications or the work reflected in the Plans and Specifications without the consent of the Landlord. Tenant's completion of the Tenant Improvements shall be performed by Tenant's contractors, who shall (a) be selected by Tenant and approved by Landlord (such approval not to be unreasonably withheld), and (b) work under the direction of Tenant or Tenant's qualified representative. Landlord shall have the right to have its representative at the Premises at all times during the construction of the Tenant Improvements to review and monitor the performance of same. The Tenant Improvements shall be performed by contractors employed by Tenant under one or more construction contracts, in form and content approved in advance in writing by Landlord (which approval shall be subject to Landlord's discretion and may include a requirement that the prime contractor and the respective subcontractors of any tier: (a) be parties to, and bound by, a collective bargaining agreement with a labor organization affiliated with the Building and Construction Trades Council of the AFL-CIO and (b) employ only members of such organization to perform work within their respective jurisdictions). Such contractors also shall comply with all requirements in Paragraph 4.5 of this Lease.

2.5.2 Prior to commencing any work on the Tenant Improvements, Tenant shall submit a budget for the Tenant Improvements (which shall include all Tenant Improvement Costs) to Landlord for Landlord's approval. Upon Landlord's approval of such a budget, the same shall be referred to herein as the "Approved Budget". If the aggregate of the Tenant Improvement Costs (taking into account any increases as a result of change orders requested by Tenant and approved by Landlord) at any time exceeds the Tenant Improvement Allowance, such excess shall be referred to herein as "Tenant's Contribution".

2.5.3 All Tenant Improvements, regardless of which party constructed or paid for them, shall become the property of Landlord and shall remain upon and be surrendered with the Premises upon the expiration or earlier termination of this Lease; provided that, at Landlord's election and upon notice to

Tenant, Tenant shall be required to remove all or any portion of the Tenant Improvements (including Telecommunication Facilities) upon the expiration or earlier termination of this Lease. Notwithstanding the foregoing, except as provided below in this subparagraph 2.5.3, if Tenant's submission of its Plans and Specifications to the Landlord for approval is accompanied by a written request that Landlord identify any Tenant Improvements that Landlord may require Tenant to remove upon the expiration or earlier termination of the Lease and such request includes a notice at the top of the page having a heading in at least 12-point type, bold and all capital letters stating **"LANDLORD'S APPROVAL MUST IDENTIFY ANY TENANT IMPROVEMENTS WHICH LANDLORD MAY REQUIRE TENANT TO REMOVE UPON THE EXPIRATION OR EARLIER TERMINATION OF THIS LEASE",** then Landlord shall identify such Tenant Improvements (if any) by written notice to Tenant given at the time of Landlord's approval of the Plans and Specifications, and Tenant shall not be required to remove any such Tenant Improvements not so identified. In all events, Landlord reserves the right to require Tenant to remove any wiring and cabling installed by Tenant.

2.5.4 Tenant shall be solely responsible for the design and construction of the Tenant Improvements. Notwithstanding Landlord's review and approval of the Plans and Specifications, Landlord shall have no liability to Tenant or to any other person for errors or omissions in the Plans and Specifications or in the construction of the Tenant Improvements (Landlord's review and approval of the Plans and Specifications being for Landlord's own purposes). Tenant shall indemnify, defend, protect and hold Landlord and Landlord's Agents harmless from all Claims which arise in any way, directly or indirectly from or in connection with the design and construction of the Tenant Improvements, including without limitation, claims arising from the work of Tenant's architect, engineer, contractor, employees or agents.

2.5.5 Landlord shall grant an allowance to Tenant in an amount equal to the Tenant Improvement Allowance (as defined in Section 1.1 hereof) to be used solely to reimburse the Tenant for the Tenant Improvement Costs, provided that no more than fifteen percent (15%) of the Tenant Improvement Allowance may be used for soft costs. For avoidance of doubt, no portion of the Tenant Improvement Allowance may be used to pay for any furniture or equipment or to pay for the costs and expenses of any work at the Premises not included in the Plans and Specifications, and Tenant shall be responsible, at its sole cost and expense, for all such costs and expenses.

2.5.6 Subject to the terms and conditions hereof, the Tenant Improvement Allowance shall be available for disbursement in up to a maximum of eleven (11) monthly draws plus one (1) final draw of the Retainage (as defined below) in the following manner (each a "Tenant Allowance Advance"), provided that at no time shall Landlord be required to make a Tenant Allowance Advance if following such advance the aggregate amount of the Tenant Improvement Allowance advanced by Landlord would exceed Landlord's Share of the aggregate amount of the Tenant Improvement Costs incurred by Tenant through such date (the "Balance Requirement"). As used herein, "Landlord's Share" means and refers to a fraction (expressed as a percentage), the numerator of which is the original amount of the Tenant Improvement Allowance and the denominator of which is the total amount of the Approved Budget (taking into account any increases as a result of change orders requested by Tenant and approved by Landlord).. At least twenty (20) Business Days before the date upon which the Tenant desires a Tenant Allowance Advance, the Tenant shall submit an itemized requisition (a "Requisition") on a form acceptable to the Landlord, stating the amount of the advance, the items(s) to be reimbursed or paid from the proceeds thereof, and the date upon which the advance is desired. In addition to the overall Balance Requirement, each Tenant Allowance Advance shall be limited to Landlord's Share of the Tenant Improvement Costs incurred by Tenant during the applicable period and each Tenant Allowance Advance (except the last) shall be subject to retainage in the amount of ten percent (10%) (the "Retainage"). Landlord's obligation to make any Tenant Allowance Advance shall be subject to Tenant's satisfaction of all of the following conditions other than item number (6), and Landlord's obligation to advance the Retainage shall be subject to Tenant's satisfaction of each and all of the following conditions numbered (1) through (6): (1) Tenant shall have submitted to Landlord a certification signed by Tenant's architect certifying that all work on the Tenant Improvements which is included in such Requisition has been completed in accordance with Plans and Specifications approved by the Landlord and attaching thereto an executed waiver or release of liens from Tenant's general contractor for the Tenant Improvements for all work performed and materials delivered that are included in such Requisition, which waiver and release shall be in such form as Landlord may reasonably require, (2) Tenant shall have provided Landlord with executed waivers or

releases of liens from each of Tenant's subcontractors and suppliers for all work performed and materials delivered that are included in such Requisition, which waivers and releases shall be in such form as Landlord may reasonably require, (3) Tenant shall have submitted to Landlord a certification of Tenant's general contractor for the Tenant Improvements identifying each contractor, subcontractor and supplier who performed labor and/or supplied materials for the Tenant Improvements that are included in such Requisition, (4) Tenant shall have furnished Landlord with copies of third party invoices (and paid receipts in the case of a disbursement of the Tenant Improvement Allowance), for all work performed and materials delivered which are included in such Requisition, (5) at the time of such Tenant Allowance Advance there shall exist no event which is, or solely with the passage of time and/or giving of notice would be, an Event of Default, and (6) with respect to the advance of the Retainage, Tenant shall have submitted to Landlord an issued and effective certificate of occupancy for the Premises for the Permitted Use and a certification signed by Tenant's architect certifying that the Tenant Improvements have been completed in accordance with Plans and Specifications approved by the Landlord and attaching thereto executed final waivers or releases of liens from Tenant's general contractor and each of Tenant's subcontractors and suppliers in such form as Landlord may reasonably require, plus a certificate of Tenant's general contractor identifying each contractor, subcontractor and supplier who performed labor and/or supplied materials for the Tenant Improvements. The foregoing items (1) through (6) above are herein collectively referred to as the "Tenant Allowance Conditions". Subject to satisfaction of the Balance Requirement and all of the Tenant Allowance Conditions applicable to a particular Tenant Allowance Advance, Landlord shall pay to Tenant from the remaining undisbursed Tenant Improvement Allowance, within twenty (20) Business Days after receipt by Landlord of a written request from Tenant for a Tenant Allowance Advance in accordance with the foregoing (or on such later date as requested by Tenant), Landlord's Share of the amount of the Tenant Improvement Costs incurred by Tenant during the applicable period (after deducting the applicable Retainage, except in the case of a final Requisition for the Retainage). Tenant shall not be entitled to any credit, trade off or cash payment for any unused portion of the Tenant Improvement Allowance, and Landlord shall have no obligation to Tenant with respect to any such unused portion of the Tenant Improvement Allowance. Further, notwithstanding anything herein to the contrary, in the event that Tenant has not completed the Tenant Improvements and/or satisfied all of the conditions for payment of the Tenant Improvement Allowance on or before the date which is eighteen (18) months after the Commencement Date, Landlord shall have no further obligation to make any Tenant Allowance Advance.

2.5.7 In all events, Tenant shall complete the Tenant Improvements on or before the date which is eighteen (18) months after the Commencement Date. In addition, on or before the date which is the earlier to occur of the date which is thirty (30) days after substantial completion of the Tenant Improvements and the date which is eighteen (18) months after the Commencement Date, if not already done pursuant to Paragraph 2.5.6 above, Tenant shall submit to Landlord an issued and effective certificate of occupancy for the Premises for the Permitted Use and a certification signed by Tenant's architect certifying that the Tenant Improvements have been completed in accordance with Plans and Specifications approved by the Landlord, together with executed final waivers or releases of liens from Tenant's general contractor and each of Tenant's subcontractors and suppliers in connection with the Tenant Improvements in such form as Landlord may reasonably require, plus a certificate of Tenant's general contractor identifying each contractor, subcontractor and supplier who performed labor and/or supplied materials for the Tenant Improvements.

2.6 Lease Memorandum. Following the Commencement Date„ Landlord may prepare and submit to the Tenant a Lease Memorandum in the form of Exhibit D, completed in good faith by Landlord, and executed by Landlord. The information inserted on the Lease Memorandum shall be controlling and conclusive and shall prevail over any inconsistent provision in this Lease on (a) the mutual execution of the Lease Memorandum by Landlord and Tenant or (b) the lapse of seven (7) days following delivery of the Lease Memorandum to Tenant without Tenant delivering to Landlord a written objection to all or part of the information in the Lease Memorandum. If Tenant does object in good faith to any information set forth in the Lease Memorandum, it shall execute the Lease Memorandum subject to its specifically-stated, written objections. Tenant must explain the reasons for its objections in reasonable detail. That portion of the Lease Memorandum to which no objection was made shall be conclusive and controlling. Pending resolution of any dispute by agreement or a final determination by a court of competent jurisdiction in accordance with this Lease, Landlord's information as inserted in the Lease Memorandum shall be utilized subject to any later adjustment agreed or found to be appropriate. Tenant's refusal or failure to

execute a Lease Memorandum shall neither prevent nor delay the occurrence of the Commencement Date. In no event shall the Lease Memorandum be recorded.

2.7 Use and Conduct of Business.

2.7.1 The Premises are to be used only for the Permitted Uses, and for no other business or purpose without the prior consent of Landlord. Landlord makes no representation or warranty as to the suitability of the Premises for Tenant's intended use. Tenant shall, at its own cost and expense, obtain and maintain any and all licenses, permits, and approvals necessary or appropriate for its use, occupation and operation of the Premises for the Permitted Uses. Tenant's inability to obtain or maintain any such license, permit or approval necessary or appropriate for its use, occupation or operation of the Premises shall not relieve it of its obligations under this Lease, including the obligation to pay Base Rent and Additional Rent.

2.7.2 No act shall be done in or about the Premises that is unlawful or that will increase the existing rate of insurance on any or all of the Land or Building. Tenant shall not commit or allow to be committed or exist: (a) any waste upon the Premises, (b) any public or private nuisance, or (c) any act or condition which disturbs the quiet enjoyment of any other tenant in the Building, violates any of Landlord's contracts affecting any or all of the Land or Building, creates or contributes to any work stoppage, strike, picketing, labor disruption or dispute, interferes in any way with the business of Landlord or any other tenant in the Building or with the rights or privileges of any contractors, subcontractors, licensees, agents, concessionaires, subtenants, servants, employees, customers, guests, invitees or visitors or any other persons lawfully in and upon the Land or Building, or causes any impairment or reduction of the good will or reputation of the Land or Building.

2.7.3 Tenant shall not, without the prior consent of Landlord, use any apparatus, machinery, device or equipment in or about the Premises which will cause any substantial noise or vibration or any increase in the normal consumption level of electric power. If any of Tenant's apparatus, machinery, devices or equipment should disturb the quiet enjoyment of any other tenant in the Building, then Tenant shall provide, at its sole cost and expense, adequate insulation or take other such action, including removing such apparatus, machinery, devices or equipment, as may be necessary to eliminate the disturbance. No food or beverage dispensing machines shall be installed by Tenant in the Premises without the prior written consent of Landlord.

2.7.4 Tenant shall not use or operate the Premises in any manner that will cause the Building or any part thereof not to conform with Landlord's sustainability practices or the certification of the Building issued pursuant to any Green Agency Rating.

2.7.5 Except in the case of an emergency and subject to Governmental Requirements and the terms and conditions hereof, Tenant and Tenant's employees shall have access to and the right to use the Premises twenty-four (24) hours per day, seven (7) days a week subject to Landlord's building security procedures and requirements, Building rules and regulations and maintenance requirements.

2.8 Compliance with Governmental Requirements and Rules and Regulations. Tenant shall comply with all Governmental Requirements and Restrictions relating to its use, occupancy and operation of the Premises and shall observe such reasonable rules and regulations as may be adopted and published by Landlord from time to time for the safety, care and cleanliness of the Premises and the Building, and for the preservation of good order in the Building and for the administration and management of the Building. Current Rules and Regulations are attached to this Lease as Exhibit E. Landlord shall comply with all Governmental Requirements and Restrictions, including Access Laws, relating to the common areas of the Land and Building, provided that Tenant shall be responsible for all repairs, modifications, or installations to the foregoing (a) required due to the Tenant Improvements, any Tenant Alterations, or any repairs by Tenant in the Premises or Tenant's particular manner of use of the Premises, or (b) required due to the act or negligence of any of the Tenant or Tenant's Agents, or (c) which are Tenant's responsibility pursuant to other provisions of this Lease.

2.9 Intentionally Omitted.

2.10 Sustainable Building Operations

2.10.1 This Building is or may become in the future certified under certain Green Agency Ratings or operated pursuant to Landlord's sustainable building practices, as same may be in effect or modified from time to time. Landlord's sustainability practices address, without limitation, whole-building operations and maintenance issues including chemical use; indoor air quality; energy efficiency; water efficiency; recycling programs; exterior maintenance programs; and systems upgrades to meet green building energy, water, Indoor Air Quality, and lighting performance standards. All of Tenant's

construction and maintenance methods and procedures, material purchases, and disposal of waste must be in compliance with minimum standards and specifications as outlined by the Green Agency Ratings, in addition to all Governmental Requirements so long as said compliance is achievable at no additional cost to Tenant.

2.10.2 Tenant shall use reasonable efforts to use proven energy and carbon reduction measures, including energy efficient bulbs in task lighting; use of lighting controls; daylighting measures to avoid overlighting interior spaces; turning off lights and equipment at the end of the work day; and purchasing ENERGY STAR® qualified equipment, including but not limited to lighting, office equipment, commercial and residential quality kitchen equipment, vending and ice machines; and purchasing products certified by the U.S. EPA's Water Sense® program so long as said compliance is achievable at no additional cost to Tenant..

2.11 **Recycling and Waste Management.** Tenant covenants and agrees, at its sole cost and expense: (a) to comply with all present and future Governmental Requirements regarding the collection, sorting, separation, and recycling of garbage, trash, rubbish and other refuse (collectively, "trash"); (b) to comply with Landlord's recycling policy, as stated in the Rules and Regulations (as such policy may be amended or supplemented from time to time subject to Paragraph 2.8 hereof), as part of Landlord's sustainability practices where it may be more stringent than applicable Governmental Requirements, including without limitation, recycling such categories of items designated by Landlord and transporting such items to any recycling areas designated by Landlord; (c) to sort and separate its trash and recycling into such categories as are provided by Governmental Requirements or Landlord's then-current sustainability practices; (d) that each separately sorted category of trash and recycling shall be placed in separate receptacles as directed by Landlord; (e) that Landlord reserves the right to refuse to collect or accept from Tenant any waste that is not separated and sorted as required by Governmental Requirements, and to require Tenant to arrange for such collection at Tenant's sole cost and expense, utilizing a contractor satisfactory to Landlord; and (f) that Tenant shall pay all costs, expenses, fines, penalties or damages that may be imposed on Landlord or Tenant by reason of Tenant's failure to comply with the provisions of this paragraph 2.11.

SECTION 3: BASE RENT, ADDITIONAL RENT AND OTHER SUMS PAYABLE UNDER LEASE

3.1 **Payment of Rental.** Tenant agrees to pay Base Rent, Additional Rent and any other sum due under this Lease to Landlord without demand, deduction, credit, adjustment or offset of any kind or nature, in lawful money of the United States when due under this Lease, at the Rent Payment Address, or to such other party or at such other place as Landlord may from time to time designate in writing.

3.2 **Base Rent.** On execution of this Lease, Tenant shall pay to Landlord the amount specified in the definition of Prepaid Rent for the month specified in the definition of that term. Tenant agrees to pay the monthly installments of Base Rent to Landlord, without demand and in advance, on or before the first day of each calendar month of the Lease Term. The monthly Base Rent installment for any partial month at the beginning or end of the Lease Term shall be prorated. Base Rent for any partial month at the beginning of the Lease Term shall be paid by Tenant on the Commencement Date.

3.3 **Lease Security Provisions.**

3.3.1 On execution of this Lease, as security for the full and faithful payment of all sums due under this Lease and the full and faithful performance of every covenant and condition of this Lease to be performed by Tenant, Tenant shall deliver a letter of credit in the amount of Nine Hundred Eighteen Thousand Three Hundred Fifty-Five and 02/100 Dollars ($918,355.02) in favour of Landlord. The letter of credit initially delivered pursuant to this paragraph and all substitutions, replacements and renewals of it, must be consistent with and shall satisfy all the requirements in the letter of credit criteria set forth on Exhibit F hereto. The term "Letter of Credit" shall mean and refer to a letter of credit conforming to this subparagraph. If a Letter of Credit has not been delivered to and accepted by Landlord on or before the full execution of this Lease, at Landlord's election, the failure to deliver such Letter of Credit may be treated by Landlord (a) as a condition subsequent to the effectiveness of this Lease such that this Lease shall be voidable by Landlord by notice to Tenant at any time prior to Landlord's receipt of the Letter of Credit or (b) an Event of Default. If Landlord elects to treat the failure to deliver the Letter of Credit on execution of this Lease as an Event of Default, Landlord may pursue all available rights and remedies, including the right to specific performance and the right to attach assets of Tenant. Pending delivery of

the Letter of Credit, Landlord also may defer contracting for Tenant Improvements and/or suspend work on same.

3.3.2 Tenant shall have the right to reduce the amount of the Letter of Credit on or after each of the dates set forth below to the amount set forth opposite such date (each such date on which the amount of the Letter of Credit may first be reduced is referred to herein as a "Reduction Date"), provided that on each Reduction Date and on the date any such reduction is implemented (a) the Lease is in full force and effect, and (b) all Base Rent and Additional Rent then due has been paid in full and no Event of Default has theretofore occurred at any time during the Lease Term. If the conditions for reduction of the Letter of Credit are satisfied with respect to any Reduction Date, upon the written request of the Tenant, Landlord shall permit Tenant to replace or amend the Letter of Credit accordingly. If on any Reduction Date the Letter of Credit shall not be reduced because one (1) or more of the conditions set forth in clauses (a) and (b) above were not satisfied, there shall be no further reduction in the amount of the Letter of Credit and the then required amount of the Letter of Credit shall remain in effect for the remainder of the Lease Term.

Reduction Date	Required Amount of Letter of Credit	Reduction Amount
The date that is one (1) year after the Rent Commencement Date	[redacted]	[redacted]
The date that is two (2) years after the Rent Commencement Date	[redacted]	[redacted]
The date that is three (3) years after the Rent Commencement Date	[redacted]	[redacted]
The date that is four (4) years after the Rent Commencement Date	[redacted]	[redacted]
The date that is five (5) years after the Rent Commencement Date	[redacted]	[redacted]
The date that is six (6) years after the Rent Commencement Date	[redacted]	[redacted]

If the Letter of Credit is reduced to [redacted] subject to and in accordance with the terms and conditions set forth above, for avoidance of doubt Tenant acknowledges and agrees that the required amount of the Letter of Credit shall remain at [redacted] for the remainder of the Lease Term.

3.3.3 Landlord may draw on the Letter of Credit, in whole or in part at Landlord's election, without advance notice to Tenant at any time or from time to time on or after (a) the occurrence of any Event of Default, (b) if Tenant, or anyone in possession of the Leased Premises through Tenant, holds over after the expiration or earlier termination of this Lease, (c) Landlord is given _notice by-the-issuer of the Letter of Credit that it is terminating the Letter of Credit, (d) a confirming bank gives notice to Landlord that it will cease to act in that capacity, (e) the Letter of Credit expires on a specified date by its terms and is not renewed or replaced at least sixty (60) days in advance of its expiration date or (f) to the extent permitted by law, in the event any bankruptcy, insolvency, reorganization or any other debtor creditor proceeding is instituted by or against Tenant, or (g) the issuer of the letter of credit fails or ceases to maintain the minimum credit rating required under the letter of credit criteria set forth on Exhibit F hereto.

3.3.4 Landlord may apply any sum drawn on the Letter of Credit to amounts owing to Landlord under this Lease in such order and priority as Landlord elects in its absolute discretion. If any of the proceeds drawn on the Letter of Credit are not applied immediately to sums owing to Landlord under this Lease, Landlord may retain any such excess proceeds as a cash Lease Security Deposit for application, at Lender's election, to future sums owing to Landlord under this Lease, in such order and priority as

Landlord elects in its absolute discretion. Tenant shall, within fifteen (15) days after Landlord's demand, restore the amount of the Letter of Credit drawn so that the Letter of Credit is restored to the original amount of the Letter of Credit. If Tenant does not restore the Letter of Credit to its original amount within the required time period, such non-restoration shall be considered an Event of Default.

3.3.5 Additionally, Landlord's draw and application of all or any portion of the proceeds of the Letter of Credit shall not impair any other rights or remedies provided under this Lease or under applicable law and shall not be construed as a payment of liquidated damages. If Tenant shall have fully complied with all of the covenants and conditions of this Lease, the Letter of Credit shall be returned to Tenant or, if Landlord has drawn on the Letter of Credit, the remaining proceeds of the Letter of Credit which are in excess of sums due the Landlord shall be repaid to Tenant, without interest, within thirty (30) Business Days after the expiration or termination of the Lease Term and delivery of possession of the Leased Premises to Landlord in accordance with this Lease.

3.3.6 On any request by Landlord made during the Lease Term, Tenant shall cooperate in accomplishing any reasonable modification of the Letter of Credit requested by Landlord. If the Letter of Credit should be lost, mutilated, stolen or destroyed, Tenant shall cooperate in obtaining the issuance of a replacement.

3.3.7 Tenant shall not assign or grant any security interest in the Letter of Credit and any attempt to do so shall be void and of no effect.

3.3.8 In the event of a sale or transfer of Landlord's estate or interest in the Land and Building, Landlord shall have the right to transfer the Letter of Credit to the vendee or the transferee, Tenant shall pay any transfer fees charged by the issuing bank and Landlord shall thereafter be considered released by Tenant from all liability for the return of the Letter of Credit. Tenant shall cooperate in effecting such transfer.

3.3.9 No mortgagee or purchaser of any or all of the Building at any foreclosure proceeding brought under the provisions of any mortgage shall (regardless of whether the Lease is at the time in question subordinated to the lien of any mortgage) be liable to Tenant or any other person for any or all amounts drawn against the Letter of Credit or any other or additional lease security deposit or other payment made by Tenant under the provisions of this Lease), unless Landlord has actually delivered it in cash to such mortgagee or purchaser, as the case may be.

