UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 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 001-41947

Kyverna Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1365411**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
5980 Horton St., STE 550	
Emeryville, CA	**94608**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (510) 925-2492

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	KYTX	The Nasdaq Stock Market LLC

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 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

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

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

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

As of June 30, 2023, the last business day of the Registrant's most recently completed second quarter, There was no established public trading market for the Registrant's equity securities. The Registrant's common stock began trading on the Nasdaq Global Select Market on February 8, 2024.

The number of shares of Registrant's Common Stock outstanding as of March 22, 2024 was 43,115,244.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements about us and our industry within the meaning of the federal securities laws, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "target," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the initiation, timing, progress and results of our preclinical studies, clinical trials, and research programs for our product candidates;
- our ability to demonstrate, and the timing of, preclinical proof-of-concept in vivo for our product candidates;
- our ability to successfully complete our clinical trials;
- our ability to quickly leverage our initial product candidates and to progress additional candidates;
- the prevalence of certain diseases and conditions we intend to treat and the size of the market opportunity for our product candidates;
- estimates of the number of patients with certain diseases and conditions we intend to treat and the number of patients that we will enroll in our clinical trials;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates;
- the beneficial characteristics, safety, efficacy, therapeutic effects and potential advantages of our product candidates;
- the timing or likelihood of regulatory filings and approval for our product candidates;
- our ability to meet future regulatory standards with respect to our product candidates, if approved;
- our plans relating to the further development and manufacturing of our product candidates, including additional indications for which we may pursue;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the rate and degree of market acceptance and therapeutic benefits of our product candidates, if approved;
- the implementation of our strategic plans for our business, product candidates, research programs and technologies;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and genome-editing technology;
- anticipated developments related to our competitors and our industry;
- our competitive position and ability to leverage the clinical, regulatory and manufacturing advancements to accelerate our clinical trials and regulatory approval of product candidates;
- the success of competing therapies that are or may become available;
- our ability to identify and enter into future license agreements and collaborations;

- the expected potential benefits of strategic collaborations with third parties and our ability to attract collaborators with development, regulatory, manufacturing or commercialization expertise;
- our reliance on third parties to conduct clinical trials of our product candidates;
- our reliance on third parties for the manufacture of our product candidates;
- our plans relating to sales strategy, manufacturing and commercializing our product candidates, if approved;
- our ability to attract and retain sales personnel, or to contract with a sales organization, if our product candidates are approved;
- anticipated regulatory developments in the United States and foreign countries in which we may seek regulatory approval for our product candidates in the future;
- our ability to attract and retain key scientific and management personnel;
- our financial performance;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act or a smaller reporting company; and
- estimates of our expenses, capital requirements and needs for additional financing.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this Annual Report on Form 10-K.

We have based the forward-looking statements contained in this Annual Report on Form 10-K primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in Part I, Item 1A of this Annual Report on Form 10-K titled "Risk Factors" and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this Annual Report on Form 10-K. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this Annual Report on Form 10-K to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law. 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, other strategic transactions or investments we may make or enter into.

Trademarks and Service Marks

This Annual Report on Form 10-K contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Market, Industry and Other Data

Unless otherwise indicated, information contained in this Annual Report on Form 10-K concerning our industry and the markets in which we operate, including our general expectations about our product candidates, market position, market opportunity, market size, competitive position and the incidence of certain medical conditions, is based on or derived from publicly available information released by industry analysts and third-party sources, independent market research, industry and general publications and surveys, governmental agencies, our internal research and our industry experience. Our estimates of the potential market opportunities for our product candidates include a number of key assumptions based on our industry knowledge and industry publications, the latter of which may be based on small sample sizes and fail to accurately reflect such information, and you are cautioned not to give undue weight to such estimates. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions. Industry publications and third-party research often indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information and such information is inherently imprecise. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in Part I, Item 1A of this Annual Report on Form 10-K titled “Risk Factors” and elsewhere in this Annual Report on Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates made by independent third parties and by us.

PART I

Item 1. Business.