3.4 **Additional Rent.** Definitions of certain terms used in this paragraph are set forth in the last subparagraph of this paragraph entitled "Additional Rent". Tenant agrees to pay to Landlord additional rent as computed in this paragraph (individually and collectively the "Additional Rent"):

3.4.1 **Estimated Operating Costs.** Tenant shall pay to Landlord as Additional Rent one-twelfth (1/12) of the amount, if any, by which the Estimated Operating Costs Allocable to the Premises exceeds the Base Amount Allocable to the Premises. This sum shall be paid in advance on or before the first day of each calendar month of the Lease Term. Landlord shall furnish Tenant a written statement of Estimated Operating Costs Allocable to the Premises in advance of the commencement of each Year. If such written statement is furnished after the commencement of the Year (or as to the first Year during the Lease Term, after the Commencement Date), Tenant shall also make a retroactive lump-sum payment to Landlord equal to the monthly payment amount multiplied by the number of months during the Year (or as to the first Year during the Lease Term, after the Commencement Date) for which no payment was paid. Notwithstanding the foregoing, Landlord reserves the right, from time to time during each Year, to revise the Estimated Operating Costs Allocable to the Premises and upon notice to Tenant of such revision, Tenant shall adjust its payment to Landlord under this subparagraph 3.4.1 accordingly.

3.4.2 **Actual Costs.** After the close of each Year, Landlord shall deliver to Tenant a written statement setting forth the Operating Costs Allocable to the Premises during the preceding Year. If such Operating Costs Allocable to the Premises for any Year exceed the Estimated Operating Costs Allocable to the Premises paid by Tenant to Landlord pursuant to subparagraph 3.4.1 for such Year, Tenant shall pay the amount of such excess to Landlord within twenty (20) Business Days after receipt of such statement by Tenant. If such statement shows the Operating Costs Allocable to the Premises to be less than the Estimated Operating Costs Allocable to the Premises paid by Tenant to Landlord pursuant to subparagraph 3.4.1, then the amount of such overpayment shall be paid by Landlord to Tenant within twenty (20) Business Days following the date of such statement or, at Landlord's option, shall be credited towards the installment(s) of Additional Rent next coming due from Tenant.

3.4.3 **Determination.** The determination of Operating Costs Allocable to the Premises shall be made by Landlord.

3.4.4 **Operating Cost Audit.** Landlord shall maintain records concerning estimated and actual Operating Costs Allocable to the Premises for no less than twelve (12) months following the period covered by the statement or statements furnished Tenant, after which time Landlord may dispose of such records. Provided that Tenant is not then in default of its obligation to pay Base Rent, Additional Rent or other payments required to be made by it under this Lease and further provided that Tenant is not otherwise in default under this Lease, Tenant may, at Tenant's sole cost and expense, cause a Qualified Person (defined above) to inspect Landlord's records for the prior Year. Such inspection, if any, shall be conducted no more than once each Year, during Landlord's normal business hours within sixty (60) calendar days after receipt of Landlord's written statement of Operating Costs Allocable to the Premises for the previous Year, upon first furnishing Landlord at least twenty (20) Business Days prior written notice. In no event shall Tenant be permitted to review Landlord's records for any particular Year more than once. As a condition to Tenant's right to conduct such inspection, Tenant agrees (i) to promptly furnish Landlord (at Tenant's cost) with a copy of all draft and final reports of Tenant's examination of Landlord's records, and (ii) except as required by applicable law, that neither Tenant nor any of Tenant's Agents shall divulge the contents of Landlord's records or the results of its examination to any third party. Any errors disclosed by the review shall be promptly corrected by Landlord; provided, however, that if Landlord disagrees with any such claimed errors, Landlord shall have the right to cause another review to be made by an auditor of Landlord's choice. In the event the results of the review of records (taking into account, if applicable, the results of any additional review caused by Landlord) reveal that Tenant has overpaid obligations for a preceding period, the amount of such overpayment shall be paid by Landlord to Tenant within thirty (30) days following such review or, at Landlord's option (except after the expiration of the Lease Term), credited against Tenant's subsequent installment(s) of Operating Costs Allocable to the Premises due to Landlord under the Lease. In the event that such results show that Tenant has underpaid its obligations for a preceding period, the amount of such underpayment shall be paid by Tenant to Landlord with the next succeeding installment obligation of estimated Operating Costs Allocable to the Premises (except after the expiration of the Lease Term, in which case Tenant shall pay Landlord the amount of such underpayment within thirty (30) days following such examination)..

3.4.5 **End of Term.** If this Lease shall terminate on a day other than the last day of a Year, (a) Landlord shall estimate the Operating Costs Allocable to the Premises and Property Taxes Allocable to the Premises for such Year predicated on the most recent reliable information available to Landlord; (b) the amount determined under clause (a) of this sentence shall be prorated by multiplying such amount by a fraction, the numerator of which is the number of days within the Lease Term in such Year and the denominator of which is 360; (c) the Operating Costs Base Amount Allocable to the Premises shall be prorated in the manner described in clause (b); (d) the clause (c) amount (i.e., the prorated Operating Costs Base Amount Allocable to the Premises) shall be deducted from the clause (b) amount (i.e., the prorated Operating Costs Allocable to the Premises); (e) if the clause (d) amount exceeds the Estimated Operating Costs Allocable to the Premises paid by Tenant for the last Year in the Lease Term, then Tenant shall pay the excess to Landlord within ten (10) Business Days after Landlord's delivery to Tenant of a statement for such excess; and (f) if the Estimated Operating Costs Allocable to the Premises paid by Tenant for the last Year in the Lease Term exceeds the clause (d) amount, then Landlord shall refund to Tenant the excess within the ten (10) Business Day period described in clause (e) if Tenant is not then in default of any of its obligations under this Lease. Landlord's and Tenant's obligations under this paragraph shall survive the expiration or other termination of this Lease.

3.4.6 **Definitions.** Each underlined term in this subparagraph shall have the meaning set forth next to that underlined term:

Operating Costs Base Amount Allocable to the Premises: The Operating Costs Allocable to the Premises for the year beginning January 1, 2018 and ending December 31, 2018 (the "Base Year").

Estimated Operating Costs Allocable to the Premises: Landlord's written estimate of Operating Costs Allocable to the Premises for a Year to be given by Landlord to Tenant pursuant to subparagraph 3.4.1.

Operating Costs (net of Property Taxes): All expenses paid or incurred by Landlord for maintaining, operating, owning and repairing any or all of the Land, Building, Premises, related improvements, and the personal property used in conjunction with such Land, Building, Premises and related improvements, except for Property Taxes. Included are all expenses paid or incurred by Landlord for: (a) utilities, including electricity, water, gas, sewers, fire sprinkler charges, refuse

collection, Telecommunication Services, cable television, steam, heat, cooling or any other similar service and which are not payable directly by tenants in the Building; (b) supplies; (c) cleaning, painting and janitorial services (including window washing), landscaping and landscaping maintenance (including irrigating, trimming, mowing, fertilizing, seeding and replacing plants), snow removal and other services; (d) security services, if any; (e) insurance premiums and applicable insurance deductible payments by Landlord; (f) management fees, which fees in any calendar year shall not exceed an amount equal to four percent (4%) of the gross revenues for the Land and the Building; (g) compensation (including employment taxes and fringe benefits) of all persons and business organizations who perform duties in connection with any service, repair, maintenance, replacement or improvement or other work included in this subparagraph; (h) license, permit and inspection fees; (i) assessments and special assessments due to deed restrictions, declarations or owners associations or other means of allocating costs of a larger tract of which the Land is a part,; (j) rental of any machinery or equipment; (k) audit fees and accounting services related to the Building, and charges for the computation of the rents and charges payable by tenants in the Building (but only to the extent the cost of such fees and services are in addition to the cost of the management fee); (I) the cost of repairs or replacements; (m) charges under maintenance and service contracts; (n) legal fees and other expenses of legal or other dispute resolution proceedings; (o) maintenance and repair of the roof and roof membranes, (p) costs incurred by Landlord for compliance with any and all Governmental Requirements, including Access Laws (excluding costs incurred by Landlord to correct any violation existing as of the Commencement Date of any valid, applicable Governmental Requirement in effect and as interpreted by governmental authorities as of the Commencement Date), and to increase the efficiency of any electrical, mechanical or other system servicing the Building or the Land; (q) elevator service and repair, if any; (r) business taxes and license fees; (s) any other expense or charge which in accordance with generally accepted accounting and management principles would be considered an expense of maintaining, operating, owning or repairing the Building; (t) insurance endorsements or insurance policies purchased in order to repair, replace and re-commission the Building for re-certification pursuant to any Green Agency Rating (or, in the event the Building has not achieved any certification under any Green Agency Rating, such insurance that is purchased in order to facilitate rebuilding the building upon a casualty so as to achieve such certification) or support achieving energy and carbon reduction targets; (u) all costs of maintaining, managing, reporting, commissioning, and recommissioning the Building or any part thereof that was designed and/or built to be sustainable and conform with any commissioning the Building or any part thereof to seek certification under any Green Agency Rating; and (v) the amortization of costs of capital improvements in accordance with the next sentence. Costs associated with capital improvements installed or constructed by Landlord other than in the initial construction of the Building, whether such were constructed or installed before or after the Commencement Date, shall be amortized with interest return at the Prime Rate plus two (2) percentage points over the estimated useful life of the capital improvement as determined by Landlord and the annual amortization of principal and interest attributable to the Lease Term shall be an Operating Cost. The capital improvements referred to in the previous sentence shall include: replacement of roof structure and roof membranes; exterior painting; parking area resurfacing, resealing and restriping parking areas and driveways and upgrading Building common systems and facilities (including HVAC systems, and if owned by Landlord, Telecommunication Facilities).

Exclusions from Operating Costs: Operating Costs shall not include any of the following: ground rent; interest and amortization of funds borrowed by Landlord for items other than capital improvements; leasing commissions and advertising and space planning expenses incurred in procuring tenants; costs incurred by Landlord to the extent that Landlord is actually reimbursed by insurance proceeds or is otherwise actually reimbursed by another third party (in each case less costs of recovery, which shall be included in Operating Costs); costs incurred by Landlord due solely to the violation by Landlord or any other tenant of the terms and conditions of any lease of space in the Building; Landlord's general corporate overhead and administrative expenses not directly attributable to the operation and management of the Building, except to the extent included in the management fee permitted hereby; costs to the extent arising from the negligence or willful misconduct of Landlord or Landlord's Agents as finally determined by judgment of a

court of competent jurisdiction which is not subject to appeal; and salaries, wages, or other compensation paid to officers or executives of Landlord in their capacities as officers and executives.

Gross-Up Provision: If less than ninety-five hundred percent (95%) of the net rentable area of the Building is occupied by tenants at all times during any Year, then Operating Costs for such Year may include all additional costs and expenses that Landlord reasonably determines would have been incurred had ninety-five hundred percent (95%) of the Building been occupied at all times during such Year by tenants.

Operating Costs Allocable to the Premises: The product of Tenant's Pro Rata Share times Operating Costs (net of Property Taxes).

Qualified Person: This means an accountant or other person experienced in accounting for income and expenses of office projects, who is engaged solely by Tenant on terms which do not entail any compensation based or measured in any way upon any savings in Additional Rent or reduction in Operating Costs Allocable to the Premises achieved through the inspection process described in this subparagraph.

Property Tax Base Amount: Tenant's Pro Rata Share of the Property Taxes payable for the fiscal tax year 2019 (beginning July 1, 2018 and ending June 30, 2019); provided however, if the City of Boston's assessment for fiscal tax year 2019 does not reflect the approximate full square footage of the Building that is shown on the plans and specifications that have been filed with the City of Boston as of the Effective Date, the Property Tax Base Amount will be the fiscal year that does reflect the approximate full square footage of the Building as set forth on such plans and specifications.

Property Taxes Allocable to the Premises: Tenant's Pro Rata Share of Property Taxes.

3.4.7 Property Tax Escalation. In addition to the payments required by the previous subparagraphs of this paragraph, Tenant shall pay as Additional Rent to Landlord one-twelfth (1/12) of the amount, if any, by which (a) Landlord's estimate of the Property Taxes Allocable to the Premises for the current tax year exceeds the Property Tax Base Amount. This sum shall be paid in advance on or before the first day of each calendar month of the Lease Term. After the close of each tax year during the Lease Term, Landlord shall deliver to Tenant a written statement setting forth (1) the actual Property Taxes Allocable to the Premises for the preceding tax year, (2) the difference between the amount referred to in clause (1) and the Property Tax Base Amount and (3) the differential between the amount referred to in clause (2) and the sum of the tentative monthly payments toward such amount made by Tenant. If the differential referred to in clause (3) of the previous sentence represents an underpayment by Tenant, such differential shall be paid to Landlord within twenty (20) Business Days after delivery of Landlord's written statement to Tenant; if such differential represents an overpayment by Tenant, Landlord shall, at its option, either credit such overpayment to the installment(s) of Additional Rent next coming due from Tenant or refund such overpayment to Tenant within twenty (20) Business Days after Tenant's concurrence in the amount due as a refund. If the Lease Term begins or ends on a day other than the beginning or end of a tax year, the amount due as described in clause (2) of this subparagraph shall be prorated on a per diem basis with reference to the tax year. The provisions of this subparagraph shall survive the expiration or other termination of this Lease.

3.4.8 Tenant's Costs. Tenant agrees to reimburse or pay Landlord within twenty (20) Business Days after invoice from Landlord for (a) any cleaning expenses incurred by Landlord, including carpet cleaning, garbage and trash removal expenses, over and above the normal cleaning provided by Landlord, if any, or due to the presence of a lunchroom or kitchen or food or beverage dispensing machines within the Premises, (b) any expense incurred by Landlord for usage in the Premises of heating, ventilating and air conditioning services, elevator services, electricity, water, janitorial services, or any other services or utilities over and above the normal usage for the Premises, (c) any expense incurred by Landlord relating to or arising out of the usage by Tenant or Tenant's Agents of the public or common areas of the Building or Land, or any of the equipment contained therein, which usage is over and above the normal usage for such public or common areas or equipment, and (d) any other direct expense incurred by Landlord on Tenant's behalf. Landlord reserves the right to install and activate separate metering of electricity, water or other utilities to the Premises, and Tenant agrees to reimburse or pay Landlord within twenty (20) Business Days after invoice from Landlord for all costs of such

separate metering, in which case the Operating Costs Base Amount Allocable to the Premises and Operating Costs shall be adjusted accordingly.

3.4.9 **Payments Deemed Additional Rent.** Any sums payable under this Lease pursuant to this paragraph or otherwise shall be Additional Rent and, in the event of nonpayment of such sums, Landlord shall have the same rights and remedies with respect to such nonpayment as it has with respect to nonpayment of the Base Rent due under this Lease.

3.5 Utilities

3.5.1 Landlord shall have the right from time to time to select the company or companies providing electricity, gas, fuel, one or more categories of Telecommunication Services and any other utility services to the Building. Landlord reserves the right to change electricity providers for the Building at any time and to purchase green or renewable energy. Electricity service for the Premises (including lights, plugs and electricity to power HVAC) shall be separately metered to the Premises and separately accounted for and billed to Tenant by the utility provider. The direct meter for electricity shall be installed by Tenant at Tenant's expense as a part of the Tenant Improvements. With the exception of water and sewer, Tenant shall contract directly and pay for all utilities used on or from the Premises together with any taxes, penalties, surcharges or similar charges relating to such utilities. If any such service is not separately accounted for and billed to Tenant by the utility provider, at Landlord's option the cost therefor shall either be (a) paid by Tenant to Landlord or (b) included as an Operating Cost under this Lease.

3.5.2 Tenant acknowledges that space on the Building rooftop and in Building risers, equipment rooms and equipment closets is limited. If Tenant requires Telecommunication Services for the Premises other than from the provider or providers of Telecommunication Services selected by Landlord and whose Telecommunication Facilities are installed in or about the Building or on the rooftop of the Building, provision for alternate or supplemental Telecommunication Services or Telecommunication Facilities has been made in a license agreement accompanying and made part of this Lease. Unless otherwise required by law, neither Tenant, nor a provider of Telecommunication Services to Tenant, in the future shall be entitled to locate or install Telecommunication Facilities in, on or about the Building without (a) first obtaining Landlord's advance, written consent (given in its absolute discretion) and (b) the advance execution by Landlord and Tenant of a satisfactory agreement granting a license to Tenant for such purposes and setting forth the scope, the additional rent, if any, royalties and the other terms and conditions of that license, and (c) Tenant negotiating and obtaining the right, if any is required, to bring such Telecommunication Facilities across public or private property to an approved entry point to the Building. The agreement referred to in clause (b) of the previous sentence shall be incorporated in and become part of this Lease. Any future application by Tenant for permission to locate or install Telecommunication Facilities shall (1) be in such form and shall be accompanied by such supporting information as the Landlord may require, (2) be subject to such procedures, regulations and controls as the Landlord may specify and (3) be accompanied by such payment as the Landlord may reasonably request to reimburse Landlord for its costs of evaluating and processing the application and in negotiating and preparing the agreement described earlier in this subparagraph.

3.5.3 Landlord shall in no case be liable or in any way be responsible for damages or loss to Tenant arising from the failure of, diminution of or interruption in electrical power, natural gas, fuel, Telecommunication Services, sewer, water, or garbage collection services, other utility service or building service of any kind to the Premises, unless such interruption in, deprivation of or reduction of any such service was caused by the gross negligence or willful misconduct of Landlord, its agents or contractors or by a failure in facilities, equipment or systems in the Landlord's ownership. To the extent that Landlord bears any responsibility for any such interruption, deprivation or reduction in utility or building services to the Premises, Landlord's responsibility and Tenant's remedy shall be limited to an abatement in Base Rent for the period beginning with (a) the day which is five (5) Business Days after the date on which Tenant delivers notice to Landlord of such interruption, deprivation or reduction and that Tenant is being deprived of all reasonable use of the Premises and ending on (b) the date such interruption, deprivation or reduction which is Landlord's responsibility is not causing Tenant to be deprived of all reasonable use of the Premises.

3.5.4 HVAC service shall be provided to the Premises Mondays through Fridays from 8:00 a.m. to 6:00 p.m. except for holidays ("Building Standard Hours"), Landlord shall provide HVAC service at times in addition to Building Standard Hours ("After-Hours HVAC"); provided, however, Tenant gives Landlord notice prior to 1:00 p.m. on the same day such After-Hours HVAC is required with respect to service on Business Days and prior to 1:00 p.m. on the immediately preceding Business Day with respect

to service on non-Business Days. The charge to Tenant for After-Hours HVAC shall be at Landlord's then-standard hourly rate in effect from time to time for After-Hours HVAC (currently $35.00 per hour but subject to change in accordance with the foregoing); provided, however there will be no charge for After-Hours HVAC on Saturdays between 9:00 AM and 1:00 PM (although Tenant must request same as set forth in the preceding sentence). Any HVAC service on holidays shall be considered After-Hours HVAC. Notwithstanding the foregoing, Landlord agrees not to charge Tenant for the first twenty (20) hours of After-Hours HVAC provided to the Premises in any calendar month (the "Monthly After-Hours HVAC Allotment"). For avoidance of doubt, Tenant shall not be entitled to any credit, trade off or cash payment for any unused portion of the Monthly After-Hours HVAC Allotment for any calendar month any no unused portion of the Monthly After-Hours HVAC Allotment for any calendar month may be used in any future month or otherwise carried forward.

3.5.5 Tenant shall not install any supplemental HVAC, space heaters or other utilities or energy-intensive equipment ("Supplemental Utilities Equipment") in the Premises without Landlord's prior written consent. In the event that Landlord consents in writing to such installation, Tenant shall be responsible, all at its sole cost and expense, for the installation, maintenance, and repair of any of Supplemental Utilities Equipment, and, at Landlord's election, shall remove same from the Premises upon the expiration or termination of the Lease Term at Tenant's sole cost and expense. Tenant agrees that it will maintain and repair any Supplemental Utilities Equipment, and major components thereof, in first-class condition, and any such equipment will be operated on sensors or timers that limit the operation of such Supplemental Utilities Equipment to hours of occupancy in the areas immediately adjacent to the occupying personnel. Tenant shall, at its sole cost and expense, enter into a regularly scheduled preventative maintenance/service contract with a maintenance contractor or the seller of any such Supplemental Utilities Equipment, and upon Landlord's reasonable request, Tenant will provide Landlord with reasonable evidence of such maintenance and repair. Upon Landlord's request, at reasonable times and upon prior notice to Tenant (except in the event of an emergency, where no notice is required) Landlord shall have the right to inspect, on not less than a monthly basis, the aforementioned Supplemental Utilities Equipment and major components provided Landlord shall use commercially reasonable efforts to minimize Landlord's interference with Tenant's business. Tenant shall not permit any Supplemental Utilities Equipment to disturb or interfere with any of the Building's systems or any other tenant in the Building, and Tenant will remove, at Tenant's sole cost and expense, any such Supplemental Utilities Equipment at Landlord's direction in the event of such disturbance or interference. Landlord reserves the right to separately submeter (or cause Tenant to separately submeter) any Supplemental Utilities Equipment, all at Tenant's sole cost and expense. Notwithstanding anything herein to the contrary, in the event that any Supplemental Utilities Equipment is required to be removed from the Premises by Tenant pursuant to the terms of this paragraph 3.5.5, Landlord may perform such removal at its election, and Tenant shall reimburse Landlord for any costs relating thereto, or in the event that Tenant performs such removal, Tenant shall be responsible to Landlord for any damage caused to the Premises or Building in connection therewith.

3.5.6 Tenant shall be required to submit to Landlord any electricity consumption data and costs in a format deemed reasonably acceptable by Landlord.

3.5.7 Subject to the terms and conditions hereof, Landlord shall also furnish janitorial services to the Premises in accordance with the cleaning specifications attached hereto as Exhibit I, as such specifications may be modified from time to time by the Landlord in its reasonable discretion.

3.6 **Holdover.** Tenant is not authorized to hold over beyond the expiration or earlier termination of the Lease Term. If Lardlord consents to a holdover and no other agreement is reached between Tenant and Landlord concerning the duration and terms of the Holdover, Tenant's holdover shall be a month-to-month tenancy. During such tenancy, Tenant shall pay to Landlord one and one-half times (150%) the rate of Base Rent in effect on the expiration or termination of the Lease Term plus all Additional Rent and other sums payable under this Lease, and shall be bound by all of the other covenants and conditions specified in this Lease, so far as applicable. If the Landlord does not consent to the Tenant's remaining in possession, Landlord shall have all the rights and remedies provided for by law and this Lease, including the right to recover consequential damages suffered by Landlord in the event of Tenant's wrongful refusal to relinquish possession of the Premises for a period of more than fifteen (15) days. The Base Rent applicable for the period that Tenant wrongfully remains in possession shall in be increased to one hundred fifty percent (150%) of the rate of Base Rent in effect on the expiration or termination of the

Lease Term for the first thirty (30) days of such unauthorized holdover and thereafter to twice the rate of Base Rent in effect on the expiration or termination of the Lease Term.

3.7 **Late Charge.** If Tenant fails to make any payment of Base Rent, Additional Rent or other amount when due under this Lease, a late charge is immediately due and payable by Tenant equal to five percent (5%) of the amount of any such payment. Landlord and Tenant agree that this charge compensates Landlord for the administrative costs caused by the delinquency. The parties agree that Landlord's damage would be difficult to compute and the amount stated in this paragraph represents a reasonable estimate of such damage. Assessment or payment of the late charge contemplated in this paragraph shall not excuse or cure any Event of Default or breach by Tenant under this Lease or impair any other right or remedy provided under this Lease or under law.

3.8 **Default Rate.** Any Base Rent, Additional Rent or other sum payable under this Lease which is not paid when due shall bear interest at a rate equal to the lesser of: (a) the published prime or reference rate then in effect at a national banking institution designated by Landlord (the "Prime Rate"), plus four (4) percentage points, or (b) the maximum rate of interest per annum permitted by applicable law (the "Default Rate"), but the payment of such interest shall not excuse or cure any Event of Default or breach by Tenant under this Lease or impair any other right or remedy provided under this Lease or under law.

SECTION 4: MANAGEMENT AND LEASING PROVISIONS

4.1 **Maintenance and Repair by Landlord.**

4.1.1 Subject to the paragraphs captioned "Damage or Destruction" and "Condemnation", Landlord shall endeavor to maintain the public and common areas of the Building in reasonably good order and condition subject to reasonable wear and tear. Landlord shall make such repairs thereto as become necessary after obtaining actual knowledge of the need for such repairs. All repair costs shall be included in Operating Costs, except for damage occasioned by the act or omission of Tenant or Tenant's Agents which shall be paid for entirely by Tenant upon demand by Landlord. In the event any or all of the Building becomes in need of maintenance or repair which Landlord is required to make under this Lease, Tenant shall immediately give written notice to Landlord, and Landlord shall not be obligated in any way to commence such maintenance or repairs until a reasonable time elapses after Landlord's receipt of such notice.