Overview

We are a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases. Our goal is to bring disease-modifying therapeutic benefits to patients suffering from autoimmune diseases through our patient-centered approach, our broad platform, our insights into treating immune disorders and the learnings from successful application of cell therapy in other areas of medicine. Our cell therapy approach to the treatment of autoimmune diseases is supported by the scientific publication of multiple autoimmune case studies using CD19 CAR T-cell treatment as well as early clinical data from our ongoing trials illustrating the disease-modifying potential of these therapies. This validation provides us with a clear path to continue advancing our lead product candidate, KYV-101, through clinical development across two broad areas of autoimmune disease: rheumatology and neurology.

Our lead program, KYV-101, is an autologous CD19 CAR T-cell product candidate made from an underlying chimeric antigen receptor, or CAR, that we have licensed from the National Institutes of Health, or the NIH. This underlying CAR in KYV-101 has completed a 20-patient Phase 1 trial in oncology conducted by the NIH, and the results from this Phase 1 trial published in *Nature Medicine* reported improved tolerability in the clinic among adult oncology patients using the same CAR construct in KYV-101, as compared to the CAR used to create Yescarta®. This underlying CAR in KYV-101 was designed by the NIH to improve tolerability through a systematic comparison of CARs created with alternate domain structures, identifying the use of a fully human CD19 binding domain and optimized hinge and transmembrane domains. We believe that these differentiated properties of the underlying CAR construct in KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

We intend to develop KYV-101 in two broad areas of autoimmune disease: rheumatology and neurology. Our initial rheumatology development focus is on lupus nephritis, or LN, and systemic sclerosis, or SSc. We are conducting two trials of KYV-101 in patients with LN, an autoimmune disease in which more than half of patients do not achieve a complete response to current therapies and are at risk of developing kidney failure. In addition to LN, we received Investigational New Drug, or IND, clearance in October 2023 for a Phase 1/2 study in SSc. We intend to initially focus our neurology development on myasthenia gravis, or MG, and multiple sclerosis, or MS. We received IND clearance in November 2023 for a Phase 2 study in MG, and we received IND clearance in December 2023 for a Phase 2 study in MS. We believe our approach may present a significant advantage over current standard-of-care therapies for autoimmune diseases by aiming to directly deplete B cells and potentially resetting disease-contributing B cells.

We are also actively developing an allogeneic, off-the-shelf approach to further broaden patient access. To this end, we have partnered with Intellia Therapeutics, Inc., or Intellia, a leader in the field of gene editing, to develop KYV-201, an allogeneic CD19 CAR T-cell product candidate. Our research-stage programs are focused on developing product candidates to treat other autoimmune diseases, such as inflammatory bowel disease, or IBD, which includes Crohn's disease and ulcerative colitis, and extend beyond CD19 CAR-T approaches, including regulatory T cells, or T-regs, and novel humanized CAR constructs developed by us for use in autoimmune diseases.

On February 12, 2024, we closed an initial public offering, or the IPO, of 16,675,000 shares of our common stock at a price to the public of $22.00 per share, including the exercise in full by the underwriters of their option to purchase 2,175,000 additional shares of our common stock, and received gross proceeds of $366.9 million. Net proceeds were approximately $336.2 million, after deducting underwriting discounts and commissions and estimated other offering costs.

Translating transformational experience with cell therapies to autoimmune diseases

We believe the success of cell therapies such as CAR T-cell therapies in oncology have paved the way for the application of cell therapies in other therapeutic areas. Pathologic B cells are the cause of a number of hematological malignancies, such as B-cell lymphoma. In recent years, multiple engineered cell therapies have been approved that can eliminate these B cells, resulting in long-term complete responses in lymphoma patients refractory to other

therapies. One of the most widely used, studied, and clinically validated engineered cell therapies is CAR T-cell therapy, a form of immunotherapy whereby the patient's T cells are engineered to express a CAR that recognizes and binds to a specific antigen present on tumor cells to generate an anti-tumor immune response. CAR T cells for this therapy are generated by isolating T cells from the patient and introducing a CAR construct that directs these modified T cells to attack B cells based on the expression of a common antigen, CD19.

Autoimmune diseases affect organs throughout the body. A common characteristic of many of these diseases is the presence of autoantibodies, antibodies produced by the body's B cells that mistakenly attack other cells and tissues in the body. Given that the therapeutic benefit associated with B-cell depletion is common between B-cell-driven hematologic malignancies and autoimmune diseases, we anticipated that CD19 CAR T cells would have therapeutic benefits in autoimmune diseases, a result that has now been observed in the publication of a number of case studies.