4.1.2 Landlord shall not be liable by reason of any injury to or interference with Tenant/s business arising from the making of any repairs, alterations, additions or improvements in or to the Premises or the Building or to any appurtenances or equipment therein. There shall be no abatement of rent because of such repairs, alterations, additions or improvements or because of any delay by Landlord in making the same.

4.2 **Maintenance and Repair by Tenant.**

4.2.1 Except as is expressly set forth as Landlord's responsibility pursuant to the paragraph captioned "Maintenance and Repair by Landlord," Tenant shall at Tenant's sole cost and expense keep, clean and maintain the Premises in good condition and repair, including interior painting, cleaning of the interior side of all exterior glass, plumbing and utility fixtures and installations, carpets and floor coverings, all interior wall surfaces and coverings (including tile and paneling), window replacement, exterior and interior doors, roof penetrations and membranes in connection with any Tenant installations on the roof, light bulb replacement (which lighting purchases must comply with Landlord's sustainability practices and shall be reported to Landlord in a format suitable to Landlord) and interior preventative maintenance. All maintenance and repairs made by Tenant must comply with Landlord's sustainability practices and any applicable Green Agency Rating, as the same may change from time to time. If Tenant fails to maintain or repair the Premises in accordance with this paragraph, then Landlord may, but shall not be required to, enter the Premises upon two (2) Business Days prior written notice to Tenant (or immediately without any notice in the case of an emergency) to perform such maintenance or repair at Tenant's sole cost and expense. Tenant shall pay to Landlord the cost of such maintenance or repair plus a five percent (5%) administration fee within ten (10) Business Days of written demand from Landlord.

4.2.2 Without limiting the generality of paragraphs 3.5.5 or 4.2.1 hereof, Tenant shall be responsible at Tenant's sole cost and expense for the maintenance, repair and/or replacement of any special heating, ventilating, air conditioning, plumbing, electrical or other systems and fixtures installed solely to service the Premises, whether installed or paid for by Landlord or Tenant.

4.3 **Common Areas/Security.**

4.3.1 The common areas of the Building shall be subject to Landlord's sole management and control. Without limiting the generality of the immediately preceding sentence, Landlord reserves the exclusive right as it deems necessary or desirable to install, construct, remove, maintain and operate lighting systems, facilities, improvements, equipment, Telecommunication Facilities and signs on, in or to all parts of the common areas; change the number, size, height, layout, or locations of walks, driveways and truckways or parking areas now or later forming a part of the Land or Building; make alterations or additions to the Building or common area; close temporarily all or any portion of the common areas to make repairs, changes or to avoid public dedication; grant easements to which the Land will be subject; replat, subdivide, or make other changes to the Land; place or relocate or cause to be placed or located utility lines and Telecommunication Facilities through, over or under the Land and Building; and use or permit the use of all or any portion of the roof of the Building. Landlord reserves the right to relocate parking areas and driveways (if any) and to build additional improvements in the common areas.

4.3.2 Landlord has no duty or obligation to provide any security services in, on or around the Premises, Land or Building, and Tenant recognizes that security services, if any, provided by Landlord will be for the sole benefit of Landlord and the protection of Landlord's property and under no circumstances shall Landlord be responsible for, and Tenant waives any rights with respect to, Landlord providing security or other protection for Tenant or Tenant's Agents or property in, on or about the Premises, Land or Building. Subject to Landlord's prior approval, Tenant may, at its sole cost and expense, install, establish and maintain security services within the Premises; provided that, such security services (including any apparatus, facilities, equipment or people utilized in connection with the provision of such security services) comply with the Governmental Requirements and shall not cause the Building to be out of compliance with the Governmental Requirements. Notwithstanding the foregoing, any such security services installed, established or maintained by Tenant must not affect or impact any portion of the Building or the Land other than the Premises and shall not in any way limit or interfere with Landlord's ability to exercise its rights as provided in the paragraph captioned "Access". Tenant's rights under this subparagraph are subject to all the obligations, limitations and requirements as set forth in the paragraphs captioned "Tenant Alterations" and "Tenant's Work Performance".

4.4 Tenant Alterations. Tenant shall not make any alterations, additions or improvements in or to the Premises, or make changes to locks on doors, or add, disturb or in any way change any floor covering, wall covering, fixtures, plumbing, wiring or Telecommunication Facilities (individually and collectively "Tenant Alterations"), without first obtaining the consent of Landlord which may be withheld in Landlord's absolute discretion. Notwithstanding the foregoing, upon at least fifteen (15) Business Days advance written notice to Landlord but without Landlord's consent, Tenant may make interior non-structural Tenant Alterations with an aggregate cost which does not exceed Twenty-Five Thousand Dollars ($25,000.00) in any period of twelve (12) consecutive calendar months which (a) are entirely cosmetic or functional in nature (such as painting and carpeting, shelving or cubicles), (b) do not affect any of the Building's mechanical, HVAC, electrical, plumbing or other systems, (c) do not involve the installation or demolition of any interior wall or door, and (d) do not require the issuance of any permit by any Governmental Agency (Tenant Alterations satisfying all of the foregoing items (a) through (d) are referred to herein as "Permitted Alterations"). Tenant shall deliver to Landlord full and complete plans and specifications for any proposed Tenant Alterations. All Permitted Alterations shall be performed at Tenant's expense by Tenant and, if consent by Landlord is required and given for any Tenant Alterations, all such work shall be performed at Tenant's expense by Landlord or by Tenant at Landlord's election . Tenant shall pay to Landlord all costs incurred by Landlord for any architecture, engineering, supervisory and/or legal services in connection with any Tenant Alterations, including, without limitation, Landlord's review of the Plans and Specifications. Without limiting the generality of the foregoing, Landlord may require Tenant (if Landlord has elected to require Tenant to perform the Tenant Alterations or if Tenant is performing Permitted Alterations), at Tenant's sole cost and expense, to obtain and provide Landlord with proof of insurance coverage and a payment and performance bond, in forms, amounts and by companies acceptable to Landlord. Should Tenant make any alterations without Landlord's prior written consent, or without satisfaction of any conditions established by Landlord, Landlord shall have the right, in addition to and without limitation of any right or remedy Landlord may have under this Lease, at law or in equity, to require Tenant to remove some or all of Tenant Alterations, or at Landlord's election, Landlord may remove such Tenant Alterations and restore the Premises at Tenant's expense. Nothing contained in this paragraph or the paragraph captioned "Tenant's Work Performance" shall be deemed a waiver of the provisions of the paragraph captioned "Mechanic's Liens".

4.5 Tenant's Work Performance. If Landlord elects to require Tenant to perform the Tenant Alterations, Landlord may, in its absolute discretion, require that Tenant provide a payment and performance bond to cover the entire work to be performed, which bond must be in form, amount and by a company acceptable to Landlord. Any Tenant Alterations to be performed under this paragraph shall be performed by contractors approved by Landlord and employed by Tenant under one or more construction contracts, in form and content approved in advance in writing by Landlord. Approval shall be subject to Landlord's discretion and shall include a requirement that the prime contractor and the respective subcontractors of any tier performing the Tenant Alterations: (a) be parties to, and bound by, a collective bargaining agreement with a labor organization affiliated with the Building and Construction Trades Council of the AFL-CIO applicable to the geographic area in which the Building is located and to the trade or trades in which the work under the contract is to be performed and (b) employ only members of such labor organizations to perform work within their respective jurisdictions. The previous sentence shall apply whether it is Landlord or Tenant performing or contracting for any such alterations, additions, improvements or installations. Waivers or exceptions to the requirement in the third sentence of this paragraph may be given only in writing by Landlord. With the specific, prior written approval of Landlord, which may be withheld in Landlord's sole and absolute discretion, in clause (a) of the third sentence of this paragraph the following substitutions may be made: (1) a project labor agreement in place of a collective bargaining agreement, and (2) an independent, nationally recognized labor organization in place of a labor organization affiliated with the Building and Construction Trades Council of the AFL-CIO. Tenant's contractors, workers and suppliers shall work in harmony with and not interfere with workers or contractors of Landlord or other tenants of Landlord. If Tenant's contractors, workers or suppliers do, in the opinion of Landlord, cause such disharmony or interference, Landlord's consent to the continuation of such work may be withdrawn upon written notice to Tenant. All Tenant Alterations shall be (1) completed in accordance with the plans and specifications approved by Landlord; (2) completed in accordance with all Governmental Requirements; (3) carried out promptly in a good and workmanlike manner; (4) of all new materials; and (5) free of defect in materials and workmanship. In addition to the above requirements, Tenant shall use commercially reasonable efforts to contract for services to be performed in or about the Premises with companies which are a Responsible Contractor. A "Responsible Contractor" is defined as a contractor or subcontractor who pays workers a fair wage and Fair Benefits as evidenced by payroll and employee records and who complies with a service-disabled veteran business policy. "Fair Benefits" are defined as including employer-paid family health care coverage, pension benefits, and apprenticeship programs. Any and all Tenant Alterations that affects at least fifty percent (50%) of the Premises will be performed in accordance with Landlord's sustainability practices, (as same may be in effect or amended or supplemented from time to time) and any Green Agency Ratings, as the same may change from time to time. Tenant further agrees to engage a qualified third party LEED or Green Globe Accredited Professional or similarly qualified professional during the design phase through implementation of any Tenant Alterations covered by the preceding sentence, in order to review all plans, material procurement, demolition, construction and waste management procedures to ensure they are in full conformance to Landlord's sustainability practices, as aforesaid, and Tenant agrees to seek and maintain LEED for Commercial Interiors certification for such Tenant Alterations. Tenant shall pay for all damage to the Premises, Building and Land caused by Tenant or Tenant's Agents. Tenant shall indemnify, defend and hold harmless Landlord and Landlord's Agents from any Claims arising as a result of the Tenant Alterations or any defect in design, material or workmanship of any Tenant Alterations.

4.6 Surrender of Possession. Tenant shall, at the expiration or earlier termination of this Lease, surrender and deliver the Premises to Landlord in as good condition as when received by Tenant from Landlord or as later improved, reasonable use and wear excepted, and free from all tenancies or occupancies by any person.

4.7 Removal of Property. Unless otherwise agreed to in writing by Landlord, Tenant agrees that there are and shall be no trade fixtures in the Premises owned by Tenant. Upon expiration or earlier termination of this Lease, Tenant may remove its personal property, office supplies and office furniture and equipment if (a) such items are readily moveable and are not attached to the Premises; (b) such removal is completed prior to the expiration or earlier termination of this Lease; (c) Tenant is not in default of any covenant or condition of this Lease at the time of such removal; and (d) Tenant immediately repairs all damage caused by or resulting from such removal. All other property in the Premises and any Tenant Alterations (including, wall-to-wall carpeting, paneling, wall covering, lighting fixtures and apparatus or Telecommunication Facilities or any other article affixed to the floor, walls, ceiling or any

other part of the Premises or Building) shall become the property of Landlord and shall remain upon and be surrendered with the Premises; provided, however, at Landlord's sole election, Tenant shall be obligated, at its sole cost and expense, to remove all (or such portion as Landlord shall designate) of the Tenant Alterations (including Telecommunication Facilities), repair any damages resulting from such removal and return the Premises to the same condition as existed prior to such Tenant Alterations. Tenant waives all rights to any payment or compensation for such Tenant Alterations (including Telecommunication Facilities). If Tenant shall fail to remove any of its property from the Premises, Building or Land at the expiration or earlier termination of this Lease or when Landlord has the right of re-entry, Landlord may, at its option, remove and store such property at Tenant's expense without liability for loss of or damage to such property, such storage to be for the account and at the expense of Tenant. Tenant shall pay all costs incurred by Landlord within five (5) Business Days after demand for such payment. **If** Tenant fails to pay the cost of storing any such property, Landlord may, at its option, after it has been stored for a period of twenty (20) Business Days or more, sell or permit to be sold, any or all such property at public or private sale (and Landlord may become a purchaser at such sale), in such manner and at such times and places as Landlord in its sole discretion may deem proper, without notice to Tenant, and Landlord shall apply the proceeds of such sale: *first,* to the cost and expense of such sale, including reasonable attorney's fees actually incurred; *second*, to the payment of the costs or charges for storing any such property; *third,* to the payment of any other sums of money which may then be or later become due Landlord from Tenant under this Lease; and, *fourth,* the balance, if any, to Tenant.

4.8 **Access.** Tenant shall permit Landlord and Landlord's Agents to enter into the Premises and the Rooftop Deck at any time on at least one (1) Business Day's notice (except in case of emergency in which case no notice shall be required), for the purpose of inspecting the same or for the purpose of repairing, altering or improving the Premises or the Building. Nothing contained in this paragraph shall be deemed to impose any obligation upon Landlord not expressly stated elsewhere in this Lease. When reasonably necessary, Landlord may temporarily close Building or Land entrances, Building doors or other facilities, without liability to Tenant by reason of such closure and without such action by Landlord being construed as an eviction of Tenant or as relieving Tenant from the duty of observing or performing any of the provisions of this Lease. Landlord shall have the right to enter the Premises and the Rooftop Deck at any time during the Lease Term for the purpose of showing the Premises to prospective tenants and to erect on the Premises a suitable sign indicating the Premises are available. Tenant shall give written notice to Landlord at least twenty (20) Business Days prior to vacating the Premises and shall arrange to meet with Landlord for a joint inspection of the Premises and Rooftop Deck prior to vacating. In the event of Tenant's failure to give such notice or arrange such joint inspection, Landlord's inspection at or after Tenant's vacating the Premises shall be conclusively deemed correct for purposes of determining Tenant's responsibility for repairs and restoration. Landlord shall not be liable for the consequences of admitting by passkey, or refusing to admit to the Premises, Tenant or any of Tenant's Agents, or other persons claiming the right of admittance.

4.9 **Damage or Destruction.**

4.9.1 If the Premises or the Rooftop Deck are damaged by fire, earthquake or other casualty, Tenant shall give immediate written notice thereof to Landlord. If Landlord estimates that the damage can be repaired in accordance with the then-existing Governmental Requirements within one hundred-twenty (120) Business Days after Landlord is notified by Tenant of such damage and if there are sufficient insurance proceeds available to repair such damage, then Landlord shall proceed with reasonable diligence to restore the Premises to substantially the condition which existed prior to the damage and this Lease shall not terminate. **If,** in Landlord's estimation, the damage cannot be repaired within such one hundred-twenty (120) Business Day period or if there are insufficient insurance proceeds available to repair such damage, Landlord may elect in its absolute discretion to either: (a) terminate this Lease or (b) restore the Premises to substantially the condition which existed prior to the damage and this Lease will continue. If Landlord restores the Premises under this paragraph, then Landlord shall use commercially reasonable efforts to proceed toward completion of the restoration and (1) the Lease Term shall be extended for the time required to complete such restoration, (2) Tenant shall pay to Landlord, upon demand, Tenant's Pro Rata Share of any applicable deductible amount specified under Landlord's insurance and (3) notwithstanding anything to the contrary contained herein, Landlord shall not be required to repair or restore Tenant Improvements, Tenant Alterations (including Telecommunication Facilities), or any or all furniture, fixtures, equipment, inventory, improvements or other property which

was in or about the Premises at the time of the damage and was not owned by Landlord. Base Rent, Additional Rent and any other sum due under this Lease during any reconstruction period shall not be abated. Tenant agrees to look to the provider of Tenant's insurance for coverage for the loss of Tenant's use of the Premises and any other related losses or damages incurred by Tenant during any reconstruction period.

4.9.2 If the Building is damaged by fire, earthquake or other casualty and more than fifty percent (50%) of the Building is rendered untenantable, without regard to whether the Premises are affected by such damage, Landlord may in its absolute discretion and without limiting any other options available to Landlord under this Lease or otherwise, elect to terminate this Lease by notice in writing to Tenant within forty (40) Business Days after the occurrence of such damage if Landlord is also terminating the leases of other tenants in the Building who are similarly situated to Tenant. Such notice shall be effective twenty (20) Business Days after receipt by Tenant unless a later date is set forth in Landlord's notice.

4.9.3 Notwithstanding anything contained in this Lease to the contrary, if there is damage to the Premises or Building and the holder of any indebtedness secured by a mortgage or deed of trust covering any such property requires that the insurance proceeds be applied to such indebtedness or if the insurance proceeds are otherwise inadequate to complete the repair of the damages to the Premises, the Building or both, then Landlord shall have the right to terminate this Lease by delivering written notice of termination to Tenant within fifteen (15) Business Days after Landlord is notified of such requirement.

4.9.4 Notwithstanding the foregoing, if the Premises or the Building are wholly or partially damaged or destroyed within the final six (6) months of the Term, Landlord may, at its option, elect to terminate this Lease upon written notice to Tenant within thirty (30) days following such damage or destruction.

4.10 **Condemnation.** If all of the Premises, or such portions of the Building as may be required for the Tenant's reasonable use of the Premises, are taken by eminent domain or by conveyance in lieu thereof, this Lease shall automatically terminate as of the date the physical taking occurs, and all Base Rent, Additional Rent and other sums payable under this Lease shall be paid to that date. In case of taking of a part of the Premises or a portion of the Building not required for the Tenant's reasonable use of the Premises, then this Lease shall continue in full force and effect and the Base Rent shall be equitably reduced based on the proportion by which the floor area of the Premises is reduced, such reduction in Base Rent to be effective as of the date the physical taking occurs. Additional Rent and all other sums payable under this Lease shall not be abated but Tenant's Pro Rata Share may be redetermined as equitable under the circumstances. Landlord reserves all rights to damages or awards for any taking by eminent domain relating to the Premises, Building, Land and the unexpired term of this Lease. Tenant assigns to Landlord any right Tenant may have to such damages or award and Tenant shall make no claim against Landlord for damages for termination of its leasehold interest or interference with Tenant's business. Tenant shall have the right, however, to claim and recover from the condemning authority compensation for any loss to which Tenant may be entitled for Tenant's moving expenses or other relocation costs; provided that, such expenses or costs may be claimed only if they are awarded separately in the eminent domain proceedings and not as a part of the damages recoverable by Landlord.

4.11 **Parking.**

4.11.1 Upon Tenant's request made on or before the Commencement Date, Landlord shall cause the operator (the "Garage Operator") of the parking garage (the "Garage") in the Building to enter into a license agreement or license agreements with Tenant pursuant to which the Garage Operator shall grant Tenant a license to use up to fifteen (15) reserved parking spaces (the "Reserved Parking Spaces") in the Garage on a month-to month basis during the Lease Term at the monthly parking rates in effect from time to time as established by the Garage Operator and on the terms set forth therein. In addition, Tenant shall be responsible for the full amount of any taxes imposed by any governmental authority in connection with the licensing of such parking spaces by Tenant or the use of the Garage by Tenant. Tenant's continued right to use the Reserved Parking Spaces is conditioned upon Tenant's payment of all monthly parking fees. The Reserved Parking Spaces initially shall be located on the first floor of the Garage (a plan depicting the first floor of the Garage is attached as Exhibit J) and closest to the elevator entrance, provided, however, Landlord and the Garage Operator reserve the right in their discretion to relocate the Reserved Parking Spaces from time to time upon not less than ten (10) Business Days' notice to Tenant. Notwithstanding the foregoing, neither Landlord nor the Garage Operator shall relocate the Reserved Parking Spaces except as Landlord and/or the Garage Operator reasonably determine may

be necessary for construction, safety or to comply with any Governmental Requirements. Landlord shall have no obligation to monitor the use of the Garage, nor shall Landlord be responsible for any loss or damage to any vehicle or other property or for any injury to any person. Tenant's Reserved Parking Spaces shall be used only for parking of automobiles no larger than full size passenger automobiles, sport utility vehicles or pick-up trucks. Tenant's license to use such parking spaces in the Garage shall be subject to the reasonable rules and regulations relating to parking adopted by Garage Operator and/or the Landlord from time to time.

4.11.2 No more often than once during any ninety (90) day period, Tenant may reduce the number of Reserved Parking Spaces to be made available to Tenant hereunder by giving Garage Operator and Landlord at least sixty (60) days advance written notice thereof. If Tenant shall have released any Reserved Parking Spaces, subject to availability as determined by Garage Operator Tenant shall have the right from time to time (but not more than once in any ninety (90) day period) upon not less than ninety (90) days advance written notice to Garage Operator and Landlord to increase the number of Reserved Parking Spaces (the location of which shall be mutually agreed upon by Tenant and the Garage Operator) to be made available up to the maximum number of parking spaces provided for in Paragraph 4.11.1 hereof.

4.11.3 Subject to Tenant obtaining any and all necessary governmental permits and approvals and the terms and conditions set forth herein, Tenant shall have the right to brand the Reserved Parking Spaces from time to time licensed by Tenant pursuant to the terms hereof with Duck Creek Technologies LLC signage (the "Parking Identification Signs"), provided that the exact size, location, colors, design, and specifications of the Parking Identification Signs shall be subject to Landlord's prior written approval and compliance with any Building signage criteria. Any and all costs in connection with the permitting, fabrication, installation and maintenance of the Parking Identification Signs shall be borne by Tenant. Tenant agrees to maintain the Parking Identification Signs in good condition at all times. Upon vacation of the Premises on the expiration or earlier termination of this Lease or at such earlier time as to any Reserved Parking Space no longer licensed by Tenant, Tenant shall be responsible, at its sole cost, for the removal of all (or the applicable) Parking Identification Signs and for the repair of any damage to the Garage or the remainder of the Building caused by such removal. If Tenant fails to perform such work after written notice from Landlord, Landlord may cause the same to be performed and the reasonable cost thereof shall be Additional Rent immediately due and payable within thirty (30) days after Landlord's delivery of a written demand and a supporting invoice for same.

4.11.4 The parking spaces licensed by Tenant pursuant to this Paragraph 4.11 are provided to the Original Tenant solely for use by Original Tenant's own personnel and such Reserved Parking Spaces may not otherwise be transferred, assigned, subleased or otherwise alienated by Tenant without Landlord's prior approval.

4.11.5 Neither the Garage Operator nor the Landlord shall have any obligation whatsoever to monitor, secure or police the use of the parking or other common areas.

4.12 Indemnification.

4.12.1 Tenant shall indemnify, defend and hold harmless Landlord and Landlord's Agents from and against any and all Claims, arising in whole or in part out of (a) the possession, use or occupancy of the Premises or the business conducted in the Premises, (b) any act, omission or negligence of Tenant or Tenant's Agents, or (c) any breach or default under this Lease by Tenant.

4.12.2 Except to the extent resulting from the negligence or willful misconduct of Tenant or any of Tenant's Agents as finally determined by a court of competent jurisdiction and subject to the terms of Paragraph 4.15 hereof Landlord shall indemnify, defend and hold harmless Tenant from and against any and all Claims, to the extent arising out of any negligence of Landlord or Landlord's Agents in failing to repair or maintain the Building as required by this Lease after notice by Tenant as required by the paragraph captioned "Maintenance and Repair by Landlord"; but in no event shall Landlord's responsibility extend to any interruption to Tenant's business or any indirect or consequential losses suffered by Tenant or Tenant's Agents or extend beyond Landlord's responsibility as set forth in the paragraph entitled "Utilities" when that paragraph is applicable.

4.12.3 Except as specified in the next sentence, neither Landlord nor Landlord's Agents shall, to the extent permitted by law, have any liability to Tenant, or to Tenant's Agents, for (1) any Claims arising out of any cause whatsoever, including repair to any portion of the Premises; (2) interruption in or interference with the use of the Premises or any equipment therein; (3) any accident or damage resulting from any use or operation by Landlord, Tenant or any person or entity of heating, cooling, electrical,

sewerage or plumbing equipment or apparatus or Telecommunication Facilities; (4) termination of this Lease by reason of damage to the Premises or Building; (5) fire, robbery, theft, vandalism, mysterious disappearance or a casualty of any kind or nature; (6) actions of any other tenant of the Building or of any other person or entity; (7) inability to furnish any service required of Landlord as specified in this Lease; or (8) leakage in any part of the Premises or the Building from rain, ice or snow, or from drains, pipes or plumbing fixtures in the Premises or the Building. Landlord shall be responsible only for Claims arising solely out of the negligence or willful misconduct of Landlord in failing to repair or maintain the Building as required by this Lease after notice by Tenant as required by the paragraph captioned "Maintenance and Repair by Landlord"; but in no event shall Landlord's responsibility extend to any interruption to Tenant's business or any indirect or consequential losses suffered by Tenant or Tenant's Agents or extend beyond Landlord's responsibility as set forth in the paragraph entitled "Utilities" when that paragraph is applicable. The obligations of this paragraph shall be subject to the paragraph captioned "Waiver of Subrogation".

4.13 Tenant Insurance.

4.13.1 Tenant shall, throughout the Lease Term, at its own expense, keep and maintain in full force and effect the following policies, each of which shall be endorsed as needed to provide that the insurance afforded by these policies is primary and that all insurance carried by Landlord is strictly excess and secondary and shall not contribute with Tenant's liability insurance:

(a) A policy of commercial general liability insurance, including a contractual liability endorsement covering Tenant's obligations under the paragraph captioned "Indemnification", insuring against claims of bodily injury and death or property damage or loss with a combined single limit at the Commencement Date of this Lease of not less than Two Million Dollars ($2,000,000.00), which limit shall be reasonably increased during the Lease Term at Landlord's request to reflect both increases in liability exposure arising from inflation as well as from changing use of the Premises or changing legal liability standards, which policy shall be payable on an "occurrence" rather than a "claims made" basis, and which policy names Landlord, Bentall Kennedy (U.S.) Limited Partnership, the Manager and, at Landlord's request, Landlord's mortgage lender(s) and/or investment advisors, as additional insureds;

(b) A policy of extended property insurance (which is commonly called "all risk") covering Tenant Improvements, Tenant Alterations (including Telecommunication Facilities), and any and all furniture, fixtures, equipment, inventory, improvements and other property in or about the Premises which is not owned by Landlord, for one hundred percent (100%) of the then current replacement cost of such property;

(c) Business interruption insurance in an amount sufficient to cover costs, damages, lost income, expenses, Base Rent, Additional Rent and all other sums payable under this Lease, should any or all of the Premises not be usable for a period of up to twelve (12) months;

(d) A policy of worker's compensation insurance as required by applicable law and employer's liability insurance with limits of no less than One Million Dollars ($1,000,000.00); and

(e) A policy of comprehensive automobile liability insurance, including loading and unloading, and covering owned, non-owned and hired vehicles, with limits of no less than One Million Dollars ($1,000,000.00) per occurrence.

4.13.2 All insurance policies required under this paragraph shall be with companies reasonably approved by Landlord and each policy shall provide that it is not subject to cancellation, lapse or reduction in coverage except after thirty (30) days' written notice to Landlord. Prior to the Commencement Date and from time to time thereafter, Tenant shall deliver to Landlord, Bentall Kennedy (U.S.), LP, the Manager, and, at Landlord's request, any other parties hereunder required to be named as additional insureds, certificates evidencing the existence and amounts of all such policies.

4.13.3 If Tenant fails to acquire or maintain any insurance or provide any certificate required by this paragraph, Landlord may, but shall not be required to, obtain such insurance or certificates and the costs associated with obtaining such insurance or certificates shall be payable by Tenant to Landlord on demand.

4.14 Landlord's Insurance. Landlord shall, throughout the Lease Term, keep and maintain in full force and effect:

4.14.1 A policy of commercial general liability insurance, insuring against claims of bodily injury and death or property damage or loss with a combined single limit at the Commencement Date of not less than One Million Dollars ($1,000,000.00) per occurrence and Two Million Dollars ($2,000,000.00) in the aggregate, which policy shall be payable on an "occurrence" rather than a "claims made" basis;

4.14.2 A policy of extended property insurance (what is commonly called "all risk") covering the Building and Landlord's personal property, if any, located on the Land in the amount of one hundred percent (100%) of the then current replacement value of such property; and

4.14.3 Landlord may, but shall not be required to, maintain other types of insurance as Landlord deems appropriate, including but not limited to, property insurance coverage for earthquakes and floods in such amounts as Landlord deems appropriate. Such policies may be "blanket" policies which cover other properties owned by Landlord.

4.15 Waiver of Subrogation. Notwithstanding anything in this Lease to the contrary, Landlord and Tenant hereby each waive and release the other from any and all Claims or any loss or damage that may occur to the Land, Building, Premises, or personal property located therein, by reason of fire or other casualty regardless of cause or origin, including the negligence or misconduct of Landlord, Tenant, Landlord's Agents or Tenant's Agents, but only to the extent of the insurance proceeds paid to such releasor under its policies of insurance or, if it fails to maintain the required policies, the insurance proceeds that would have been paid to such releasor if it had maintained such policies. Each party to this Lease shall promptly give to its insurance company written notice of the mutual waivers contained in this subparagraph, and shall cause its insurance policies to be properly endorsed, if necessary, to prevent the invalidation of any insurance coverages by reason of the mutual waivers contained in this subparagraph.

4.16 Assignment and Subletting by Tenant.

4.16.1 Tenant shall not have the right to assign, transfer, mortgage or encumber this Lease in whole or in part, nor sublet the whole or any part of the Premises, nor allow the occupancy of all or any part of the Premises by another, without first obtaining Landlord's written consent, which consent shall not be unreasonably withheld in the case of a proposed assignment or subletting provided that no Event of Default exists and further provided that the proposed assignee or subtenant (a) is not a tenant of the Building or any building located in Boston, Massachusetts owned by Landlord or an affiliate of Landlord, (b) is not a party from or to which Landlord or an affiliate of Landlord has received or issued a letter of intent or term sheet for the leasing of any space in the Building within the preceding six (6) months, and (c) will not use the Premises as a business which provides shared workspace and services (the "Restricted Use") for entrepreneurs, freelancers, startups, and other businesses, such as by way of example only, WeWork, Breather Products, and Regus. Notwithstanding any permitted assignment or subletting, Tenant shall at all times remain directly, primarily and fully responsible and liable for the payment of all sums payable under this Lease and for compliance with all of its other obligations as tenant under this Lease. Landlord's acceptance of Base Rent, Additional Rent or any other sum from any assignee, sublessee, transferee, mortgagee or encumbrance holder shall not be deemed to be Landlord's approval of any such conveyance. Upon the occurrence of an Event of Default, if the Premises or any part of the Premises are then subject to an assignment or subletting, Landlord may, at its option, collect directly from such assignee or subtenant all rents becoming due to Tenant under such assignment or sublease and apply such rents against any sums due to Landlord from Tenant under this Lease. No such collection shall be construed to constitute a novation or release of Tenant from the further performance of Tenant's obligations under this Lease. Landlord's right of direct collection shall be in addition to and not in limitation of any other rights and remedies provided for in this Lease or at law. Tenant makes an absolute assignment to Landlord of such assignments and subleases and any rent, lease security deposits and other sums payable under such assignments and subleases as collateral to secure the performance of the obligations of Tenant under this Lease.

4.16.2 In the event Tenant desires to assign this Lease or to sublet all or any portion of the Premises, Tenant shall give written notice of such desire to Landlord setting forth the name of the proposed subtenant or assignee, the proposed term, the nature of the proposed subtenant's or assignee's business to be conducted on the Premises, the rental rate, and any other particulars of the proposed subletting or assignment that Landlord may reasonably request. Without limiting the preceding sentence, Tenant shall also provide Landlord with: (a) such financial information as Landlord may request concerning the proposed subtenant or assignee, including recent financial statements certified as accurate and complete by a certified public accountant and by the president, managing partner or other appropriate officer of the proposed subtenant or assignee; (b) proof satisfactory to Landlord that the proposed subtenant or assignee will immediately occupy and thereafter use the entire Premises (or any sublet portion of the Premises) for the remainder of the Lease Term (or for the entire term of the sublease, if shorter) in compliance with the terms of this Lease; and (c) a copy of the proposed sublease or assignment or letter of intent. Tenant shall pay to Landlord, upon Landlord's demand therefor,

Landlord's reasonable attorneys' fees incurred in the review of such documentation and in documenting Landlord's consent , plus an administrative fee of $1,000.00 as Landlord's fee for processing such proposed assignment or sublease. Receipt of such fees shall not obligate Landlord to approve the proposed assignment or sublease.

4.16.3 In determining whether to grant or withhold consent to a proposed assignment or sublease, Landlord may consider, and weigh, any factor it deems relevant, in its sole and absolute discretion. In no event may Tenant or any assignee, subtenant or other occupant of any portion of the Premises use any portion of the Premises for the Restricted Use, provided that Landlord shall have the right to lease other portions of the Building for the Restricted Use.

4.16.4 Within fifteen (15) Business Days after Landlord's receipt of all required information to be supplied by Tenant pursuant to this paragraph, Landlord shall notify Tenant of Landlord's approval, disapproval or conditional approval of any proposed assignment or subletting or of Landlord's election to recapture as described below. Landlord shall have no obligation to respond unless and until all required information has been submitted. In the event Landlord approves of any proposed assignment or subletting, Tenant and the proposed assignee or sublessee shall execute and deliver to Landlord an assignment (or subletting) and assumption agreement in form and content satisfactory to Landlord.

4.16.5 Any transfer, assignment or hypothecation of any of the stock or interest in Tenant, or the assets of Tenant, or any other transaction, merger, reorganization or event, however constituted which (a) results in fifty percent (50%), or more of such stock, interest or assets going into different ownership, or (b) is a subterfuge denying Landlord the benefits of this paragraph, shall be deemed to be an assignment within the meaning and provisions of this paragraph and shall be subject to the provisions of this paragraph.

4.16.6 If Landlord consents to any assignment or sublease and Tenant receives rent or any other consideration, either initially or over the term of the assignment or sublease, in excess of the Base Rent and Additional Rent (or, in the case of a sublease of a portion of the Premises, in excess of the Base Rent paid by Tenant on a square footage basis under this Lease), Tenant shall pay to Landlord fifty percent (50%) of such excess.

4.16.7 Landlord shall have the right to recapture the Premises or the applicable portion thereof (a "Recapture") by giving written notice of such Recapture to Tenant within fifteen (15) Business Days after receipt of Tenant's written request for Landlord's consent to such proposed assignment or subletting. Tenant shall have no right to retract its request for Landlord's consent to assign or sublease once such request has been made. Such Recapture shall terminate this Lease as to the applicable space effective on the prospective effective date of assignment or subletting, which shall be the last day of a calendar month and shall not be earlier than forty-five (45) Business Days after receipt of Tenant's request hereunder. If less than the entire Premises are recaptured, this Lease shall remain in full force and effect with respect to that remaining area not recaptured by Landlord. Tenant shall surrender that portion of the Premises recaptured by Landlord in accordance with the terms and conditions of this Lease. Notwithstanding the first sentence of this subparagraph, Landlord shall have no right to Recapture the Premises or applicable portion thereof if (a) Tenant's proposed assignment or sublet together with any previous assignments and sublets encompass, in the aggregate, net rentable area equal to or less than seven thousand five hundred (7,500) rentable square feet and the term thereof shall expire at least two (2) years prior to the then expiration date of the Lease Term, or (b) Tenant's proposed assignment or sublet is made pursuant to Paragraph 4.16.8.

4.16.8 Notwithstanding anything to the contrary in this Lease, provided that all amounts due under this Lease have been paid in full and further provided that no_Event of Default exists, upon not less than fifteen (15) Business Days advance written notice to Landlord but without Landlord's consent, Tenant may assign this Lease or sublet all or any portion of the Premises to an Affiliate of the Tenant, provided that (a) Tenant has delivered to Landlord satisfactory evidence that the assignee or subtenant is an Affiliate of the Tenant, (b) such Affiliate assumes all of the liabilities and obligations of the Tenant under this Lease in a writing in form and substance reasonably satisfactory to Landlord, (c) such Affiliate has a tangible net worth immediately following such transaction certified to Landlord by the president, managing partner or other appropriate officer of the Affiliate (provided that if the Affiliate has or otherwise obtains audited financial statements, copies of same also shall be provided to Landlord) equal to or greater than the tangible net worth of Tenant as of the date of this Lease or the date immediately prior to such transaction (whichever is greater), in each case as determined in accordance with generally accepted accounting principles, (d) Tenant reimburses Landlord on demand for all reasonable costs and

expenses incurred by Landlord in determining compliance with the terms of this subparagraph 4.16.8, including reasonable attorneys' fees, and (e) such entity remains an Affiliate of the Original Tenant subsequent to the date of such assignment and for the remainder of the Lease Term (if such entity ever ceases to constitute an Affiliate of the Original Tenant, the same shall constitute an assignment of this Lease requiring Landlord's consent). In all events, Tenant shall remain liable for its obligations under this Lease despite any such transfer.

4.17 **Assignment by Landlord.** Landlord shall have the right to transfer and assign, in whole or in part, its rights and obligations under this Lease and in any and all of the Land or Building. If Landlord sells or transfers any or all of the Building, including the Premises, Landlord and Landlord's Agents shall, upon consummation of such sale or transfer, be released automatically from any liability relating to obligations or covenants under this Lease to be performed or observed after the date of such transfer, and in such event, Tenant agrees to look solely to Landlord's successor-in-interest with respect to such liability; provided that, as to the Lease Security Deposit and Prepaid Rent, Landlord shall not be released from liability therefor unless Landlord has delivered (by direct transfer or credit against the purchase price) the Lease Security Deposit or Prepaid Rent to its successor-in-interest.

4.18 **Estoppel Certificates and Financial Statements.** Tenant shall, from time to time, upon the written request of Landlord, execute, acknowledge and deliver to Landlord or its designee a written statement stating: (a) the date this Lease was executed and the date it expires; (b) the date Tenant entered into occupancy of the Premises; (c) the amount of monthly Base Rent and Additional Rent and the date to which such Base Rent and Additional Rent have been paid; and (d) certifying that (1) this Lease is in full force and effect and has not been assigned, modified, supplemented or amended in any way (or specifying the date of the agreement so affecting this Lease); (2) Landlord is not in breach of this Lease (or, if so, a description of each such breach) and that no event, omission or condition has occurred which would result, with the giving of notice or the passage of time, in a breach of this Lease by Landlord; (3) this Lease represents the entire agreement between the parties with respect to the Premises; (4) all required contributions by Landlord to Tenant on account of Tenant Improvements have been received; (5) on the date of execution, there exist no defenses or offsets which the Tenant has against the enforcement of this Lease by the Landlord; (6) no Base Rent, Additional Rent or other sums payable under this Lease have been paid in advance except for Base Rent and Additional Rent for the then current month; (7) no security has been deposited with Landlord (or, if so, the amount of such security); (8) it is intended that any Tenant's statement may be relied upon by a prospective purchaser or mortgagee of Landlord's interest or an assignee of any such mortgagee; and (9) such other information as may be reasonably requested by Landlord. If Tenant fails to respond within five (5) Business Days of its receipt of a written request by Landlord as provided in this paragraph, such shall be a breach of this Lease and Tenant shall be deemed to have admitted the accuracy of any information supplied by Landlord to a prospective purchaser, mortgagee or assignee. In addition, Tenant shall, from time to time, upon the written request of Landlord, deliver to or cause to be delivered to Landlord or its designee then current financial statements (including a statement of operations and balance sheet and statement of cash flows) certified as accurate by a certified public accountant and prepared in conformance with generally accepted accounting principles for (i) Tenant, (ii) any successor entity to Tenant by merger or operation of law, and (iii) any guarantor of this Lease. Notwithstanding the foregoing, Landlord shall not request such financial statements more than once in any calendar year, unless an Event of Default exists or such request is made in connection with a sale, financing or refinancing contemplated by Landlord.

4.19 **Modification for Lender.** If, in connection with obtaining construction, interim or permanent financing for the Building or Land Landlord's lender if any, shall request reasanable modifications to this Lease as a condition to such financing, Tenant will not unreasonably withhold or delay its consent to such modifications; provided that, such modifications do not increase the obligations of Tenant under this Lease or materially adversely affect Tenant's rights under this Lease.

4.20 **Hazardous Substances.**

4.20.1 Neither Tenant, any of Tenant's Agents nor any other person shall store, place, generate, manufacture, refine, handle, or locate on, in, under or around the Land or Building any Hazardous Substance, except for storage, handling and use of reasonable quantities and types of cleaning fluids and office supplies in the Premises in the ordinary course and the prudent conduct of Tenant's business in the Premises. Tenant agrees that (a) the storage, handling and use of such permitted Hazardous Substances must at all times conform to all Governmental Requirements and to applicable fire, safety and insurance requirements; (b) the types and quantities of permitted Hazardous Substances which are

stored in the Premises must be reasonable and appropriate to the nature and size of Tenant's operation in the Premises and reasonable and appropriate for a first-class building of the same or similar use and in the same market area as the Building; and (c) no Hazardous Substance shall be spilled or disposed of on, in, under or around the Land or Building or otherwise discharged from the Premises or any area adjacent to the Land or Building. In no event will Tenant be permitted to store, handle or use on, in, under or around the Premises any Hazardous Substance which will increase the rate of fire or extended coverage insurance on the Land or Building, unless: (1) such Hazardous Substance and the expected rate increase have been specifically disclosed in writing to Landlord; (2) Tenant has agreed in writing to pay any rate increase related to each such Hazardous Substance; and (3) Landlord has approved in writing each such Hazardous Substance, which approval shall be subject to Landlord's discretion.

4.20.2 Tenant shall indemnify, defend and hold harmless Landlord and Landlord's Agents from and against any and all Claims arising out of any breach of any provision of this paragraph, which expenses shall also include laboratory testing fees, personal injury claims, clean-up costs and environmental consultants' fees. Tenant agrees that Landlord may be irreparably harmed by Tenant's breach of this paragraph and that a specific performance action may appropriately be brought by Landlord; provided that, Landlord's election to bring or not bring any such specific performance action shall in no way limit, waive, impair or hinder Landlord's other remedies against Tenant.

4.20.3 As of the execution date of this Lease, Tenant represents and warrants to Landlord that, except as otherwise disclosed by Tenant to Landlord, Tenant has no intent to bring any Hazardous Substances on, in or under the Premises except for the type and quantities authorized in the first paragraph of the paragraph captioned "Hazardous Substances".

4.21 Access Laws.

4.21.1 Tenant agrees to notify Landlord immediately if Tenant receives notification or otherwise becomes aware of: (a) any condition or situation on, in, under or around the Land or Building which may constitute a violation of any Access Laws or (b) any threatened or actual lien, action or notice that the Land or Building is not in compliance with any Access Laws. If Tenant is responsible for such condition, situation, lien, action or notice under this paragraph, Tenant's notice to Landlord shall include a statement as to the actions Tenant proposes to take in response to such condition, situation, lien, action or notice.

4.21.2 Tenant shall not alter or permit any assignee or subtenant or any other person to alter the Premises in any manner which would violate any Access Laws or increase Landlord's responsibilities for compliance with Access Laws, without the prior approval of the Landlord. In connection with any such approval, Landlord may require a certificate of compliance with Access Laws from an architect, engineer or other person acceptable to Landlord. Tenant agrees to pay the reasonable fees incurred by such architect, engineer or other third party in connection with the issuance of such certificate of compliance. Landlord's consent to any proposed Tenant Alteration shall not (a) relieve Tenant of its obligations or indemnities contained in this paragraph or this Lease or (b) be construed as a warranty that such proposed alteration complies with any Access Law.

4.21.3 Tenant shall be solely responsible for all costs and expenses relating to or incurred in connection with: (a) failure of the Premises to comply with the Access Laws; and (b) bringing the Building and the common areas of the Building into compliance with Access Laws, if and to the extent such noncompliance arises out of or relates to: (1) Tenant's use of the Premises, including the hiring of employees; (2) any Tenant Alterations to the Premises; or (3) any Tenant Improvements constructed in the Premises at the request of Tenant, regardless of whether such improvements are constructed prior to or after the Commencement Date.

4.21.4 Landlord shall be responsible for all costs and expenses relating to or incurred in connection with bringing the common areas of the Building into compliance with Access Laws, unless such costs and expenses are Tenant's responsibility as provided in the preceding subparagraph. Any cost or expense paid or incurred by Landlord to bring the Premises or common areas of the Building into compliance with Access Laws which is not Tenant's responsibility under the preceding subparagraphs shall be amortized over the useful economic life of the improvements (not to exceed ten (10) years) with interest at the Prime Rate plus four (4) percentage points compounded daily, and shall be an Operating Cost for purposes of this Lease.

4.21.5 Tenant agrees to indemnify, defend and hold harmless Landlord and Landlord's Agents from and against any and all Claims arising out of or relating to any failure of Tenant or Tenant's Agents to comply with Tenant's obligations under this paragraph.

4.21.6 The provisions of this paragraph shall supersede any other provisions in this Lease regarding Access Laws, to the extent inconsistent with the provisions of any other paragraphs.

4.22 **Quiet Enjoyment.** Landlord covenants that Tenant, upon paying Base Rent, Additional Rent and all other sums payable under this Lease and performing all covenants and conditions required of Tenant under this Lease shall and may peacefully have, hold and enjoy the Premises without hindrance or molestation by Landlord subject to the provisions of this Lease.

4.23 **Sings.**

4.23.1 Tenant shall be permitted to have its entity name listed on the main directory sign for the Building situated in the main lobby of the Building. Tenant also shall be permitted to have one (1) entryway sign bearing Tenant's name next to Tenant's entryway into the Premises. Said sign shall be installed by Landlord at Tenant's expense and shall be of a size, design and coloration, and in a location consistent with Landlord's standard tenant entryway signage for the Building. Tenant shall reimburse Landlord for the cost of such entryway sign within ten (10) days of receipt of an invoice for same.

4.23.2 Notwithstanding anything to the contrary in the Rules and Regulations and subject to Tenant obtaining any and all necessary governmental approvals and the terms and conditions set forth herein, beginning on the Rent Commencement Date and during such portion of the Lease Term that the Original Tenant (or a Permitted Transferee of all of Tenant's rights under this Lease) itself continues to lease and actually use and occupy the entire tenth floor of the Building, Tenant shall have the non-exclusive right at Tenant's sole cost and expense to install and maintain an exterior signage plaque (a "Plaque") on the exterior of the Building identifying Tenant, provided, however, at Landlord's option the actual installation of the Plaque shall be performed by Landlord's contractors but at the Tenant's expense. The exact size, location, colors, design, and specifications of the Plaque shall be subject to Landlord's prior written approval and compliance with any Building signage criteria. Landlord shall have the right to grant other tenants of the Building the right to maintain identification signs or plaques on the exterior of the Building, provided that, as long as Tenant has the right to maintain the Plaque in accordance with the terms hereof and Tenant continues to lease more office space in the Building than any other tenant, such signs or plaques of other tenants of the Building (excluding any retail tenants) shall not be larger and more prominent than Tenant's Plaque. Prior to installation of its Plaque, Tenant shall obtain any and all necessary permits and approvals required by applicable Governmental Requirements. Thereafter, Tenant shall at all times maintain all necessary permits and approvals required by applicable Governmental Requirements in effect from time to time. Any and all costs in connection with the permitting, fabrication, installation and maintenance of the Plaque shall be borne by Tenant. The installation of Tenant's Plaque shall constitute a Tenant Alteration and, as such, shall be subject to all terms hereof applicable to Tenant Alterations, and without limiting the generality of the foregoing, such installation shall be subject to the terms and conditions of Paragraphs 4.4 and 4.5 (Tenant Alterations and Tenant Work Performance, respectively). Tenant agrees to maintain its Plaque in good condition at all times. Upon vacation of the Premises on the expiration or earlier termination of this Lease or at such earlier time as Tenant is no longer permitted to maintain its Plaque on the Building in accordance with the terms hereof, Tenant shall be responsible, at its sole cost, for the removal of such Plaque and for the repair of any damage to the Building caused by such removal. If Tenant fails to perform such work after written notice from Landlord, Landlord may cause the same to be performed and the reasonable cost thereof shall be Additional Rent immediately due and payable within thirty (30) days after Landlord's delivery of a written demand and a supporting invoice for same. Notwithstanding the foregoing or anything herein to the contrary, if, at any time during the Lease Term, the Original Tenant ceases to itself lease and actually use and occupy at least the entire tenth floor of the Building under this Lease and/or an Event of Default occurs, Landlord in its sole discretion may terminate Tenant's right to maintain the Plaque and may require Tenant to permanently remove the Plaque.