In academic clinical data published in *Nature Medicine* in September 2022, a CD19 CAR T-cell therapy was observed to induce clinical remission in all five systemic lupus erythematosus, or SLE, patients with lupus nephritis. All patients experienced significant improvements in Systemic Lupus Erythematosus Disease Activity Index 2000, or SLEDAI-2K, scores. Scores of zero, corresponding to no disease activity on such index, were achieved in four patients by three months post treatment and a score of two in one patient due to residual low-level proteinuria that was likely due to previously accumulated kidney damage. Several other important observations were the elimination of autoantibodies, B-cell reconstitution after an average time of 110 days of CAR T infusion in all patients, preservation of vaccination responses, and that treatment was well tolerated, with either no or mild cytokine release syndrome, or CRS. Further, in clinical data published in the *New England Journal of Medicine* in 2021, a 20-year-old woman with severe and refractory SLE was observed to experience rapid remission of symptoms and autoantibody levels following a single treatment with autologous CD19 CAR T cells. This patient has been in remission for at least 600 days and is included in the *Nature Medicine* publication mentioned above. We believe the foregoing academic clinical data, including the rapid depletion of B cells upon initiation of treatment and subsequently observed naïve B-cell reconstitution, suggest that CD19 CAR T-cell therapy could potentially lead to significant clinical benefit and reset the immune system with a single, well-tolerated treatment. However, the foregoing data was obtained by a third party outside of a formal clinical trial setting and we are seeking to validate this premise through well-controlled, multicenter clinical trials that demonstrate statistically significant results.

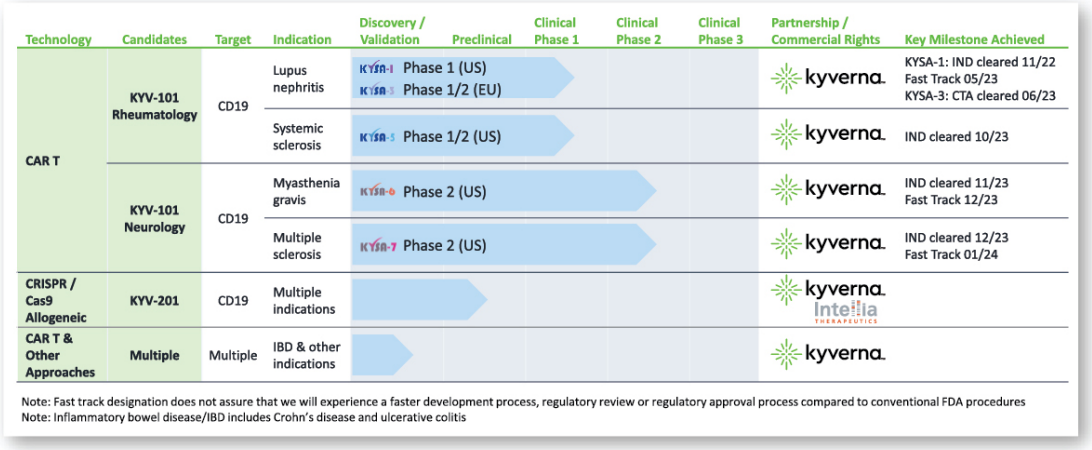
High prevalence and unmet need across autoimmune diseases

Over 80 diseases are classified as autoimmune diseases affecting up to 8% of the U.S. population. Moreover, the prevalence of autoimmunity is on the rise in the United States. Over the last 25 years, researchers have observed a 44% increase in the presence of antinuclear antibodies, the autoantibody in lupus, affecting 41 million people. These autoantibodies represent an early sign of autoimmune diseases, which develop in about 30% of these individuals over a five- to ten-year period. The chronic and debilitating nature of these diseases leads to both high medical costs and reduced quality of life, creating a significant burden for patients, their families and the health care system. It is estimated that sales for autoimmune disease therapies were greater than $80 billion globally in 2021. Despite the availability of many approved drugs, there remains substantial unmet clinical need, as existing therapies are rarely considered curative and the majority of patients do not respond optimally, if at all, to these therapies.