4.24 **Subordination.**

4.24.1 Tenant subordinates this Lease and all rights of Tenant under this Lease to any mortgage, deed of trust, ground lease or vendor's lien, or similar instrument which may from time to time be placed upon the Premises (and all renewals, modifications, replacements and extensions of such encumbrances), and each such mortgage, deed of trust, ground lease or lien or other instrument shall be superior to and prior to this Lease. Notwithstanding the foregoing, the holder or beneficiary of such mortgage, deed of trust, ground lease, vendor's lien or similar instrument shall have the right to subordinate or cause to be subordinated any such mortgage, deed of trust, ground lease, vendor's lien or similar instrument to this Lease or to execute a non-disturbance agreement in favor of Tenant on the

standard form utilized by such lender or ground lessor. At the request of Landlord, the holder of such mortgage or deed of trust or any ground lessor, Tenant shall execute, acknowledge and deliver promptly in recordable form any instrument or subordination agreement in the standard form customarily employed by such holder. Tenant further covenants and agrees that if the lender or ground lessor acquires the Premises as a purchaser at any foreclosure sale or otherwise, Tenant shall recognize and attorn to such party as landlord under this Lease, and shall make all payments required hereunder to such new landlord without deduction or set-off and, upon the request of such purchaser or other successor, execute, deliver and acknowledge documents confirming such attornment. Notwithstanding anything herein to the contrary, in no event shall the lender or ground lessor which acquires the Premises as a purchaser at any foreclosure sale or otherwise be (i) bound by any payment of Base Rent or Additional Rent for more than one month in advance, (ii) bound by any amendment or modification of this Lease made without the consent of the lender or ground lessor, (iii) liable in any way to Tenant for any act or omission, neglect or default on the part of the Landlord under this Lease (provided that the foregoing shall not relieve any successor landlord from the Landlord's maintenance and repair obligations under this Lease with respect to any condition existing as of the date such successor landlord acquires title to the Premises), (iv) obligated to perform any work or improvements to be done by Landlord in the Premises or to provide any tenant improvement or other allowance to Tenant, or (v) subject to any counterclaim or setoff which theretofore accrued to Tenant against Landlord. Tenant waives the provisions of any law or regulation, now or hereafter in effect, which may give or purport to give Tenant any right to terminate or otherwise adversely affect this Lease or the obligations of Tenant hereunder in the event that any such foreclosure or termination or other proceeding is prosecuted or completed.

4.24.2 If at any time during the Lease Term the Building is encumbered by a mortgage, then upon Tenant's written request, Landlord shall obtain for Tenant, at no cost to Landlord, a subordination, non-disturbance and attornment agreement from the holder of such mortgage, in the standard form customarily employed by such holder. Tenant shall reimburse Landlord, within ten (10) days after demand therefor, for Landlord's out-of-pocket costs, including fees charged by the holder(s) of any mortgage(s) and its or their counsel and other reasonable attorney's fees and disbursements, incurred in connection with such subordination, non-disturbance and attornment agreement.

4.25 **Workers Compensation Immunity.** If and to the extent that Tenant is obligated to indemnify, defend or hold harmless Landlord or Landlord's Agents from any Claims arising from its use of the Premises or any act or failure to act by Tenant or Tenant's Agents or otherwise, Tenant expressly waives, to and in favor of Landlord and Landlord's Agents, its statutory workers compensation act employers immunity relative to any injury to an employee or employees of Tenant.

4.26 **Brokers.** Each party to this Lease shall indemnify, defend and hold harmless the other party from and against any and all Claims asserted against such other party by any real estate broker, finder or intermediary relating to any act of the indemnifying party in connection with this Lease. Landlord shall be responsible for paying any commission or fee owed to Landlord's broker, CB Richard Ellis-N.E. Partners, LP, in connection with this Lease pursuant to a written agreement between CB Richard Ellis-N.E. Partners, LP and Landlord.

4.27 **Limitation on Recourse.** Landlord has executed this Lease by its authorized representative signing solely in a representative capacity. Notwithstanding anything contained in this Lease to the contrary, Tenant confirms that the covenants of Landlord are made and intended, not as personal covenants of the Landlord's authorized representative, or for the purpose of binding such authorized representative personally, but solely in the exercise of the representative powers conferred upon such authorized representative by their principal Liability with respect to the entry and performance of this Lease by or on behalf of Landlord, however it may arise, shall be asserted and enforced only against Landlord's estate and equity interest in the Building. Neither Landlord nor any of Landlord's Agents shall have any personal liability in the event of any claim against Landlord arising out of or in connection with this Lease, the relationship of Landlord and Tenant or Tenant's use of the Premises. Further, in no event whatsoever shall any Landlord's Agent have any liability or responsibility whatsoever arising out of or in connection with this Lease, the relationship of Landlord and Tenant or Tenant's use of the Premises. Any and all personal liability, if any, beyond that which may be asserted under this paragraph, is expressly waived and released by Tenant and by all persons claiming by, through or under Tenant.

4.28 **Mechanic's Liens and Tenant's Personal Property Taxes.**

4.28.1 Tenant shall have no authority, express or implied, to create or place any lien or encumbrance of any kind or nature whatsoever upon, or in any manner to bind, the interest of Landlord or

Tenant in the Premises or to charge the rentals payable under this Lease for any Claims in favor of any person dealing with Tenant, including those who may furnish materials or perform labor for any construction or repairs. Tenant shall immediately pay or cause to be paid all sums legally due and payable by it on account of any labor performed or materials furnished in connection with any work performed on the Premises on which any lien is or can be validly and legally asserted against its leasehold interest in the Premises and Tenant shall indemnify, defend and hold harmless Landlord from any and all Claims arising out of any such asserted Claims. Tenant agrees to give Landlord immediate written notice of any such Claim.

4.28.2 Tenant shall be liable for all taxes levied or assessed against personal property, furniture or fixtures placed by Tenant in the Premises. If any such taxes for which Tenant is liable are levied or assessed against Landlord or Landlord's property and Landlord elects to pay them or if the assessed value of Landlord's property is increased by inclusion of such personal property, furniture or fixtures and Landlord elects to pay the taxes based on such increase, Tenant shall reimburse Landlord for the sums so paid by Landlord, upon demand by Landlord.

4.29 **No Offset; Independent Covenants; Waiver.** Rent shall be paid without notice or demand, and without setoff, counterclaim, defense, abatement, suspension, deferment, reduction or deduction, except as expressly provided herein. Tenant waives all rights (i) to any abatement, suspension, deferment, reduction or deduction of or from Rent, except to the extent otherwise expressly set forth herein, and (ii) to quit, terminate or surrender this Lease or the Premises or any part thereof, except as expressly provided herein. **TENANT HEREBY ACKNOWLEDGES AND AGREES THAT THE OBLIGATIONS OF TENANT HEREUNDER SHALL BE SEPARATE AND INDEPENDENT COVENANTS AND AGREEMENTS, THAT RENT SHALL CONTINUE TO BE PAYABLE IN ALL EVENTS AND THAT THE OBLIGATIONS OF TENANT HEREUNDER SHALL CONTINUE UNAFFECTED, UNLESS THE REQUIREMENT TO PAY OR PERFORM THE SAME SHALL HAVE BEEN TERMINATED PURSUANT TO AN EXPRESS PROVISION OF THIS LEASE. LANDLORD AND TENANT EACH ACKNOWLEDGES AND AGREES THAT THE INDEPENDENT NATURE OF THE OBLIGATIONS OF TENANT HEREUNDER REPRESENTS FAIR, REASONABLE, AND ACCEPTED COMMERCIAL PRACTICE WITH RESPECT TO THE TYPE OF PROPERTY SUBJECT TO THIS LEASE, AND THAT THIS AGREEMENT IS THE PRODUCT OF FREE AND INFORMED NEGOTIATION DURING WHICH BOTH LANDLORD AND TENANT WERE REPRESENTED BY COUNSEL SKILLED IN NEGOTIATING AND DRAFTING COMMERCIAL LEASES IN MASSACHUSETTS, AND THAT THE ACKNOWLEDGEMENTS AND AGREEMENTS CONTAINED HEREIN ARE MADE WITH FULL KNOWLEDGE OF THE HOLDING IN WESSON V. LEONE ENTERPRISES, INC., 437 MASS. 708 (2002). SUCH WAIVER AND ACKNOWLEDGEMENTS BY TENANT ARE A MATERIAL INDUCEMENT TO LANDLORD ENTERING INTO THIS LEASE.**

SECTION 5: DEFAULT AND REMEDIES

5.1 **Events of Default.**

5.1.1 The occurrence of any one or more of the following events shall constitute a material default and breach of this Lease by Tenant ("Event of Default"):

(a) vacation or abandonment of all or any portion of the Premises;

(b) failure by Tenant to make any payment of Base Rent, Additional Rent or any other sum payable by Tenant under this Lease within five (5) days after written notice that such payment was not paid when due, provided, however, Landlord need not give any such notice nore than once in any twelve (12) month period, and any further failure by Tenant within any such twelve (12) month period to make any payment of Base Rent, Additional Rent or any other sum payable by Tenant under this Lease within five (5) days after its due date shall constitute an immediate Event of Default without any notice from Landlord;

(c) failure by Tenant to observe or perform any covenant or condition of this Lease, other than the making of payments, where such failure shall continue for a period of ten (10) Business Days after written notice from Landlord;

(d) the failure of Tenant to surrender possession of the Premises at the expiration or earlier termination of this Lease in the condition required by this Lease;

(e) (1) the making by Tenant of any general assignment or general arrangement for the benefit of creditors; (2) the filing by or against Tenant of a petition in bankruptcy, including reorganization

or arrangement, unless, in the case of a petition filed against Tenant, unless the same is dismissed within twenty (20) Business Days; (3) the appointment of a trustee or receiver to take possession of substantially all of Tenant's assets located in the Premises or of Tenant's interest in this Lease; (4) any execution, levy, attachment or other process of law against any property of Tenant or Tenant's interest in this Lease, unless the same is dismissed within twenty (20) Business Days; (5) adjudication that Tenant is bankrupt; (6) the making by Tenant of a transfer in fraud of creditors; or (7) the failure of Tenant to generally pay its debts as they become due; or

(f) any information furnished by or on behalf of Tenant to Landlord in connection with the entry of this Lease is determined to have been materially false, misleading or incomplete when made; or

(g) a failure of the Tenant to deliver the Letter of Credit within seven (7) calendar days of the Effective Date.

5.1.2 Tenant shall notify Landlord promptly of any Event of Default or any facts, conditions or events which, with the giving of notice or passage of time or both, would constitute an Event of Default.

5.1.3 If a petition in bankruptcy is filed by or against Tenant, and if this Lease is treated as an "unexpired lease" under applicable bankruptcy law in such proceeding, then Tenant agrees that Tenant shall not attempt nor cause any trustee to attempt to extend the applicable time period within which this Lease must be assumed or rejected.

5.2 **Remedies.** If any Event of Default occurs, Landlord may at any time after such occurrence, with or without notice or demand except as stated in this paragraph, and without limiting Landlord in the exercise of any right or remedy at law which Landlord may have by reason of such Event of Default, exercise the rights and remedies, either singularly or in combination, as are specified or described in the subparagraphs of this paragraph.

5.2.1 Landlord may terminate this Lease and all rights of Tenant under this Lease either immediately or at some later date by giving Tenant written notice that this Lease is terminated. If Landlord so terminates this Lease, then Landlord may recover from Tenant the sum of:

(a) the unpaid Base Rent, Additional Rent and all other sums payable under this Lease which have been earned at the time of termination;

(b) interest at the Default Rate on the unpaid Base Rent, Additional Rent and all other sums payable under this Lease which have been earned at the time of termination; plus

(c) the amount by which the unpaid Base Rent, Additional Rent and all other sums payable under this Lease which would have been earned after termination until the time of award exceeds the amount of such rental loss, if any, as Tenant affirmatively proves could have been reasonably avoided and interest on such excess at the Default Rate; plus

(d) the amount by which the aggregate of the unpaid Base Rent, Additional Rent and all other sums payable under this Lease for the balance of the Lease Term after the time of award exceeds the amount of such rental loss, if any, as Tenant affirmatively proves could be reasonably avoided, with such difference being discounted to present value at the Prime Rate at the time of award; plus

(e) any other amount necessary to compensate Landlord for the detriment proximately caused by Tenant's failure to perform Tenant's obligations under this Lease or which, in the ordinary course of things, would be likely to result from such failure, including, leasing commissions, tenant improvement costs, renovation costs and advertising costs; plus

(f) all such other amounts in addition to or in lieu of the foregoing as may be permitted from time to time by applicable law.

5.2.2 Landlord shall also have the right, with or without terminating this Lease, to re-enter the Premises and remove all persons and property from the Premises. Landlord may cause property so removed from the Premises to be stored in public warehouse or elsewhere at the expense and for the account of Tenant.

5.2.3 Intentionally Deleted.

5.2.4 If Tenant vacates, abandons or surrenders the Premises without Landlord's consent, or if Landlord re-enters the Premises as provided in subparagraph 5.2.2 or takes possession of the Premises pursuant to legal proceedings or through any notice procedure provided by law, then, if Landlord does not elect to terminate this Lease, Landlord may, from time to time, without terminating this Lease, either (a) recover all Base Rent, Additional Rent and all other sums payable under this Lease as they become due or (b) relet the Premises or any part of the Premises on behalf of Tenant for such term or terms, at such rent or rents and pursuant to such other provisions as Landlord, in its sole discretion, may deem

advisable, all with the right, at Tenant's cost, to make alterations and repairs to the Premises and recover any deficiency from Tenant as set forth in subparagraph 5.2.6.

5.2.5 None of the following remedial actions, singly or in combination, shall be construed as an election by Landlord to terminate this Lease unless Landlord has in fact given Tenant written notice that this Lease is terminated: (a) an act by Landlord to maintain or preserve the Premises; (b) any efforts by Landlord to relet the Premises; (c) any repairs or alterations made by Landlord to the Premises; (d) re-entry, repossession or reletting of the Premises by Landlord pursuant to this paragraph; or (e) the appointment of a receiver, upon the initiative of Landlord, to protect Landlord's interest under this Lease. If Landlord takes any of the foregoing remedial action without terminating this Lease, Landlord may nevertheless at any time after taking any such remedial action terminate this Lease by written notice to Tenant.

5.2.6 If Landlord relets the Premises, Landlord shall apply the revenue from such reletting as follows: *first,* to the payment of any indebtedness of Tenant to Landlord other than Base Rent, Additional Rent or any other sums payable by Tenant under this Lease; *second*, to the payment of any cost of reletting (including finders' fees and leasing commissions); *third,* to the payment of the cost of any alterations, improvements, maintenance and repairs to the Premises; and *fourth*, to the payment of Base Rent, Additional Rent and other sums due and payable and unpaid under this Lease. Landlord shall hold and apply the residue, if any, to payment of future Base Rent, Additional Rent and other sums payable under this Lease as the same become due, and shall deliver the eventual balance, if any, to Tenant. Should revenue from letting during any month, after application pursuant to the foregoing provisions, be less than the sum of the Base Rent, Additional Rent and other sums payable under this Lease and Landlord's expenditures for the Premises during such month, Tenant shall be obligated to pay such deficiency to Landlord as and when such deficiency arises.

5.2.7 Pursuit of any of the foregoing remedies shall not preclude pursuit of any of the other remedies provided in this Lease or by law (all such remedies being cumulative), nor shall pursuit of any remedy provided in this Lease constitute a forfeiture or waiver of any Base Rent, Additional Rent or other sum payable under this Lease or of any damages accruing to Landlord by reason of the violation of any of the covenants or conditions contained in this Lease.

5.3 Right to Perform. If Tenant shall fail to pay any sum of money, other than Base Rent or Additional Rent, required to be paid by it under this Lease or shall fail to perform any other act on its part to be performed under this Lease, and such failure shall continue for ten (10) Business Days after notice of such failure by Landlord, or such shorter time if reasonable under the circumstances, Landlord may, but shall not be obligated to, and without waiving or releasing Tenant from any obligations of Tenant, make such payment or perform such other act on Tenant's part to be made or performed as provided in this Lease. Landlord shall have (in addition to any other right or remedy of Landlord) the same rights and remedies in the event of the nonpayment of sums due under this paragraph as in the case of default by Tenant in the payment of Base Rent.

5.4 Landlord's Default. Landlord shall not be in default under this Lease unless Landlord fails to perform obligations required of Landlord within twenty (20) Business Days after written notice is delivered by Tenant to Landlord and to the holder of any mortgages or deeds of trust (collectively, "Lender") covering the Premises whose name and address shall have theretofore been furnished to Tenant in writing, specifying the obligation which Landlord has failed to perform; provided, however, that if the nature of Landlord's obligation is such that more than twenty (20) Business Days are required for performance, then Landlord shall not be in default if Landlord or Lender commences performance within such twenty (20) Business Day period and thereafter diligently prosecutes the same to completion. All obligations of Landlord hereunder shall be construed as covenants, not conditions. In the event of any default, breach or violation of Tenant's rights under this Lease by Landlord, Tenant's exclusive remedy shall be either an action for specific performance or an action for actual damages. Tenant hereby waives the benefit of any laws granting it the right to perform Landlord's obligation, a lien upon the property of Landlord and/or upon Rent due Landlord, or the right to terminate this Lease or withhold Rent on account of any Landlord default.

SECTION 6: MISCELLANEOUS PROVISIONS

6.1 Notices. Any notice, request, approval, consent or written communication required or permitted to be delivered under this Lease shall be: (a) in writing; (b) transmitted by personal delivery, express or

courier service, United States Postal Service in the manner described below, or electronic means of transmitting written material; and (c) deemed to be delivered on the earlier of the date received or four (4) Business Days after having been deposited in the United States Postal Service, postage prepaid. Such writings shall be addressed to Landlord or Tenant, as the case may be, at the respective designated addresses set forth opposite their signatures, or at such other address(es) as they may, after the execution date of this Lease, specify by written notice delivered in accordance with this paragraph, with copies to the persons at the addresses, if any, designated opposite each party's signature. Those notices which contain a notice of breach or default or a demand for performance may be sent by any of the methods described in clause (b) above, but if transmitted by personal delivery or electronic means, shall also be sent concurrently by certified or registered mail, return receipt requested.

6.2 Attorney's Fees and Expenses. In the event either party requires the services of an attorney in connection with enforcing the terms of this Lease, or in the event suit is brought for the recovery of Base Rent, Additional Rent or any other sums payable under this Lease or for the breach of any covenant or condition of this Lease, or for the restitution of the Premises to Landlord or the eviction of Tenant during the Lease Term or after the expiration or earlier termination of this Lease, the non-breaching party shall be entitled to a reasonable sum for attorney's and paralegal's fees, expenses and court costs, including those relating to any appeal.

6.3 No Accord and Satisfaction. No payment by Tenant or receipt by Landlord of an amount less than the Base Rent or Additional Rent or any other sum due and payable under this Lease shall be deemed to be other than a payment on account of the Base Rent, Additional Rent or other such sum, nor shall any endorsement or statement on any check or any letter accompanying any check or payment be deemed an accord and satisfaction, nor preclude Landlord's right to recover the balance of any amount payable or Landlord's right to pursue any other remedy provided in this Lease or at law.

6.4 Successors; Joint and Several Liability. Except as provided in the paragraph captioned "Limitation on Recourse" and subject to the paragraph captioned "Assignment and Subletting by Landlord", all of the covenants and conditions contained in this Lease shall apply to and be binding upon Landlord and Tenant and their respective heirs, executors, administrators, successors and assigns. In the event that more than one person, partnership, company, corporation or other entity is included in the term "Tenant", then each such person, partnership, company, corporation or other entity shall be jointly and severally liable for all obligations of Tenant under this Lease.

6.5 Choice of Law. This Lease shall be construed and governed by the laws of the state in which the Land is located. Tenant consents to Landlord's choice of venue for any legal proceeding brought by Landlord or Tenant to enforce the terms of this Lease.

6.6 No Waiver of Remedies. The waiver by Landlord of any covenant or condition contained in this Lease shall not be deemed to be a waiver of any subsequent breach of such covenant or condition nor shall any custom or practice which may develop between the parties in the administration of this Lease be construed to waive or lessen the rights of Landlord to insist on the strict performance by Tenant of all of the covenants and conditions of this Lease. No act or thing done by Landlord or Landlord's Agents during the Lease Term shall be deemed an acceptance or a surrender of the Premises, and no agreement to accept a surrender of the Premises shall be valid unless made in writing and signed by Landlord. The mention in this Lease of any particular remedy shall not preclude Landlord from any other remedy it might have, either under this Lease or at law, nor shall the waiver of or redress for any violation of any covenant or condition in this Lease or in any of the rules or regulations attached to this Lease or later adopted by Landlord, prevent a subsequent act, which would have originally constituted a violation, from having all the force and effect of an original violation. The receipt by Landlord of Base Rent, Additional Rent or any other sum payable under this Lease with knowledge of a breach of any covenant or condition in this Lease shall not be deemed a waiver of such breach. The failure of Landlord to enforce any of the rules and regulations attached to this Lease or later adopted, against Tenant or any other tenant in the Building, shall not be deemed a waiver. Any waiver by Landlord must be in writing and signed by Landlord to be effective.

6.7 Offer to Lease. The submission of this Lease in a draft form to Tenant or its broker or other agent does not constitute an offer to Tenant to lease the Premises. This Lease shall have no force or effect until: (a) it is executed and delivered by Tenant to Landlord; and (b) it is executed and delivered by Landlord to Tenant.

6.8 Force Majeure. In the event that Landlord shall be delayed, hindered in or prevented from the performance of any act or obligation required under this Lease by reason of acts of God, strikes, lockouts,

labor troubles or disputes, inability to procure or shortage of materials or labor, failure of power or utilities, delay in transportation, fire, vandalism, accident, flood, severe weather, other casualty, Governmental Requirements (including mandated changes in the Plans and Specifications or the Tenant Improvements resulting from changes in pertinent Governmental Requirements or interpretations thereof), riot, insurrection, civil commotion, sabotage, explosion, war, natural or local emergency, acts or omissions of others, including Tenant, or other reasons of a similar or dissimilar nature not solely the fault of, or under the exclusive control of, Landlord, then performance of such act or obligation shall be excused for the period of the delay and the period for the performance of any such act or obligation shall be extended for the period equivalent to the period of such delay.

6.9 Landlord's Consent. Unless otherwise provided in this Lease, whenever Landlord's consent, approval or other action is required under the terms of this Lease, such consent, approval or action shall be subject to Landlord's judgment or discretion exercised in good faith and shall be delivered in writing.

6.10 Severability; Captions. If any clause or provision of this Lease is determined to be illegal, invalid, or unenforceable under present or future laws, the remainder of this Lease shall not be affected by such determination, and in lieu of each clause or provision that is determined to be illegal, invalid or unenforceable, there be added as a part of this Lease a clause or provision as similar in terms to such illegal, invalid or unenforceable clause or provision as may be possible and be legal, valid and enforceable. Headings or captions in this Lease are added as a matter of convenience only and in no way define, limit or otherwise affect the construction or interpretation of this Lease.

6.11 Interpretation. Whenever a provision of this Lease uses the term (a) "include" or "including", that term shall not be limiting but shall be construed as illustrative, (b) "covenant", that term shall include any covenant, agreement, term or provision, (c) "at law", that term shall mean as specified in any applicable statute, ordinance or regulation having the force of law or as determined at law or in equity, or both, and (d) "day", that uncapitalized word shall mean a calendar day. This Lease shall be given a fair and reasonable interpretation of the words contained in it without any weight being given to whether a provision was drafted by one party or its counsel.

6.12 Incorporation of Prior Agreement; Amendments. This Lease contains all of the agreements of the parties to this Lease with respect to any matter covered or mentioned in this Lease, and no prior agreement or understanding pertaining to any such matter shall be effective for any purpose. No provision of this Lease may be amended or added to except by an agreement in writing signed by the parties to this Lease or their respective successors in interest.

6.13 Authority. If Tenant is a partnership, company, corporation or other entity, each individual executing this Lease on behalf of Tenant represents and warrants to Landlord that he or she is duly authorized to so execute and deliver this Lease and that all partnership, company, corporation or other entity actions and consents required for execution of this Lease have been given, granted or obtained. If Tenant is a partnership, company, corporation or other business organization, it shall, (a) at or prior to the execution of this Lease, deliver to Landlord certificates of good standing for Tenant issued by the Secretary of State of Delaware and the Secretary of State of Massachusetts, and (b) within ten (10) Business Days after demand by Landlord, deliver to Landlord satisfactory evidence of the due authorization of this Lease and the authority of the person executing this Lease on its behalf.

6.14 Time of Essence. Time is of the essence with respect to the performance of every covenant and condition of this Lease.

6.15 Survival of Obligations. Notwithstanding anything contained in this Lease to the contrary or the expiration or earlier termination of this Lease, any and all obligations of either party accruing prior to the expiration or termination of this Lease, shall survive the expiration or earlier termination of this Lease, and either party shall promptly perform all such obligations whether or not this lease has expired or terminated. Such obligations shall include any and all indemnity obligations set forth in this Lease.