Current autoimmune disease treatments such as hematopoietic stem cell transplantation, or HSCT, and the use of B-cell-targeting monoclonal antibodies have led to therapeutic responses, but the majority of patients do not benefit either because of unacceptable toxicity risks or due to weak or short-lived activity. The HSCT process leads to depletion of the patient's immune system, and is a procedure associated with potentially life-threatening complications and its use to treat autoimmune disease is primarily as a salvage therapy for patients with severe refractory disease. Poor or mixed results have also been reported from patients with SLE, inflammatory myositis and autoimmune hepatitis when using monoclonal antibodies targeted against CD20, such as rituximab. We believe that the poor efficacy of anti-CD20 antibodies for these indications may be due in part to limited antibody activity in diseased tissue due to the weak tissue-penetrating ability of antibodies.

Our pipeline and programs

Our portfolio of product candidates for the treatment of autoimmune diseases is summarized in the figure below:



KYV-101, a fully human CD19 CAR T-cell therapy, was created using a CAR designed by the NIH to improve tolerability through the use of a fully human CD19 binding domain and optimized hinge and transmembrane domains. We in-licensed this highly differentiated CD19 CAR contained in KYV-101 and KYV-201 from the NIH. We believe that this combination of components produces a CAR with a differentiated safety profile. In an oncology Phase 1 trial conducted at the National Cancer Institute of the NIH, patients treated with the CD19 CAR used in KYV-101, referred to as Hu19-CD828Z, were found to experience lower levels of inflammatory cytokines, such as TNFα and IL-6, versus alternative CARs such as FMC63-28Z, the CAR used to create Yescarta®. Treatment with Hu19-CD828Z CAR T cells resulted in significantly lower rate of mild and severe neurotoxicity than previously observed in patients treated with FMC63-CD28Z at the same clinic. Despite the lower levels of inflammatory cytokine and neurotoxicity, Hu19-CD828Z still led to similar rates of durable antitumor responses. We believe that this favorable profile has the potential to be critical for the application of CAR T-cell therapies in indications such as autoimmune diseases, where there may be lower tolerance for treatment-related serious, and potentially fatal, adverse events.

We intend to develop KYV-101 in two broad areas of autoimmune disease: rheumatology and neurology. Our first clinical development program for KYV-101 is in lupus nephritis, a kidney disease that commonly develops in patients with SLE. We estimate that there are up to 40,000 lupus nephritis patients in the U.S. that are resistant to current therapies and are at high risk of developing kidney failure. In addition to this high unmet clinical need, there are several factors that we believe position lupus nephritis as an attractive lead indication, including promising early data from our ongoing clinical studies; clinical insights from promising case reports; the ability to achieve and measure clinically meaningful improvements in relatively short clinical trials; and recent regulatory precedents establishing clear and objective clinical endpoints for approval. We are conducting and sponsoring clinical trials in lupus nephritis in both the United States and Germany.

We are exploring the potential of KYV-101 in other indications through a combination of investigator-initiated clinical trials in the United States and named patient activities by individual physicians (including, for example, "*Individueller Heilversuch*," or single-patient treatment healing attempts, in Germany) outside of our sponsored clinical trials. We supply KYV-101 for use in qualified patients who have exhausted other treatment options and for whom there are strong patient- and indication-related scientific rationales. This strategy aligns with our mission to prioritize patient needs while providing us insight to help de-risk additional potential indications where our autoimmune cell therapy approach can benefit patients who are refractory to existing therapies. These investigator-initiated trials and named patient activities are not part of our clinical trials for KYV-101 and data from these trials and activities are reported by the relevant investigators and physicians. Such data are not obtained using

a single protocol or designed to be aggregated or reported as study results, and may be highly variable. While we do not expect to be able to use the results from these investigator-initiated trials or named patient activities in our applications for marketing approval to the U.S. Food and Drug Administration, or the FDA, or other foreign regulatory agencies, we believe that this strategy may provide some competitive advantage as we will be able to acquire additional clinical insights beyond highly focused clinical trials in specific geographies.

In September 2023, Stanford received IND clearance for an investigator-initiated trial of KYV-101 in MS, and in November 2023, the University of Pennsylvania received IND clearance for an investigator-initiated trial of KYV-101 in a basket of rheumatology indications. Additionally, the University of California, San Francisco and the University of Massachusetts are also preparing additional IND applications to begin investigator-initiated trials of KYV-101. Other academic institutions involved in a combination of named patient activities, investigator-initiated trials and translational collaboration include Charité-Universitätsmedizin Berlin, Department of Rheumatology and Clinical Immunology, Friedrich-Alexander-Universität (FAU) Erlangen-Nürnberg, Heinrich Heine Universität Dusseldorf, University Medical Center Hamburg Eppendorf and Taichung Veterans General Hospital, with areas of focus across neurology, rheumatology, biomarkers and lymphodepletion.

In the near term, we plan to initiate KYV-101 in Kyverna-sponsored clinical trials in SSc, MG and MS. In October 2023, we received IND clearance for SSc, in November 2023 we received IND clearance for a Phase 2 study in MG, and in December 2023 we received IND clearance for a Phase 2 study in MS.

We are also developing KYV-201, an allogeneic therapy containing the same CAR as KYV-101, with the intent of developing it in multiple autoimmune diseases. We believe that developing an allogeneic CD19 CAR T-cell therapy could further broaden patient access to potentially transformative CAR T-cell therapy. We have partnered with Intellia to apply its gene editing technology to the creation of KYV-201. The combination of our CD19 CAR licensed from the NIH and Intellia's differentiated technology platform has led to the creation of a product candidate in which *in vitro* activity matches the cell killing activity of KYV-101 but does so in the context of allogeneic cells.

Our research-stage programs are focused on developing product candidates to treat other autoimmune diseases such as inflammatory bowel disease, or IBD, which includes Crohn's disease and ulcerative colitis. These programs include a suite of capabilities related to T-regs developed through our completed research collaboration with Gilead Sciences, Inc., or Gilead, and novel humanized CAR constructs developed by us for use in autoimmunity. T-regs are a subset of CD4+ T cells that maintain tolerance in the periphery through multiple mechanisms involving both soluble mediators and direct cell-cell interactions. Clinical use of polyclonal, non-engineered T-regs has not yielded optimal therapeutic effects to date in autoimmune disease settings. However, we believe the use of antigen-specific T-regs, possibly through use of a CAR, holds promise by enhancing homing to antigen-specific effector T cells or sites of inflammation. Published reports in multiple pre-clinical animal models of autoimmunity have demonstrated that antigen-specific T-regs are significantly more effective than polyclonal T-regs. We are in the process of preparing a publication that addresses the therapeutic use of T-regs using a CAR and our differentiated approach that is the product of our significant investments in this modality.

Manufacturing capabilities

We are developing a robust manufacturing process for KYV-101 and have partnered with an experienced contract development and manufacturing organization, WuXi ATU Advanced Therapies, Inc., or WuXi, to generate KYV-101 for near-term clinical trials and named patient supply. In parallel, we are developing Ingenui-T, a manufacturing process designed to improve patient experience and manufacturing capabilities through partnerships with world-class organizations in cell therapy manufacturing, including ElevateBio, LLC.

Our company history and team

Based both on our initial product candidate KYV-101 and on our emerging research efforts, it is our ambition to become the leader in the development of cell therapies for the treatment of immune diseases. We were founded in 2018 after recognizing the potential of CD19 CAR T-cell therapies in autoimmune disease, and we successfully pursued the rights to a highly differentiated CAR construct from the NIH with the goal of bringing life-changing therapeutic benefits to patients suffering from autoimmune diseases. We began to license this construct in 2020

before investigators published a series of highly cited publications that confirmed our hypothesis. While developing a clinical development plan for this asset, we also anticipated the potential that an allogeneic CD19 CAR T-cell therapy could have in the treatment of autoimmune diseases and partnered with Intellia to incorporate its gene editing technology into a second product candidate. The potential for cell therapies in autoimmune diseases extends beyond products based on CD19 CAR T cells and we believe that our preclinical research efforts in these areas will serve to position us at the forefront of the field.

Our leadership team has deep industry experience:

Peter Maag, Ph.D., our Chief Executive Officer, has over 20 years of executive management experience in the pharmaceutical and diagnostic industries, most recently serving as Executive Chairman and CEO of CareDx, which he led from its time as a small startup through its emergence as a public company with a $5 billion market value in 2022.