6.16 Consent to Service. Tenant irrevocably consents to the service of process of any action or proceeding at the address of the Premises. Nothing in this paragraph shall affect the right to serve process in any other manner permitted by law.

6.17 Landlord's Authorized Agents. Notwithstanding anything contained in the Lease to the contrary, including without limitation, the definition of Landlord's Agents, only officers of Landlord, are authorized to amend, renew or terminate this Lease, or to compromise any of Landlord's claims under this Lease or to bind Landlord in any manner. Without limiting the effect of the previous sentence, no property manager or broker shall be considered an authorized agent of Landlord to amend, renew or

terminate this Lease, to compromise any of Landlord's claims under this Lease or to bind Landlord in any manner.

6.18 **Waiver of Jury Trial.** Landlord and Tenant irrevocably waive the respective rights to trial by jury in any action, proceeding or counterclaim brought by either against the other (whether in contract or tort) on any matter arising out of or relating in any way to this Lease, the relationship of Landlord and Tenant or Tenant's use or occupancy of the Premises.

6.19 **Specially Designated National or Blocked Person.** Tenant hereby represents its compliance with all applicable anti-money laundering laws, including, without limitation, the USA Patriot Act, and the laws administered by the United States Treasury Department's Office of Foreign Assets Control, including, without limitation, Executive Order 13224. Tenant further represents (i) that it is not, and it is not owned or controlled directly or indirectly by any person or entity, on the Specially Designated Nationals (SDN) List published by the United States Treasury Department's Office of Foreign Assets Control and (ii) that it is not a person otherwise identified by government or legal authority as a person with whom a U.S. Person is prohibited from transacting business. As of the date hereof, a list of such designations is available at http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx and the text of Executive Order 13224 is available at http://www.state.gov/j/ct/rls/other/des/122570.htm.. Tenant covenants and agrees to deliver to Landlord any certification or other evidence requested from time to time by Landlord in its reasonable discretion, confirming Tenant's compliance with this paragraph 6.19.

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IN WITNESS WHEREOF, this Lease has been executed the day and year first above set forth.

Designated Address for Landlord:

MEPT Seaport 13 Stillings LLC
c/o Bentall Kennedy (U.S.) Limited Partnership
Attn: Director of Asset Management - MEPT
7315 Wisconsin Avenue
Suite 200W
Bethesda, MD 20814
Fax: 301-656-9339

with copies to:

MEPT Seaport 13 Stillings LLC
c/o Bentall Kennedy (US) LP
Attention: Director of Asset Management - MEPT
1215 Fourth Avenue
Suite 2400
Seattle, WA 98161
Fax: 206-682-4769

and

MEPT Seaport 13 Stillings LLC
c/o NewTower Trust Company
7315 Wisconsin Avenue
Suite 350W
Bethesda, MD 20814
Attn: Robert B. Edwards or President
Fax: 240-235-9961

with a copy to Manager at:

CB Richard Ellis - N.E. Partners, LP
101 Seaport Blvd.
Boston, Massachusetts 02210
Facsimile: (617) 261 7870

LANDLORD:

MEPT Seaport 13 Stillings LLC, a Delaware limited liability company

By: MEPT Edgemoor REIT LLC, a Delaware limited liability company, its Manager

By: Bentall Kennedy (U.S.) Limited Partnership, its Authorized Signatory

By: Bentall Kennedy (U.S.) G.P., LLC, its General Partner

By: _____
Name: _____
Its: _____

By: _____
Name: _____
Its: _____

Designated Address for Tenant:

Prior to the Rent Commencement Date:

Duck Creek Technologies LLC
51 Sleeper Street
Boston, MA 02210
Attn: President
Facsimile: _____

From and after the Rent Commencement Date:
Duck Creek Technologies LLC
22 Boston Wharf Road
Boston, MA 02210
Attn: President

TENANT:

Duck Creek Technologies LLC, a Delaware limited liability company.

By: /s/ Vincent A. Chippari
Name: Vincent A. Chippari
Its: Chief Financial Officer

IN WITNESS WHEREOF, this Lease has been executed the day and year first above set forth.

Designated Address for Landlord:

MEPT Seaport 13 Stillings LLC
c/o Bentall Kennedy (U.S.) Limited Partnership
Attn: Director of Asset Management - MEPT
7315 Wisconsin Avenue
Suite 200W
Bethesda, MD 20814
Fax: 301-656-9339

with copies to:

MEPT Seaport 13 Stillings LLC
c/o Bentall Kennedy (US) LP
Attention: Director of Asset Management - MEPT
1215 Fourth Avenue
Suite 2400
Seattle, WA 98161
Fax: 206-682-4769

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c/o NewTower Trust Company
7315 Wisconsin Avenue
Suite 350W
Bethesda, MD 20814
Attn: Robert B. Edwards or President
Fax: 240-235-9961

with a copy to Manager at:

CB Richard Ellis - N.E. Partners, LP
101 Seaport Blvd.
Boston, Massachusetts 02210
Facsimile: (617) 261 7870

LANDLORD:

MEPT Seaport 13 Stillings LLC, a Delaware limited liability company

By: MEPT Edgemoor REIT LLC, a Delaware limited liability company, its Manager

By: Bentall Kennedy (U.S.) Limited Partnership, its Authorized Signatory

By: Bentall Kennedy (U.S.) G.P., LLC, its General Partner

By: /s/ Philip Down
Name: Philip Down
Its: Vice President

By: /s/ Jeanette R. Flory
Name: Jeanette R. Flory
Its: SVP

Designated Address for Tenant:

Prior to the Rent Commencement Date:

Duck Creek Technologies LLC
51 Sleeper Street
Boston, MA 02210
Attn: President
Facsimile: 857 239 5601

From and after the Rent Commencement Date:

Duck Creek Technologies LLC
22 Boston Wharf Road
Boston, MA 02210
Attn: President

TENANT:

Duck Creek Technologies LLC, a Delaware limited liability company

By: /s/ Vincent A. Chippari
Name: Vincent A. Chippari
Its: Chief Financial Officer

Facsimile: _____

With a copy to:

Burns & Levinson LLP
125 Summer Street
Boston, MA 02110
Attn: Michael D. MacClary, Esq.
Facsimile: (617) 345-3299

EXHIBIT A to Lease

Mandatory Tenant LEED Design, Construction and Performance Requirements

Section 1A. Mandatory Leadership in Energy and Environmental Design (LEED) Tenant Compliance. The Tenant shall adhere to the following design and construction requirements in support of and in compliance with the LEED-CS prerequisites and credits satisfied by the base-building scope of work::

a. WEc3 Water Use Reduction: All tenants are required to install efficient flush/flow fixtures that do not exceed the flush/flow rates of the base-building fixtures shown below:

Fixture Type	Max Flush/Flow Rate:
Water Closet:	1.28 gpf
Urinal:	0.125 gpf
Lays:	0.5 gpm (metered)
Kitchen Sink:	2.2 gpm
Showers:	1.5 gpm

b. EAp3 Fundamental Refrigerant Management: Any additional work that is executed by the Tenant must adhere to *"zero use of chlorofluorocarbon (CFC)-based refrigerants in new base building heating, ventilating, air conditioning and refrigeration (HVAC&R) systems. Small HVAC units (defined as containing less than 0.5 pounds (228 grams) of refrigerant) and other equipment, such as standard refrigerators, small water coolers and any other equipment that contains less than 0.5 pounds (228 grams) of refrigerant, are not considered part of the base building system and are not subject to the requirements of this prerequisite"*.

c. EAc1 Optimize Energy Performance/Energy Conservation Measures

Mandatory Tenant Energy Conservation Measures (ECMs): Tenants fit up design must comply with the following performance requirements to support and align with the Energy Conservation Measures (ECMs) incorporated in the base-building Core and Shell building systems and building envelope design and the LEED-CS whole building energy model.

Landlord shall supply electricity to the Premises. Lighting and, normal office machines at base building standard receptacles should meet a demand requirement not to exceed 5 watts per rentable square foot for lighting and outlets, and Tenant agrees in its use of the Premises (i) not to exceed such requirements, and (ii) that its total connected lighting load it will not exceed the maximum from time to time permitted under applicable governmental regulations.

Lighting Power: Tenants are required to comply with lighting power density (Watts/sf) requirements as per Sections 9.5-9.6 of ASHRAE 90.1-2013. The applicable LPD requirement for office space type is 0.82 W/SF when using the building Area Method.

Lighting Controls: Office tenants are required to provide the following lighting controls:

Automatic Lighting Controls: Tenants are required to install lighting controls, including automatic

lighting shut-offs, vacancy sensors, and daylighting controls as per Section 9.4 of ASHRAE 90.1-2013.

Occupancy Sensors on Lighting: Occupancy sensors must be provided for light control in all applicable areas within tenant spaces.

Fan Powered Boxes: The base building systems are designed such that the tenant fit-outs are required to include the installation of fan powered boxes in perimeter spaces.

d. IEQp1 Minimum Air Quality Performance: All mechanical ventilation systems installed by the Tenant must *"meet the minimum requirements of Sections 4 through 7 of ASHRAE Standard 62.1-2007, Ventilation for Acceptable Indoor Air Quality. Mechanical ventilation systems must be designed using the ventilation rate procedure or the applicable local code, whichever is more stringent."*

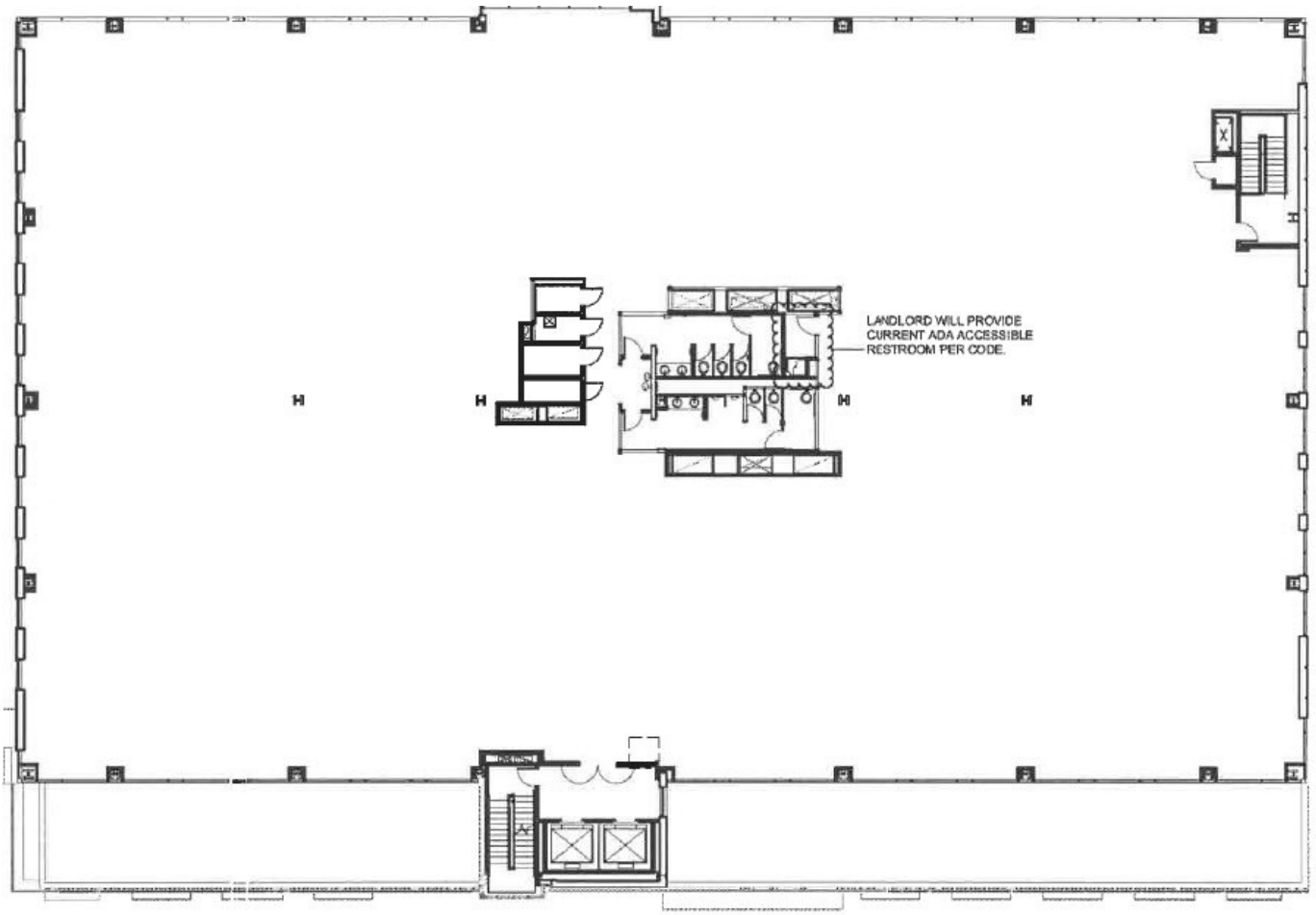
e. IEQp2 Environmental Tobacco Smoke Control (ETS): The Tenant is required to *"Prohibit smoking in the building. Prohibit on-property smoking within 25 feet (8 meters) of entries, outdoor air intakes and operable windows. Provide signage to allow smoking in designated areas, prohibit smoking in designated areas or prohibit smoking on the entire property."*

f. IEQc7.1 Thermal Comfort - Design: All tenants are required to, *"design heating ventilation and air conditioning systems and the building envelope to meet the requirements of ASHRAE Standard 55-2004, Thermal Environmental Conditions for Human Occupancy. Demonstrate design compliance in accordance with Section 6.1.1 documentation."* Furthermore, tenant spaces such as restaurants or fitness centers that are anticipated to have a time-average metabolic rate above 2.0 MET need to *"meet the cooling/humidity temperature set points for spaces with MET levels of 2.0. Time-weighted average metabolic rates should be determined based on guidance in ASHRAE 55-2004, Normative Appendix A"*.

EXHIBIT B to Lease

DRAWING SHOWING LOCATION OF THE PREMISES

(see attached)



LEVEL 10 FLOOR PLAN

EXHIBIT C to Lease

LISTING OF PLANS AND SPECIFICATIONS FOR TENANT IMPROVEMENTS

EXHIBIT D to Lease

FORM OF LEASE MEMORANDUM

MEPT Seaport 13 Stillings LLC, a Delaware limited liability company, as Landlord, and Duck Creek Technologies LLC, a Delaware limited liability company. as Tenant, executed that Lease dated as of_____, 2017 (the "Lease").

The Lease contemplates that this document shall be delivered and executed as set forth in the paragraph entitled "Lease Memorandum". This Lease Memorandum shall become part of the Lease.

Landlord and Tenant agree as follows:

1. The Commencement Date of the Lease is _____

2. The Rent Commencement Date of the Lease is _____

3. The end of the Lease Term and the date on which this Lease will expire is _____

4. The Lease is in full force and effect as of the date of this Lease Memorandum. By execution of this Lease Memorandum, Tenant confirms that as of the date of the Lease Memorandum (a) Tenant has no claims against Landlord and (b) Landlord has fulfilled all of its obligations under the Lease required to be fulfilled by Landlord.

5. The Premises consist of approximately thirty thousand one hundred ten (30,110) rentable square feet.

6. The amount of Base Rent and the portion of the Lease Term during which such Base Rent is payable shall be determined from the following table:

Applicable Portion of Lease Term		Rate Per/Rentable Sq. Ft./ Annum	Annual Base Rent	Monthly Base Rent Installment (Annual ÷ 12)
Beginning	Ending			
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]
		[redacted]	[redacted]	[redacted]

Notwithstanding the foregoing, Landlord shall abate all Base Rent applicable to the Premises for the period beginning on_____and ending on _____(the "Abatement Period"). Although Landlord shall abate Base Rent payable for the Abatement Period, Tenant acknowledges and agrees that Tenant shall be liable for all Additional Rent payable during such period. If the Rent Commencement Date is a date other than the first day of a calendar month, Base Rent for the partial month in which the Rent Commencement Date occurs shall be prorated as provided in Paragraph 3.2 hereof.

7. Tenant's Pro Rata Share is 30,110/123,977 = twenty-four and twenty-nine one-hundredths percent (24.29%), which shall be final, conclusive and controlling during the Lease Term for all purposes.

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Dated: _____

LANDLORD:

MEPT Seaport 13 Stillings LLC, a Delaware limited liability company

By: MEPT Edgemoor REIT LLC, a Delaware limited liability company, its Manager

By: Bentall Kennedy (U.S.) Limited Partnership, its Authorized Signatory

By: Bentall Kennedy (U.S.) G.P., LLC, its General Partner

By: _____
Name: _____
Its: _____

By: _____
Name: _____
Its: _____

Dated: July 28, 2017

TENANT:

Duck Creek Technologies LLC, a Delaware limited liability company.

By: /s/ Vincent A. Chippari
Name: Vincent A. Chippari
Its: Chief Financial Officer

Dated: _____

LANDLORD:

MEPT Seaport 13 Stillings LLC, a Delaware limited liability company

By: MEPT Edgemoor REIT LLC, a Delaware limited liability company, its Manager

By: Bentall Kennedy (U.S.) Limited Partnership, its Authorized Signatory

By: Bentall Kennedy (U.S.) G.P., LLC, its General Partner

By: /s/ Philip Down
Name: Philip Down
Its: Vice President

By: /s/ Jeanette R. Flory
Name: Jeanette R. Flory
Its: SVP

Dated: July 28, 2017

TENANT:

Duck Creek Technologies LLC, a Delaware limited liability company.

By: /s/ Vincent A. Chippari
Name: Vincent A. Chippari
Its: Chief Financial Officer

EXHIBIT E to Lease

RULES AND REGULATIONS

1. No sign, placard, picture, advertisement, name or notice shall be installed or displayed on any part of the outside or inside of the Building or Land without the prior written consent of the Landlord. Landlord shall have the right to remove, at Tenant's expense and without notice, any sign installed or displayed in violation of this rule. All approved signs or lettering on doors and walls shall be printed, painted, affixed or inscribed at the expense of Tenant by a person chosen by Landlord.

2. If Landlord objects in writing to any curtains, blinds, shades, screens or hanging plants or other similar objects attached to or used in connection with any window or door of the Premises, Tenant shall immediately discontinue such use. No awning shall be permitted on any part of the Premises. Tenant shall not place anything against or near glass partitions or doors or windows, which may appear unsightly from outside the Premises.

3. Tenant shall not obstruct any sidewalk, halls, passages, exits, entrances, elevators, escalators, or stairways of the Building. The halls, passages, exits, entrances, elevators, escalators and stairways are not open to the general public. Landlord shall in all cases retain the right to control and prevent access to such areas of all persons whose presence in the judgment of Landlord would be prejudicial to the safety, character, reputation and interest of the Land, Building and the Building's tenants; provided that, nothing in this Lease contained shall be construed to prevent such access to persons with whom any Tenant normally deals in the ordinary course of its business, unless such persons are engaged in illegal activities. Tenant shall not go upon the roof of the Building.

4. The directory of the Building will be provided exclusively for the display of the name and location of tenants only, and Landlord reserves the right to exclude any other names therefrom.

5. All cleaning and janitorial services for the Building and the Premises shall be provided exclusively through Landlord, and except with the written consent of Landlord, no person or persons other than those approved by Landlord shall be employed by Tenant or permitted to enter the Building for the purpose of cleaning the same. Cleaning and janitorial services shall be provided five (5) days per week. Tenant shall not cause any unnecessary labor by carelessness or indifference to the good order and cleanliness of the Premises. Landlord shall not in any way be responsible to any Tenant for any loss of property on the Premises, however occurring, or for any damage to any Tenant's property by the janitor, any of Landlord's Agents or any other person.

6. Landlord will furnish Tenant, free of charge, two (2) keys to each door lock in the Premises. Landlord may make a reasonable charge for any additional keys. Tenant shall not make or have made additional keys, and Tenant shall not alter any lock or install a new additional lock or bolt on any door of its Premises. Tenant, upon the termination of its tenancy, shall deliver to Landlord the keys of all doors which have been furnished to Tenant, and in the event of loss of any keys so furnished, shall pay Landlord therefor.

7. HVAC service shall be provided to the Premises Mondays through Fridays from 8:00 a.m. to 6:00 p.m., except for holidays ("Building Standard Hours"). Landlord shall provide HVAC service at times in addition to Building Standard Hours ("After-Hours HVAC"); provided, however, Tenant gives Landlord notice prior to 1:00 p.m. on the same day such After Hours HVAC is required with respect to service on Business Days and prior to 1:00 p.m. on the immediately preceding Business Day with respect to service on non-Business Days. The charge to Tenant for After-Hours HVAC shall be at Landlord's then-standard hourly rate in effect from time to time for After-Hours HVAC (currently $35.00 per hour but subject to change in accordance with the foregoing); provided, however there will be no charge for After-Hours HVAC on Saturdays between 9:00 AM and 1:00 PM (although Tenant must request same as set forth in the preceding sentence). Any HVAC service on holidays shall be considered After-Hours HVAC.

8. If Tenant requires telegraphic, telephonic, computer circuits, burglar alarm or similar services, it shall first obtain, and comply with, Landlord's instructions for their installation, and shall pay the entire cost of such installation(s).

9. Tenant shall not place a load upon any floor of the Premises which exceeds the load per square foot which such floor was designed to carry and which is allowed by Governmental Requirements. Landlord shall have the right to prescribe the weight, size and position of all equipment, materials, furniture or other property brought into the Building. Heavy objects shall, if considered necessary by Landlord, stand on such platforms as determined by Landlord to be necessary to properly distribute the weight. Business machines and mechanical equipment belonging to Tenant, which cause noise or vibration that may be transmitted to the structure of the Building or to any space in the Building or to any other tenant in the Building, shall be placed and maintained by Tenant, at Tenant's expense, on vibration eliminators or other devices sufficient to eliminate noise or vibration. The persons employed to move such equipment in or out of the Building must be acceptable to Landlord. Landlord will not be responsible for loss of, or damage to, any such equipment or other property from any cause, and all damage done to the Building by maintaining or moving such equipment or other property shall be repaired at the expense of Tenant.

10. Tenant shall not use or keep in the Premises any kerosene, gasoline or inflammable or combustible fluid or material other than those limited quantities permitted by the Lease. Tenant shall not use or permit to be used in the Premises any foul or noxious gas or substance, or permit or allow the Premises to be occupied or used in a manner offensive or objectionable to Landlord or other occupants of the Building by reason of noise, odors or vibrations nor shall Tenant bring into or keep in or about the Premises any birds or animals.

11. Tenant shall not use any method of heating or air-conditioning other than that supplied by Landlord.

12. Tenant shall not waste any utility provided by Landlord and agrees to cooperate fully with Landlord to assure the most effective operation of the Building's heating and air-conditioning and to comply with any governmental energy-saving rules, laws or regulations of which Tenant has actual notice.

13. Landlord reserves the right, exercisable without notice and without liability to Tenant, to change the name and street address of the Building.

14. Landlord reserves the right to exclude from the Building between the hours of 6 p.m. and 7 a.m. the following day, or such other hours as may be established from time to time by Landlord, and on Sundays and legal holidays, any person unless that person is known to the person or employee in charge of the Building and has a pass or is properly identified. Tenant shall be responsible for all persons for whom it requests passes and shall be liable to Landlord for all acts of such persons. Landlord shall not be liable for damages for any error with regard to the admission to or exclusion from the Building of any person. Landlord reserves the right to prevent access to the Building in case of invasion, mob, riot, public excitement or other commotion by closing the doors or by other appropriate action.

15. Tenant shall close and lock the doors of its Premises and entirely shut off all water faucets or other water apparatus, and electricity, gas or air outlets before Tenant and its employees leave the Premises. Tenant shall be responsible for any damage or injuries sustained by other tenants or occupants of the Building or by Landlord for noncompliance with this rule.

16. Tenant shall not obtain for use on the Premises ice, drinking water, food, beverage, towel or other similar services, except at such hours and under such regulations as may be fixed by Landlord.

17. The toilet rooms, toilets, urinals, wash bowls and other apparatus shall not-be used for any purpose other than that for which they were constructed and no foreign substance of any kind whatsoever shall be deposited in them. The expenses of any breakage, stoppage or damage resulting from the violation of this rule shall be borne by Tenant if it or its employees or invitees shall have caused it.