Dominic Borie, M.D., Ph.D., our President, Research and Development, has a deep background in immunology and is a digestive tract and liver transplant surgeon. Dr. Borie previously had leadership positions at Horizon Therapeutics, Genentech, Amgen and Roche.

James Chung, M.D., Ph.D., our Chief Medical Officer, previously served as Executive Medical Director and head of Inflammation and Neuroscience, Global Medical Organization, and Global Development Leader for ENBREL® at Amgen.

Karen Walker, our Chief Technology Officer, has broad and deep industry experience in developing biopharmaceuticals and cell and gene therapy products at Roche/Genentech, Seattle Genetics, Novartis and other leading pharmaceutical companies.

Ryan Jones, our Chief Financial Officer, was part of our founding team and has extensive industry experience in healthcare and life science, previously at GE Ventures and Thermo Fisher Scientific.

Our Strategy

Our mission is to bring life-changing therapeutic benefits to patients suffering from autoimmune diseases. We intend to develop cell therapy product candidates with efficacy across multiple types of autoimmune diseases, including highly prevalent indications with high unmet clinical needs. We plan to pursue our mission through the following strategies:

- **Transforming autoimmune patients' experiences through cell therapies.** Our success is dependent on our ability to address the need for safe and effective therapies for patients, especially those who are refractory to other available therapies. Despite an abundance of marketed therapies in some autoimmune indications, many patients are nevertheless severely underserved. In addition, patients' daily lives are often considerably compromised, making broad and impactful interventions all the more imperative. We strive to always consider the patient's perspective as we decide how to create, develop, manufacture and potentially commercialize our product candidates, if approved. We prioritize following patients treated in our clinical trials not only through the course of treatment, but for many years thereafter.
- **Advancing KYV-101 through a broad clinical trial program, and driving the value of CD19 CAR T-cell therapy in autoimmune diseases.** We appreciate that there is both a high demand for novel therapies for autoimmune diseases and significant competition in developing cell therapies, motivating us to move quickly and decisively. We are enrolling two open-label, multicenter clinical trials of KYV-101 in lupus nephritis.
- **Advancing KYV-201 into clinical trials**. Successful development of allogeneic therapies for the treatment of autoimmune diseases enables the expansion of patient access and the treatment of highly prevalent diseases with off-the-shelf therapies based on cells from healthy donors.
- **Expanding access and clinical experience with our product candidates through investigator-initiated trials and named patient activities in line with our patient-centered focus.** We actively

partner with leading clinicians interested in assessing the potential of our product candidates to treat patients who are refractory to existing therapies, by either initiating their own clinical trials in the United States, or treating a single patient who has exhausted other treatment options on a named patient basis outside of the United States. While we do not expect to be able to use the results from these trials or activities in our application for marketing approval to the FDA or other foreign regulatory agencies, our openness to named patient treatments and other such non-traditional clinical approaches serves our mission to prioritize patient needs while providing us insight into potential areas for future clinical development. Pursuing investigator-initiated trials also increases physician familiarity with our company and broadens our network of potential prescribers for our therapies if they are approved.

- **Investing in early-stage research programs to expand our pipeline and capabilities through selectively acquiring highly differentiated technologies.** Treatment of the wide spectrum of autoimmune diseases will require more than the ability to target B cells with CD19 CAR T-cell therapies. We have developed T-reg capabilities through our completed research collaboration with Gilead and novel humanized CAR constructs that we have created for use in autoimmunity. Similar to our successful efforts to license the technologies behind KYV-101 and KYV-201, we intend to continue to actively pursue technologies through capital-efficient acquisitions or partnerships that offer us the possibility of developing safe and effective cell therapies for autoimmune diseases.
- **Investing in technologies to prepare for commercialization and selectively evaluating strategic partnerships to improve patient experience or enable greater patient access**. We plan to build a fully integrated biopharmaceutical company capable of executing registrational trials, obtaining regulatory approvals and commercializing our drugs globally. We plan to invest in manufacturing technologies, commercial supply advancements and demand planning processes to provide us with distinct competitive advantages, maximize patient access and overcome historical supply challenges for this modality.

Autoimmune Disease Market Background

Autoimmune disease arises from an immune response directed not against pathogenic cells but rather against the body's own cells and tissues. In a healthy individual, immune cells such as B cells and T cells that recognize normal cells and tissues – and could thus cause harm – are either eliminated before they mature, or have their activities suppressed by other mechanisms. However, in autoimmune disease patients, these preventative measures fail due to a combination of both a person's genetic makeup and his or her exposure to certain antigens from infections or the environment.

Autoimmune disease is widely and increasingly prevalent, evidenced by over 80 autoimmune diseases impacting up to 8% of the U.S. population. Over the last 25 years, researchers have observed a 44% increase in the presence of antinuclear antibodies, the autoantibody in lupus, affecting 41 million people. These autoantibodies represent an early sign of autoimmune diseases, which develop in about 30% of these individuals over a five- to ten-year period.

The chronic and debilitating nature of these diseases leads to both high medical costs and reduced quality of life, creating a significant burden for patients, their families and the health care system. It is estimated that sales for autoimmune disease therapies were greater than $80 billion globally in 2021. Despite the availability of many approved drugs, there remains substantial unmet clinical need, as existing therapies are rarely considered curative and the majority of patients do not respond optimally, if at all, to these therapies.

There is a wide spectrum of diseases and symptoms driven by autoimmunity. The presence of autoantibodies, a product of autoreactive B cells, is a hallmark of many of these diseases. Although the identity of the autoantigen targeted and the tissue or organ with the most significant pathology may differ among autoimmune diseases, the production of autoantibodies by B cells is a common characteristic among many of them. There is also growing evidence that autoreactive B cells may also drive many autoimmune diseases through their interactions with T cells and the production of cytokines. This unifying biology provides us with the opportunity to create therapies for many autoimmune diseases by targeting autoantibody production by B cells.

The following table sets forth for select B-cell-driven diseases the number of diagnosed patients in the United States, the European Union and Japan in 2022:

B Cell-Driven Diseases	Estimated Number of Diagnosed Patients in US + EU + Japan as of 2022
Rheumatoid Arthritis	4,700,000
Multiple Sclerosis	1,520,000
Sjogren's disease	750,000
Systemic Lupus Erythematosus (SLE)	560,000
Systemic sclerosis	200,000
Lupus nephritis	160,000
Myasthenia gravis	160,000
Inflammatory myositis	120,000
ANCA-Associated Vasculitis	100,000
Neuromyelitis Optica	20,000
Total	~8.3 Million Patients

Limitations of Current Autoimmune Disease Therapies

Two therapeutic approaches serve to validate the broad potential of B-cell-targeted therapies: stem-cell transplant and anti-CD20 antibodies. Patients with B-cell hematologic malignancies, such as multiple myeloma, can obtain deep, durable remissions of their disease by autologous hematopoietic stem cell transplant, or HSCT. The HSCT process involves isolating hematopoietic stem cells from a patient and treating the patient with high-dose chemotherapy to eliminate tumor cells. This process also leads to depletion of the patient's immune system, which can be reconstituted by administration of the hematopoietic stem cells, and has been shown to be effective in treating autoimmune disease, resulting in durable responses. HSCT, however, is a procedure associated with potentially life-threatening complications and its use to treat autoimmune disease is primarily as a salvage therapy for patients with severe refractory disease.