18. Tenant shall not sell, or permit the sale at retail, of newspapers, magazines, periodicals, theater tickets or any other goods or merchandise to the general public in or on the Premises. Tenant shall not make any room-to-room solicitation of business from other tenants in the Building. Tenant shall not use the Premises for any business or activity other than that specifically provided for in the Lease.

19. Tenant shall not install any radio or television antenna, loudspeaker or other device on the roof or exterior walls of the Building. Tenant shall not interfere with radio or television broadcasting or reception from or in the Building or elsewhere.

20. Tenant shall not mark, drive nails, screws or drill into the partitions, woodwork or plaster or in any way deface the Premises. Landlord reserves the right to direct electricians as to where and how telephone and telegraph wires are to be introduced to the Premises. Tenant shall not cut or bore holes for wires. Tenant shall not affix any floor covering to the floor of the Premises in any manner except as approved by Landlord. Tenant shall repair any damage resulting from noncompliance with this rule.

21. Tenant shall not install, maintain or operate upon the Premises any vending machine without the written consent of Landlord.

22. Canvassing, soliciting and distribution of handbills or any other written material, and peddling in the Building or Land are prohibited, and Tenant shall cooperate to prevent the same.

23. Landlord reserves the right to exclude or expel from the Building and Land any person who, in Landlord's judgment, is intoxicated, under the influence of liquor or drugs or in violation of any of these Rules and Regulations.

24. Tenant shall store all of its trash and garbage within the Premises. Tenant shall not place in any trash box or receptacle any material, which cannot be disposed of in the ordinary and customary manner of trash and garbage disposal. All garbage and refuse disposal shall be made in accordance with directions issued from time to time by Landlord.

25. The Premises shall not be used for lodging or any improper or immoral or objectionable purpose. No cooking shall be done or permitted by Tenant, except that use by Tenant of Underwriters' Laboratory approved equipment for brewing coffee, tea, hot chocolate and similar beverages shall be permitted; provided that, such equipment and its use is in accordance with all Governmental Requirements.

26. Tenant shall not use in the Premises or in the public halls of the Building any hand truck except those equipped with rubber tires and side guards or such other material-handling equipment as Landlord may approve. Tenant shall not bring any other vehicles of any kind into the Building.

27. Without the prior written consent of Landlord, Tenant shall not use the name of the Building in connection with or in promoting or advertising the business of Tenant except as Tenant's address.

28. Tenant shall comply with all safety, fire protection and evacuation procedures and regulations established by Landlord or any governmental agency.

29. Tenant assumes any and all responsibility for protecting the Premises from theft, robbery and pilferage, which includes keeping doors locked and other means of entry to the Premises closed.

30. The requirements of Tenant will be attended to only upon appropriate application to the Manager of the Building by an authorized individual. Employees of Landlord are not required to perform any work or do anything outside of their regular duties unless under special instructions from Landlord, and no employee of Landlord is required to admit Tenant to any space other than the Premises without specific instructions from Landlord.

31. Tenant shall not park its vehicles in any parking areas designated by Landlord as areas for parking by visitors to the Building or Land. Tenant shall not leave vehicles in the parking areas overnight nor park any vehicles in the Building parking areas other than automobiles, motorcycles, motor driven or nonmotor driven bicycles or four-wheeled trucks.

32. Landlord may waive any one or more of these Rules and Regulations for the benefit of Tenant or any other tenant, but no such waiver by Landlord shall be construed as a waiver of such Rules and Regulations in favor of any other person, nor prevent Landlord from thereafter revoking such waiver and enforcing any such Rules and Regulations against any or all of the tenants of the Building.

33. These Rules and Regulations are in addition to, and shall not be construed to in any way modify or amend, in whole or in part, the covenants and conditions of any lease of premises in the

Building. If any provision of these Rules and Regulations conflicts with any provision of the Lease, the terms of the Lease shall prevail.

34. Landlord reserves the right to make such other and reasonable Rules and Regulations as, in its judgment, may from time to time be needed for safety and security, the care and cleanliness of the Building and Land and the preservation of good order in the Building. Tenant agrees to abide by all the Rules and Regulations stated in this exhibit and any additional rules and regulations, which are so, made by Landlord.

35. Tenant shall be responsible for the observance of all of the foregoing rules by Tenant and Tenant's Agents.

EXHIBIT F to Lease

LETTER OF CREDIT CRITERIA

1. The letter of credit shall be clean, irrevocable and unconditional.

2. The letter of credit shall be in the amount specified in the Lease paragraph captioned "Security Provisions".

3. The letter of credit must either (i) be issued by a national bank which is a member of the New York Clearing House and which has a banking office dedicated to the administration and payment of letters of credit in New York City or Boston, Massachusetts or (ii) if issued by any bank which is not described in clause (i), be confirmed by a bank described in clause (i). The issuing bank must have been assigned by Standard & Poors Investor Services a Bank Financial Strength Rating of BBB+, or better. If clause (ii) is applicable, the confirming bank must be assigned by Standard & Poors Investor Services a Bank Financial Strength Rating of BBB+, or better. The identity of the issuing bank and of any confirming bank shall also be reasonably satisfactory to Landlord.

4. The letter of credit shall have an expiration date no earlier than the first anniversary of the date of its issuance and shall provide for its automatic renewal from year to year unless terminated by the issuing bank by notice to Landlord given not less than sixty (60) days prior to its expiration date by registered or certified mail. The final expiration date of the letter of credit and all renewals of it shall be no earlier than sixty (60) days following the end of the Lease Term.

5. The letter of credit shall be issued in favor of Landlord and shall be effective immediately on its issuance.

6. The letter of credit may be drawn at the New York City or Boston banking office of either the issuer of the letter of credit described in clause (i) of paragraph 3 or, if clause (ii) of paragraph 3 is applicable, the confirming bank described in clause (i) of such paragraph 3. It must allow for draws to be made at sight on a draft drawn under the letter of credit which has been approved as to form by Landlord. It must allow for one draw in the whole amount or multiple partial draws. The Landlord shall not as a condition to any draw be required to deliver any certificate, affidavit or other writing to the issuer expressing the basis for the draw.

7. The letter of credit shall be transferable.

8. The letter of credit shall be governed by (i) the International Standby Practices (SP 98 published by the International Chamber of Commerce) and (ii) the United Nations Convention on Independent Guarantees and Standby Letters of Credit. Alternatively, if approved by the lender and if required by either the issuing bank or the confirming bank the Uniform Customs and Practices for Documentary Credits published by the International Chamber of Commerce may be substituted for the Practices referred to in clause (a) to the extent such Customs and Practices are not inconsistent with the criteria in this Exhibit F.

9. The letter of credit shall otherwise be in such form and shall be subject to such requirements as Landlord may reasonably require.

10. Unless otherwise directed by the Landlord, the letter of credit shall be addressed to the Landlord as follows: MEPT Seaport 13 Stillings LLC, c/o NewTower Trust Company, Attn: Robert B. Edwards or President, 7315 Wisconsin Avenue, Suite 350W, Bethesda, MD 20814.

EXHIBIT G to Lease

ROOFTOP DECK AREA

(see attached)

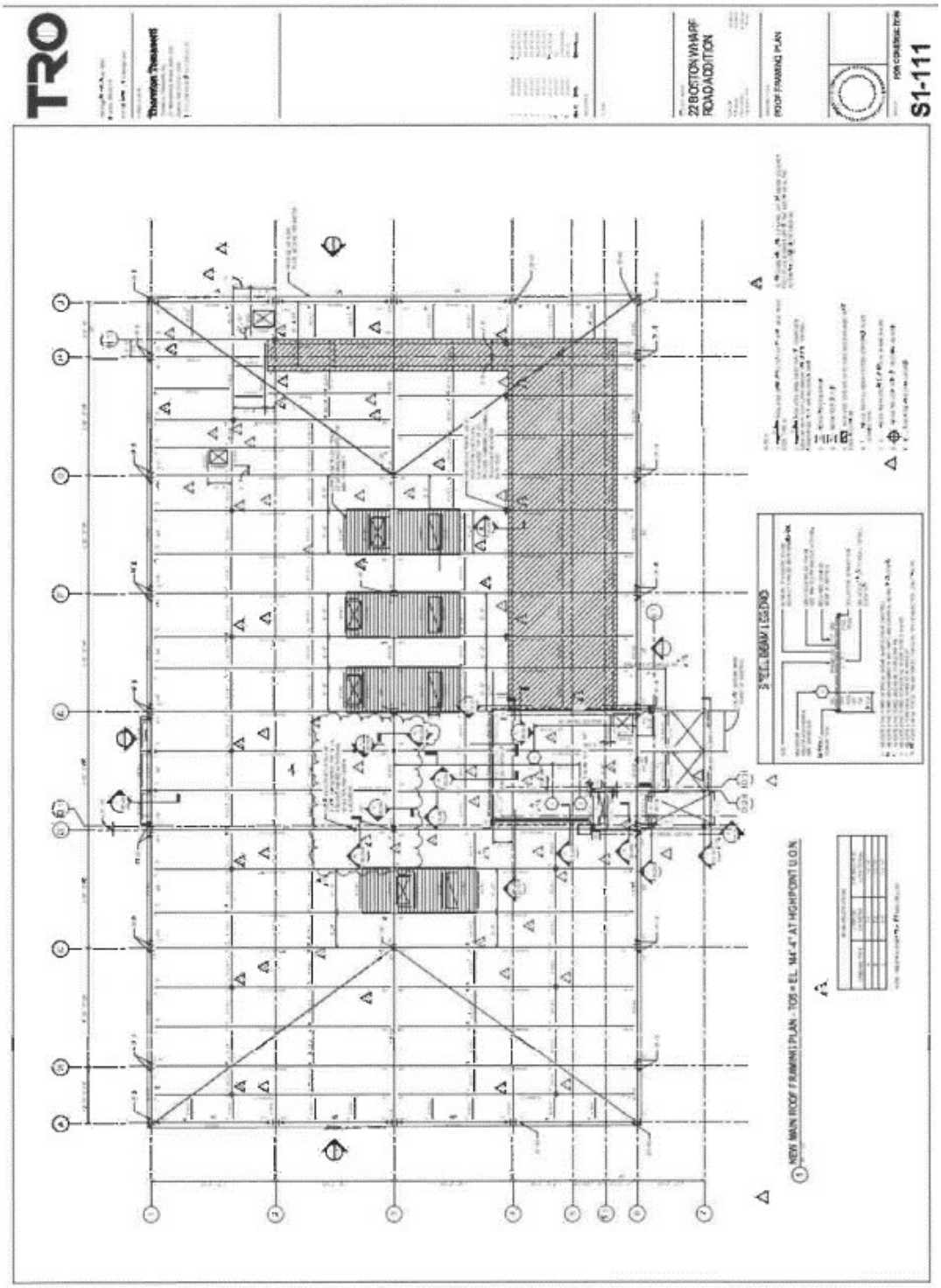
TRO
Thornton Tomasetti
22 BOSTON WHARF ROAD ADDITION
ROOF FRAMING PLAN
S1-111
3" STEEL DECK LEGEND
NEW MAIN ROOF FRAMING PLAN - TOS = EL. 164'-4" AT HIGHPOINT U.O.N.

EXHIBIT H to Lease

LANDLORD'S BASE BUILDING WORK

22 BOSTON WHARF ROAD

SITEWORK	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Sidewalks, landscaping, street furnishings, etc.	X		X		X		X	

STRUCTURE	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Floor to Floor Height: 13'-9 $^{1}/_{2}$ " on 7th floor, 18'-11 $^{1}/_{2}$ " on 8th floor; 13'6" on the 9th floor and 14'-1"on the 10th floor. Ceiling heights will be based on tenant specific requirements. See plans for ceiling height information based on base building infrastructure.	X		X		X		X	
Fireproofing	**X**		**X**		**X**		**X**	
Design Floor Load: 50 PSF	**X**		**X**		**X**		X	
Tenant to reinforce floor locally if specialty program exceeds **50 PSF.**		**X**		**X**		**X**		**X**
Framed openings for additional tenant shafts not part of base building		X		X		X		X

MISCELLANEOUS METALS	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Misc. Iron for base building elements (canopies, elevators, railings, etc.)	X		X		X		X	
Specialty misc. iron/structural work for tenant rooftop equipment and decks - Galvanized steel dunnage, deck framing maintenance walkways, screens, **penthouses, and railings.**		**X**		**X**		**X**		**X**
Misc. iron/structural support for base building rooftop equipment	**X**		**X**		**X**		**X**	
Concrete pads and structural modification related to tenant fit-out		**X**		**X**		**X**		**X**
Painted steel concrete filled pan stairs at egress stairs. Painted steel guardrails and handrails	X		X		X		X	
Railings at exterior terraces as shown on the contract documents	**X**		**X**		**X**		**X**	

BUILDING ENVELOPE	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Exterior Walls								
Various Wall Systems including glass/metal curtainwall, composite panel. Glazing is 1" insulated with low-e coating.	X		X		X		X	
BUILDING ENVELOPE (cont.)	**Designed**		**Furnished**		**Installed**		**Funded**	

	by:		by:		by:		by:	
Glass/Metal exterior doors of similar construction to exterior wall glazing systems	X		X		X		X	
Canopy and office entry combination of metal panel, glass and brick.	X		X		X		X	
Mechanical Penthouse: Aluminum metal panel system	X		X		X		X	
Penthouse louvers as required for building common equipment	X		X		X		X	
Penthouse louvers as required for specialty tenant equipment		X		X		X		X
Factory applied finish to metal panels, glazing system frames, aluminum doors, louvers, canopies.	X		X		X		X	
Roof								
Adhered .060 White EPDM roofing system including insulation, transition walls, parapets & accessories.	X		X		X		X	
Walkway pads to building common rooftop equipment.	X		X		X		X	
Roof penetrations for tenant rooftop equipment, vent stacks, terrace railings, deck framing		X		X		X		X

OFFICE COMMON AREAS	**Designed by:**		**Furnished by:**		**Installed by:**		**Funded by:**	
	LL	T	LL	T	LL	T	LL	T
Main Lobby - Finishes								
Stone tile flooring and base. Walk-off mat.	X		X		X		X	
Wall finishes may include; Porcelain tile and painted GWB walls.	X		X		X		X	
Ceiling finishes - Painted GWB ceilings with soffits.	X		X		X		X	
Built-in millwork reception desk at first floor entrance lobby.	X		X		X		X	
Upper Floor Elevator Lobbies								
Elevator lobbies at single & multi-tenant floors - Painted GWB walls, Stained wood fire rated doors, painted metal frames, Sealed concrete floors.	X		X		X		X	
Floor Common Area								
Mechanical/Tel-Data Rooms - Sealed Concrete Floors, Rubber Base, Painted GWB walls & no ceilings	X		X		X		X	
Electrical/Emergency Elec. Rooms - Sealed concrete floors, Rubber Base, Painted GWB walls.	X		X		X		X	
Taped and sanded GWB at tenant side of core and.mechanical rooms	X		X		X		X	
Type X GWB at interior face of exterior non-rated walls		X		X		X		X
Interior surface GWB of rated exterior walls patched and sanded, ready for paint	X		X		X		X	
Window stools - aluminum extension of glazing system.		X		X		X		X
Floor Common Area (cont.)	**Designed by:**		**Furnished by:**		**Installed by:**		**Funded by:**	
GWB at column enclosures		X		X		X		X
Base Building Door Frames - Painted Hollow Metal	X		X		X		X	

Shaft enclosures for tenant provided systems within building core		X		X		X		X
Partitions, ceilings, floorings, painting, finishes, doors, millwork, and all build-out within tenant area		X		X		X		X
Toilet Rooms - Porcelain tile on floors, Ceramic tile on wet walls, and 2'x2' ACT Ceilings, ADA bathroom accessories and fixtures, metal toilet partitions.	X		**X**		**X**		**X**	
Tenant kitchens, and tenant fit out toilet rooms and all associated plumbing		X		X		X		X
Mechanical, electrical and telecomm rooms for individual tenant systems		X		X		X		X
Window Blinds		X		X		X		X
Exit stairs. Finishes include painted steel stringers, risers and railings, sealed concrete floor and treads, vinyl base at landings, painted GWB walls (except at concrete core), no ceilings	**X**		**X**		**X**		**X**	

ELEVATORS	**Designed by:**		**Furnished by:**		**Installed by:**		**Funded by:**	
	LL	T	LL	T	LL	T	**LL**	T
Office tower passenger elevator serving Ground and 6th thru 10th floors - Geared Traction Kone- 350 FPM	X		X		X		X	
Garage tower passenger elevators serving Ground thru 6th floors — Hydraulic Kone- 125 FPM	X		X		X		X	

SPECIALTIES & EQUIPMENT	**Designed by:**		**Furnished by:**		**Installed by:**		**Funded by:**	
	LL	**T**	**LL**	T	LL	T	**LL**	T
Building common fire extinguishers with stainless steel recessed cabinets	X		X		X		X	
Tenant fire extinguishers		X		X		**X**		**X**
Tenant equipment		X		X		X		X

FIRE PROTECTION	**Designed by:**		**Furnished by:**		**Installed by:**		**Funded by:**	
	LL	**T**	**LL**	**T**	**LL**	**T**	**LL**	**T**
Combination sprinkler/ standpipe system with fire department valves	X		X		X		X	
Fire service and double-check valve assembly	X		X		X		X	
Fire pump, controller, test header	X		X		X		X	
Alarm Check valve and Siamese connection	X		X		X		X	
Floor control valve assemblies and test drains	X		X		X		X	
Sprinkler loop main and sprinkler coverage to all core areas	X		X		X		X	
Flow switches, tamper switches, pressure switches on main distribution	X		X		X		X	
All tenant spaces to be provided with upturned heads which can be modified / supplemented by the tenant	X		X		X		X	
Installation and modification of sprinkler piping and head layout to suit tenant build-out and hazard index. System shall be based on NFPA 13 - Ordinary Hazard Group 1 densities at a minimum.		X		**X**		**X**		X

PLUMBING	Designed by:		Furn shed by:		lustalled by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Domestic water from meter to all core fixtures and wet columns and penthouse requiring cold water. Backflow preventers at entrance. Pressure booster pumps if required.	**X**		**X**		**X**		**X**	
Wet columns at two locations per floor with 2" CW riser and 1-1/2" Pressure Regulating Valve and CW future, 4" waste and 4" vent	X		X		X		X	
Electric domestic water heaters and hot water supply piping to all core fixtures	X		X		X		X	
Additional plumbing fixtures / specialty equipment items for tenant fit out.		X		X		X		X
Plumbing equipment (water heater, disposal), supply piping (HW & CW) and drainage piping (Waste & Vent) for tenant fit out items.		X		X		X		X
One water fountain per office floor	X		X		X		X	
Water meter within Tenant area with remote reading device (Landlord to provide specification)		X		X		X		X

HVAC	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Central gas fired condensing hot water plant 3,000 MBH	**X**		**X**		**X**		**X**	
(4) DX Air Handling Units at 28,000 CFM (1.0 CFM/SF Cooling)	**X**		**X**		**X**		**X**	
Hot water (via high efficiency condensing boilers) pumping and distribution for base building systems	X		X		X		X	
Hot water distribution piping on floors (loop provided on 7; taps on 8, 9, 10.)		X		X		X		X
Metering of AHU and boiler plant electricity and natural gas consumption	X		X		X		X	
Exhaust capacity for mechanical and electrical rooms and toilets per code	X		X		X		X	
Supply, exhaust and return duct risers for base building systems	X		X		X		X	
Supply, exhaust and return distribution for floor common area (bathrooms, mech. Rooms, etc.) - installed in rooms by landlord and stubbed through core - tied into distribution by tenant during fit out	**X**		**X**		**X**		**X**	
Supply and return system, including medium pressure air distribution loop, distribution ductwork, control boxes, grilles, registers and diffusers in tenant areas		**X**		**X**		**X**		**X**
Heating based on 160 F hot water from high-efficiency condensing boilers capped at each floor		X		X		X		X
VAV and fan powered terminal boxes in tenant space including perimeter		X		X		X		X
Automatic temperature control system for base building systems	X		X		X		X	
Automatic temperature control system for tenant areas and systems. Tenant to tie into base building system.		X		X		X		X
Vibration isolation and sound attenuation for tenant equipment		X		X		X		X
Balancing and commissioning of systems for tenant area		X		X		X		X
Hot water piping to fan powered terminal units within tenant space		X		X		X		X

ELECTRICAL	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LL	T	LL	T	LL	T
Transformer vault with utility-supplied 480/277V transformer	X		X		X		X	
Main electrical service switchboards	X		X		X		X	
480/277V, 3 phase, 4 wire main switchboard, metered, for base building systems	X		X		X		X	
480/277V, 3 phase, 4 wire metered feed for tenant areas	X		X		X		X	
Office capacity 4 W/SF for tenant lighting and power.	X		X		X		X	
ELECTRICAL (Cont.)	**Designed by:**		**Furnished by:**		**Installed by:**		**Funded by:**	
Power and controls to VAV boxes and supplemental air conditioning (on tenant's meter)		X		X		X		X
Feeders and associated electrical distribution for tenant supplemental power		X		X		X		X
Emergency generator for base building life safety systems, including fuel storage and transfer system	X		X		X		X	
Emergency egress lighting within tenant areas		X		X		X		X
Electric closets at floor for base building systems and core areas	X		X		X		X	
Additional electric closets, if required for tenant areas		X		X		X		X
Power distribution for tenant areas		X		X		X		X
Fire alarm system and risers	X		X		X		X	
Fire alarm devices and exit signs in tenant spaces. Compliant to tie into base building systems		X		X		X		X
Lighting in common and base building areas	X		X		X		X	
Lighting in tenant areas		X		X		X		X
Lightning protection system for base building systems	X		X		X		X	
Lightning protection system for tenant systems		X		X		X		X
Temporary code-minimum lighting, fire alarm and exit signs at unoccupied tenant areas	X		X		X		X	
Electrified hardware for base building card key access doors	X		X		X		X	
Electrified hardware for tenant card key access doors (including doors to the egress stairs)		X		X		X		X

TELCOM	Designed by:		Furnished by		Installed by:		Funded by	
	LL	T	LL	T	LL	T	LL	T
4 - 4" telephone/data conduit sleeves from the secondary Tel/data closet floor IDF closet on floors 7-10	X		X		X		X	
Main & Secondary building telecommunications rooms (interconnected)	X		X		X		X	
Telephone/data system, including service, risers, wiring closets, and distribution		X		X		X		X
Cable TV service		X		X		X		X

SECURITY	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	**T**	**LL**	**T**	**LL**	**T**	**LL**	**T**
Card access at office building entries and within elevators	**X**		**X**		**X**		**X**	
Card access at exit stair doors on every floor		X		**X**		**X**		**X**
Card access and/or alarm systems into or within tenant areas		X		**X**		**X**		**X**
Security system and access control for tenant areas. Tenant systems need to be coordinated with the base building system		X		X		X		X

ACOUSTICAL	Designed by:		Furnished by:		Installed by:		Funded by:	
	LL	T	LI	**T**	**LL**	**T**	**LL**	**T**
Acoustical sound attenuation and isolation of base building systems	X		X		**X**		X	
Acoustical sound attenuation and isolation of tenant systems		X		X		**X**		**X**

TRO
Thornton Tomasetti
27 BOSTON WHARF
ROAD ADDITION
FLOOR LOADING
LIVE LOADING
S0-003
2 ROOF LOADING DIAGRAM
1 OFFICE FLOOR LOADING DIAGRAM

EXHIBIT I to Lease

CLEANING SPECIFICATIONS

MAIN LOBBY

Daily*

- o Empty trash receptacles; replace liners (as necessary)
- o Vacuum walk-off mats and carpeted areas
- o Spot-clean carpets with approved spotter
- o Sweep and damp-mop hard-surface floors
- o Clean glass—includes doors, windows within reach of cleaner, and floor directories
- o Spot-clean and sanitize horizontal and vertical surfaces; remove fingerprints, smudges, and stains
- o Wipe down and polish elevator doors

Weekly

- o Dust horizontal surfaces—includes moldings, baseboards, railings, charts, pictures, window ledges, sills, and other surfaces within reach of cleaner.

Monthly

- o High-dust horizontal and vertical surfaces—includes lobby, tops of vestibules, and other surfaces beyond reach of cleaner

Quarterly

- o Carpet Clean Main Entrance Upon **request as extra service**

* *Daily* = Five (5) *days a week*

ELEVATORS

Daily

- Clean interior walls, doors, ceiling, and bright work
- Clean and polish exterior doors, trim, and track
- Vacuum carpeted floors
- Spot-clean carpets with approved spotter

Quarterly

- Carpet Clean elevator cabs **Upon request as extra service**

CORRIDORS, STAIRS, COMMON AREA

Daily

- Vacuum carpeted floors
- Spot-clean carpets with approved spotter
- Spot-clean and sanitize horizontal and vertical surfaces; remove fingerprints, smudges, and stains
- Police stairwell for trash

Weekly

- Dust railings, ledges, fixtures, and fire extinguishers
- Damp-mop stairs

Quarterly

- Carpet Clean Main Entrance **Upon request as extra service**

* *Daily = Five (5) days a week*

RESTROOMS

Daily

- Empty trash and feminine receptacles; replace liners (as necessary)
- Clean and polish stainless steel surfaces
- Refill paper and hand-soap dispensers
- Clean and sanitize urinals, sinks, toilets, and shower stalls
- Polish mirrors and chrome fittings
- Sweep and damp-mop floors using germicidal solution
- Spot-clean walls and partitions
- Dust horizontal and vertical surfaces

Quarterly

- Machine-scrub restroom floors using germicidal solution

Upon request as extra service

TENANT OFFICE AREA

Daily

- Empty trash receptacles; replace liners (as necessary)
- Remove articles labeled “throw out”
- Sweep and damp-mop hard surface floors
- Vacuum carpeted floors
- Spot-clean carpets with approved spotter
- Straighten reception areas—neaten magazines, polish glass tables, etc.

Weekly

- Dust horizontal surfaces—includes, pictures, window sills, tops of cubicles and other surfaces within reach of cleaner.

Bi-Annually

- Dust heating and A/C diffusers

TENANT KITCHENETTES

Daily

- Empty trash receptacles; replace liners (as necessary)
- Clean and sanitize sinks, tables, countertops; wipe dry
- Sweep and damp-mop floors using germicidal solution

Yearly

- Strip and refinish VCT tiled floor surfaces using two (2) coats of seal and three (3) coats of finish **Upon request as extra service**

* *Daily = Five (5) days a week*

TENANT CONFERENCE ROOMS

Daily

- Empty trash receptacles; replace liners (as necessary)
- Remove articles labeled “throw out”
- Vacuum carpeted area
- Spot-clean carpets with approved spotter.
- Spot-clean and sanitize horizontal and vertical surfaces, walls, switch plates, and doors; remove smudges and stains
- Clean and polish conference table
- Reposition furniture

Weekly

- Dust window ledges, sills, doors, door frame, wall hangings, wood trim, baseboards, moldings, ledges, and horizontal and vertical surfaces.

Bi-Annually

- Dust heating and A/C diffusers

* *Daily = Five (5) days a week*

RECEIVING AREA

Daily

- Sweep and mop floors
- Wash walls and doors

* *Daily = Five (5) days a week*

STAIRS, BACK LOBBY

Daily

- Damp-mop and vacuum stairs and back entrance floor
- Clean both sides of glass back door
- Dust railings and ledges
- Polish brass

Weekly

- Dust railings, ledges, fixtures, and fire extinguishers
- Edge-vacuum carpeted stairs
- Damp-mop stairwells from top to bottom

* *Daily = Five (5) days a week*

Specialty Services

In addition to your janitorial needs. DCS also offers the following

- 24-hour emergency cleaning—fire, flood, etc.
- Anti-static treatment
- Carpet shampooing
- Computer room cleaning
- Facility/office services personnel—day porter/matron service, elevator operators, shipping/receiving, restroom attendants, light fixture porters
- Furniture cleaning, polishing, restoration
- Furniture moving
- Graffiti removal
- Landscaping
- Leather upholstery cleaning
- Light bulb replacement
- Floor care—marble, tile, wood
- Metal restoration and maintenance
- Parking lot maintenance
- Pest control
- Power/pressure cleaning— idewalks, building facades
- Recycling programs
- Snow removal
- Specialty products—mats, cleaning supplies, paper products, etc.
- Trash removal
- Upholstery and fabric partition cleaning
- Window cleaning

EXHIBIT J to Lease

Drawing Showing the First Floor of the Garage

(see attached)

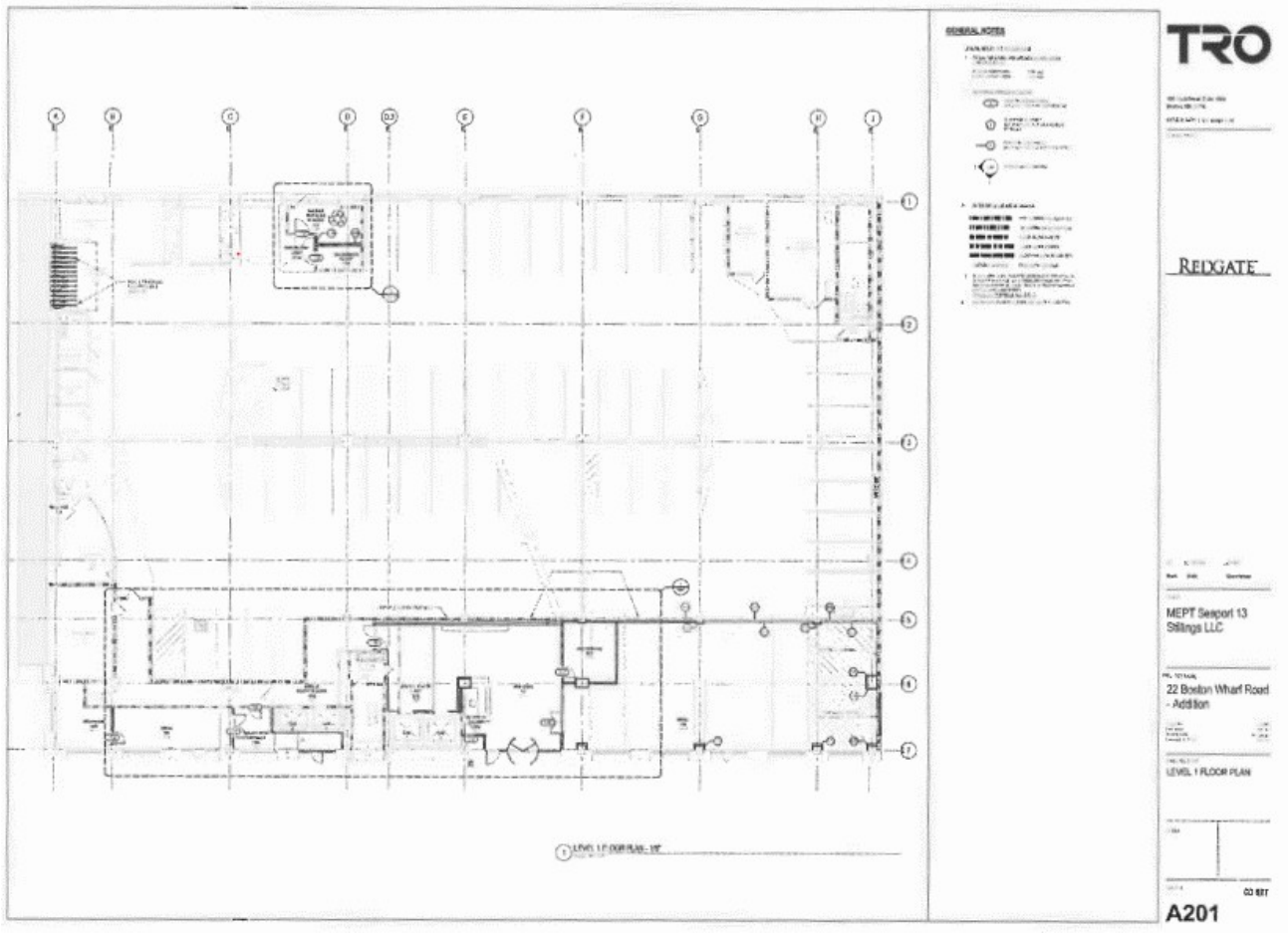
TRO
REDGATE
MEPT Seaport 13 Stillings LLC
22 Boston Wharf Road - Addition
LEVEL 1 FLOOR PLAN
A201

EXHIBIT K to Lease

RENDERING OF BUILDING LOBBY

The parties hereto acknowledge and agree that the drawing on the following page is merely a rendering and that Landlord's plans and specification for the Building lobby that are included in the Landlord's Base Building Work shall control.

(see next page)

FIRST FLOOR LOBBY

EXHIBIT B

MASTER LESSOR CONSENT

[SEE ATTACHED]

Boston 22 Warf location Inventory – 12/19/2023

Please use this as a reference point for mapping the inventory to its location

Inventory List by Location

1.) Kitchen\Breakroom: 2 Big fridges, 1 mini drink fridge, 3 microwaves, dishwasher, Samsung TV (HDMI connection) Speakers on the ceiling, 4 booths, 4 wall tables with 8 chairs, 6 dining tables with 24 chairs.

2.) Conference table +12 chars, 3 wall benches, 1 conference phone, TV on wall + Clickshare, speakers on the ceiling.

3 & 4.) This is an executive Office: Desk+ 3 chairs, 2 Monitors, TV(HDMI/WIPS), round table + 4 chairs

5.) Coffee table, TV(HDMI) , 4 Lounge Chairs

6.) Office Desk + 3 chairs, 2 monitors

7.) 2 Phone Booths

8 & 9 & 10.) Desk + 3 Chairs, 2 Monitors

11.) Large Table + 10 Chairs, TV+ Clickshare

12.) Small table + 2 chairs, File Cabinet, Conference Phone

13.) & 14.) Med table + 4 chairs, TV (HDMI)

15.) Small table + 2 Chairs, Wall Bench

16.) Small Table + 4 Chairs, TV(HDMI)

17.) 6 Desk + 1 Monitor, 2 lounge Chairs, 3 TVs(HDMI), Storage Cabinet (All other desk have been moved to engineering section including podium. Older HuddleCam but is not connected or in use.

18.) Small table, 3 wall benches

19.) Printer Room Storage cabinets on top wall + bottom Storage cabinet

20.) Table + 4 chairs, TV(HDMI)

21.) Server room: 2 server cages, AV Switch, APC. (AV buildout and AV contacts included in **separate attachment)**

22 & 23 & 24 & 25 & 26 & 27.) Office Desk + 3 Chairs, 2 Monitors (room 22 has 1 monitor and room 23 only has 2 chairs)

28.) 2 Rooms with 1 Chair each

29.) Printing Room: Storage Cabinets on wall

30.) Wellness Room: Sink, mini fridge, lounge Chair, small side table

31.) Table + 4, Chairs TV(HDMI)

32.) 2 Rooms with 1 Chair each

33.) Table + 10 chairs, TV + Clickshare

34 & 35 & 36 & 37.) Office Desk + 3 Chairs, 2 Monitors

38.) Innovation Room: Large Table Conference table + 19 chairs, 3 TVs + Clickshare screen sharing, 2 Cameras on ceiling, Speakers on ceiling, Microphones on ceiling, AV Junction Box behind TV, 4 high tables + 11 chairs

39.) Small attached kitchen space: Sink, Mini fridge, Cabinet Storage, Coffee Machine and Grinder

40.) Printer Space / Cabinet

41. & 43 & 45.) Executive Office Desk + 3 Chairs, Small Table + 4 Chairs, TV(HDMI/WIPS)

42.) Assistant Space, 2 Desk + 2 chairs, 4 Monitors, 2 Filing Cabinets

44.) Table + 8 Chairs, TV + Clickshare

46.) Table + 12 chairs, Speakers on ceiling, TV (on TV Stand) + Clickshare, Conference phone

Other .) Left Side Lounge Space = 11 Chairs & 9 tables of different size. Top Lounge Space = 4 chairs, Right Lounge Space = 10 chairs & 7 tables of different size. Lobby Entrance = 2 chairs and table, bench seat, welcome TV on wall. 4 mobile TV's on a cart.

Sever Room Equipment\Access Points\TV size and details included in **separate attachment.**

FURNITURE

Model Number	Serial Number	Asset Tag
Cisco AlR-AP2802I-B-K9	FDW2142D29H	AMER-0001
Cisco AlR-AP2802I-B-K9	FDW2142D2BP	AMER-0002
Cisco AIR-AP2802I -B-K9	FDW2142B24G	AMER-0003
Cisco AIR-AP2802I -B-K9	FDW2142D2AZ	AMER-0004
Cisco AlR-AP2802I-B-K9	FDW2142B28 H	AMER-0005
Cisco AlR-AP2802I-B-K9	FDW2142B27V	AMER-0006
Cisco AlR-AP2802I-B-K9	FDW2142B23Z	AMER-0007
Cisco AlR-AP2802I-B-K9	FDW2142B24L	AMER-0008
Cisco AIR-AP2802I -B-K9	FDW2142D2AP	AMER-0009
Cisco AlR-AP2802I-B-K9	FDW2142B24H	AMER-0010
Cisco AIR-AP2802I -B-K9	FDW2142D26X	AMER-0011
Cisco AlR-AP2802I-B-K9	FDW2142D2AQ	AMER-0012
Cisco AlR-AP2802I-B-K9	FDW2142D2AK	AMER-0013
Cisco AlR-AP2802I-B-K9	FDW2142D26W	AMER-0014
Cisco AIR-AP2802 I -B-K9	FGL2044A9D1	AMER-0015
Cisco AIR-AP2802 I -B-K9	FGL2044A9CX	AMER-0016
Cisco C9300-48T-E	FOC2133Z0CF	AMER-0019
Cisco C9300-48T-E	FCW2133G0LC	AMER-0020
Cisco C9300-48T-E	FCW2133L0RD	AMER-0021
Cisco C9300-48T-E	FCW2133G0KA	AMER-0022
Cisco C9300-48T-E	FCW2133G0K3	AMER-0023
Cisco C9300-48T-E	FCW2133L0RR	AMER-0024
Cisco C9300-48P-E	FOC2151Z0AG	AMER-0025

Product	Model	QTY
APC Basic Rack PDU	AP7941	1
Minuteman UPS	PRO1500RT	1
Server Cabinet	Dell 4210 42U	1

Room Number	Room Name	TV/Phone	AV
1008	Fenway	Samsung 65”/ Yealink CP960	One Barco CX-50 ClickShare Wirleess Conference presenter unit (with 2 USB dongle) One Poly Studio X50 - all in one VTC unit with speaker, microphone and camera
1019	The Garden	LG 65”	One Barco CX-50 ClickShare Wirleess Conference presenter unit (with 2 USB dongle) One Poly Studio X50 - all in one VTC unit with speaker, microphone and camera
1030	Gillette	LG 70”/ Yealink CP960	One Barco CX-50 ClickShare Wirleess Conference presenter unit (with 2 USB dongle) One Poly Studio X50 - all in one VTC unit with speaker, microphone and camera
1047	Zakim Bridge	LG 65”	One Barco CX-50 ClickShare Wirleess Conference presenter unit (with 2 USB dongle) One Poly Studio X50 - all in one VTC unit with speaker, microphone and camera
1064	Aquarium	LG 55”	One Barco CX-50 ClickShare Wirleess Conference presenter unit (with 2 USB dongle) One Poly Studio X50 - all in one VTC unit with speaker, microphone and camera
	Kitchen	Samsung 75”	

1002	Launch Pad	LG 79” 79UX340C (xl) LG 75” 75UM3C (x2)	
1072	HR	Yealink CP960	
1075	Hatch Shell	LG 45”	
1076	Huddle MFA	LG 45”	
1074	Huddle Copley	LG 45”	
1062	DCU Training	LG 65” (x3)	
Mobile Presenter		LG 45” (x4)	

Exhibit 21.1

Subsidiaries of the Registrant

Entity	Jurisdiction of Incorporation
Astria Securities Corporation	Delaware
Quellis Biosciences, LLC	Delaware

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

1) Registration Statement (Form S-3 Nos. 333-254174, 333-264911, 333-271848, and 333-276057) of Astria Therapeutics, Inc., and

2) Registration Statement (Form S-8 Nos. 333-206394, 333-210229, 333-216793, 333-223721, 333-229643, 333-239114, 333-254151, 333-258633, 333-263459, and 333-273773) pertaining to the equity incentive plans of Astria Therapeutics, Inc.;

of our report dated March 4, 2024, with respect to the consolidated financial statements of Astria Therapeutics, Inc. included in this Annual Report (Form 10-K) of Astria Therapeutics, Inc. for the year ended December 31, 2023

/s/ Ernst & Young LLP

Boston, Massachusetts
March 4, 2024

Exhibit 31.1

CERTIFICATION

I, Jill C. Milne, certify that:

1. I have reviewed this Annual Report on Form 10-K of Astria 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.

Date: March 4, 2024

/s/ Jill C. Milne

Jill C. Milne
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Noah C. Clauser, certify that:

1. I have reviewed this Annual Report on Form 10-K of Astria 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.

Date: March 4, 2024

/s/ Noah C. Clauser

Noah C. Clauser
Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with this Annual Report on Form 10-K of Astria Therapeutics, Inc. (the "Company") for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Jill C. Milne, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to her knowledge on the date hereof:

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

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

Date: March 4, 2024

/s/ Jill C. Milne

Jill C. Milne
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with this Annual Report on Form 10-K of Astria Therapeutics, Inc. (the "Company") for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Noah C. Clauser, Chief Financial Officer and Treasurer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that, to his knowledge on the date hereof:

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

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

Date: March 4, 2024

/s/ Noah C. Clauser

Noah C. Clauser
Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 97.1

Astria Therapeutics, Inc.

Compensation Recovery Policy

This Compensation Recovery Policy (this "Policy") is adopted by Astria Therapeutics, Inc. (the "Company") in accordance with Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("Rule 10D-1"), and Nasdaq Listing Rule 5608 ("Rule 5608"). This Policy is effective as of October 2, 2023 (the "Effective Date").

1. Definitions

(a) **"Accounting Restatement"** means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the U.S. federal securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. Changes to the Company's financial statements that do not represent error corrections are not an Accounting Restatement, including: (A) retrospective application of a change in accounting principle; (B) retrospective revision to reportable segment information due to a change in the structure of the Company's internal organization; (C) retrospective reclassification due to a discontinued operation; (D) retrospective application of a change in reporting entity, such as from a reorganization of entities under common control; and (E) retrospective revision for stock splits, reverse stock splits, stock dividends or other changes in capital structure.

(b) **"Committee"** means the Compensation Committee of the Company's Board of Directors (the "Board").

(c) **"Covered Person"** means a person who served as an Executive Officer at any time during the performance period for the applicable Incentive-Based Compensation.

(d) **"Erroneously Awarded Compensation"** means the amount of Incentive-Based Compensation that was Received that exceeds the amount of Incentive-Based Compensation that otherwise would have been Received had the amount of Incentive-Based Compensation been determined based on the restated amounts, computed without regard to any taxes paid by the Covered Person or by the Company on the Covered Person's behalf. For Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the amount of Erroneously Awarded Compensation will be based on a reasonable estimate by the Committee of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq in accordance with Rule 5608.

(e) **"Executive Officer"** means the Company's executive officers as defined in Rule 16a-1(f) under the Exchange Act.

(f) **"Financial Reporting Measures"** means (A) measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures (whether or not such measures are presented within the Company's financial statements or included in a filing made with the U.S. Securities and Exchange Commission), (B) stock price and (C) total shareholder return. Financial reporting measures may include "non-GAAP financial measures" as well as other measures, metrics and ratios that are not GAAP measures. A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

(g) **"Incentive-Based Compensation"** means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

(h) Incentive-Based Compensation is deemed to be **"Received"** in the Company's fiscal period during which the Financial Reporting Measure specified in the applicable Incentive-Based Compensation award is attained, even if the payment or grant of the Incentive-Based Compensation occurs after the end of that period or is subject to additional time-based vesting requirements.

(i) **"Recovery Period"** means the three completed fiscal years immediately preceding the earlier of: (A) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement. In addition, if there is a change in the Company's fiscal year end, the Recovery Period will also include any transition period to the extent required by Rule 5608.

2. Recovery of Erroneously Awarded Compensation

Subject to the terms of this Policy and the requirements of Rule 5608, if the Company is required to prepare an Accounting Restatement, the Company shall take steps to recover, reasonably promptly, from each Covered Person, any Erroneously Awarded Compensation that was Received by such Covered Person (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Recovery Period pursuant to Incentive-Based Compensation that is subject to this Policy.

3. Interpretation and Administration

(a) Role of the Committee. This Policy will be interpreted by the Committee in a manner that is consistent with Rule 5608 and any other applicable law and will otherwise be interpreted in the business judgment of the Committee. All decisions and interpretations of the Committee will be final and binding.

(b) Compensation Not Subject to this Policy. This Policy does not apply to Incentive-Based Compensation that was Received before the Effective Date. With respect to any Covered Person, this Policy does not apply to Incentive-Based Compensation that was Received by such Covered Person before beginning service as an Executive Officer.

(c) Determination of Means of Recovery. Subject to the requirement that recovery be made reasonably promptly, the Committee will determine the appropriate means of recovery, which may vary between Covered Persons or based on the nature of the applicable Incentive-Based Compensation, and which may involve, without limitation, establishing a deferred repayment plan or setting off against current or future compensation otherwise payable to the Covered Person. Recovery of Erroneously Awarded Compensation will be made without regard to income taxes paid by the Covered Person or by the Company on the Covered Person's behalf in connection with such Erroneously Awarded Compensation.

(d) Determination That Recovery is Impracticable. The Company is not required to recover Erroneously Awarded Compensation if a determination is made by the Committee that either (A) after the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation, the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered; provided that, before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall document such reasonable attempt(s) to recover and provide that documentation to Nasdaq in accordance with Rule 5608, or (B) recovery of such Erroneously Awarded Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the registrant, to fail to meet the requirements of Section 401(a)(13) or 411(a) of the Internal Revenue Code and regulations thereunder.

(e) No Indemnification or Company-Paid Insurance. The Company will not indemnify any Covered Person against the loss of Erroneously Awarded Compensation and will not pay or reimburse any Covered Person for the purchase of a third-party insurance policy to fund potential recovery obligations.

(f) Interaction with Other Clawback Provisions. The Company will be deemed to have recovered Erroneously Awarded Compensation in accordance with this Policy to the extent the Company actually receives such amounts pursuant to any other Company policy, program or agreement, pursuant to Section 304 of the Sarbanes-Oxley Act or otherwise.

(g) Severability. If any provision of this Policy or the application of any such provision to a Covered Person shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

(h) No Limitation on Other Remedies. Nothing in this Policy will be deemed to limit the Company's right to terminate employment of any Covered Person, to seek recovery of other compensation paid to a Covered Person, or to pursue other rights or remedies available to the Company under applicable law.

(i) Successors. This Policy shall be binding and enforceable against all Covered Persons and, to the extent required by applicable law, Rule 10D-1 and/or Rule 5608, their beneficiaries, heirs, executors, administrators or other legal representatives.

(j) Amendment; Termination; Required Filings. Subject to compliance with applicable laws, including Rule 5608, the Company may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Committee shall amend this Policy as it deems necessary to comply with applicable law. The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

4. **Acknowledgment.** Each Covered Person shall be required to sign and return to the Company the acknowledgement form attached hereto as Exhibit A pursuant to which such Covered Person will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Covered Person will be fully bound by, and must comply with, the Policy, whether or not such Covered Person has executed and returned such acknowledgment form to the Company.

Adopted by the Board on October 12, 2023.

Exhibit A

Astria Therapeutics, Inc.

Compensation Recovery Policy

EXECUTIVE OFFICER ACKNOWLEDGMENT

As a condition of receiving Incentive-Based Compensation (as defined in the Policy) from Astria Therapeutics, Inc. (the "***Company***") the Company, I, the undersigned, agree and acknowledge that I am bound by, and subject to, Astria Therapeutics, Inc. Compensation Recovery Policy (the "***Policy***"). In the event of any inconsistency between the Policy and the terms of any employment agreement, offer letter or other individual agreement with the Company to which I am a party, or the terms of any compensation plan, program or agreement, whether or not written, under which any compensation has been granted, awarded, earned or paid to me, the terms of the Policy shall govern.

In the event that the Committee (as defined in the Policy) determines that any compensation granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company pursuant to the Policy, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. I further agree and acknowledge that I am not entitled to indemnification, and hereby waive any right to advancement of expenses, in connection with any enforcement of the Policy by the Company.

Agreed and Acknowledged:

_____

Name: _____

Title: _____

Date: _____