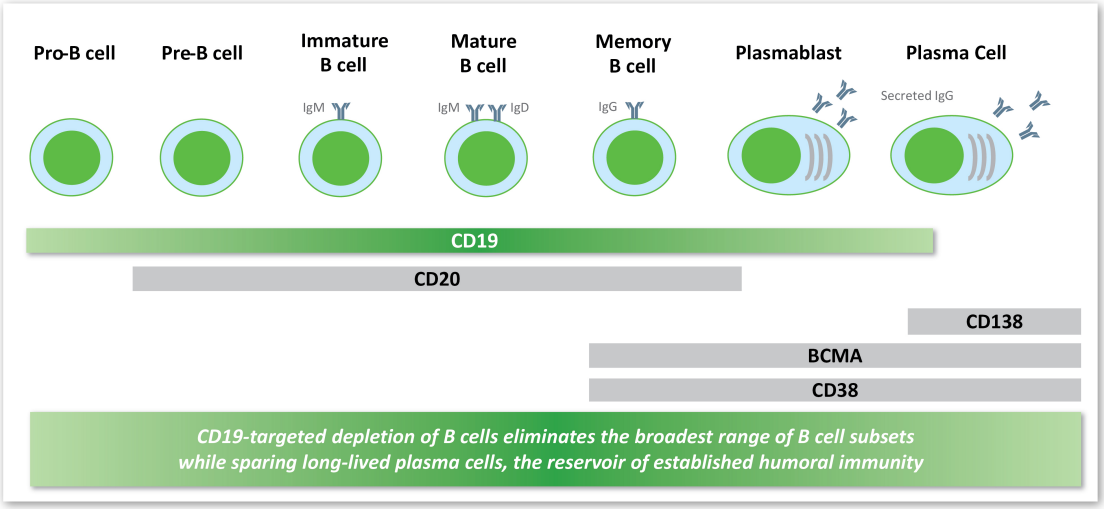
Monoclonal antibodies targeted against CD20, such as rituximab, have been approved to treat a number of diseases including hematopoietic malignancies and immune disorders. These antibodies bind to CD20, a B-cell-specific antigen, leading to B-cell depletion. More recently, rituximab has been shown to have efficacy in a number of autoimmune diseases, including rheumatoid arthritis, pemphigus vulgaris and ANCA associated vasculitis. However, poor or mixed results have been reported in other autoimmune diseases such as SLE, inflammatory myositis and autoimmune hepatitis. We believe that the poor efficacy of anti-CD20 antibodies for these indications may be due in part to limited antibody exposure in diseased tissue due to the weak tissue-penetrating ability of antibodies.

Our Solution — Cell Therapy for Autoimmune Disease Treatment

Opportunity to Harness the Power of CAR T-cell Therapy in Autoimmune Disease

We believe the success of cell therapies such as CAR T-cell therapies in oncology has paved the way for the application of cellular therapies in other therapeutics areas, including autoimmune diseases.

The first FDA-approved CAR T-cell therapies targeted CD19, a B-cell specific antigen that is highly expressed on B-cell malignancies, such as large B-cell lymphoma. Treatment with CD19 CAR T cells results in depletion of these malignant cells as well as other cells that express CD19, including healthy B cells. Given the role of B cells in multiple autoimmune diseases, we believe it is reasonable to expect that depleting these cells using CD19 CAR T cells may result in therapeutic benefits in a broad range of B-cell-driven autoimmune diseases. The following figure shows the range of B cells targeted by CD19 relative to other targets such as CD20 and BCMA:



Clinical Proof-of-Concept

The treatment of autoimmune disease patients with CD19 CAR T cells has been shown to result in rapid and durable responses in patients who were refractory to other approaches. Recent publications have described a series of case studies in which patients with autoimmune diseases who were refractory to existing therapies were observed to respond favorably to treatment with CD19 CAR T cells. These diseases include SLE, SSc and antisynthetase syndrome, a form of inflammatory myositis.

Potential to Overcome CRS Challenges of CAR T-cell Therapy

CRS is a systemic inflammatory response that is caused by the large, rapid release of cytokines in the blood by immune cells, which may result in multi-organ failure and death. The development of Grade 3 and above CRS is a serious risk associated with the first approved CD19 CAR T-cell therapy products, Yescarta®, Kymriah® and Breyanzi®.

Increased understanding of the underlying causes of CRS over time has led to the development of CAR T-cell therapies that show a reduction in the frequency of serious CRS. We believe the following factors have the potential to reduce the toxicities associated with CRS and open up the potential for the use of CAR T-cell therapies in indications where previous levels of toxicities would not be broadly tolerated.

- **Improved CAR Constructs**. CARs typically contain an extracellular antigen-binding domain, a transmembrane segment, one or more costimulatory domains, and a CD3ζ signaling domain. The transformative antitumor activities generated by early CAR T-cell products sparked broad exploration of alternative CARs leading to the identification of CARs that have reduced likelihood of generating serious CRS in clinical applications of CAR T cells.
- **Clinical Experience**. With increased experience in treating patients with CAR T cells, clinicians have found that the seriousness of CRS can be managed in some patients by anti-cytokine treatments, such as tocilizumab, an anti-IL-6 drug, with or without corticosteroids.

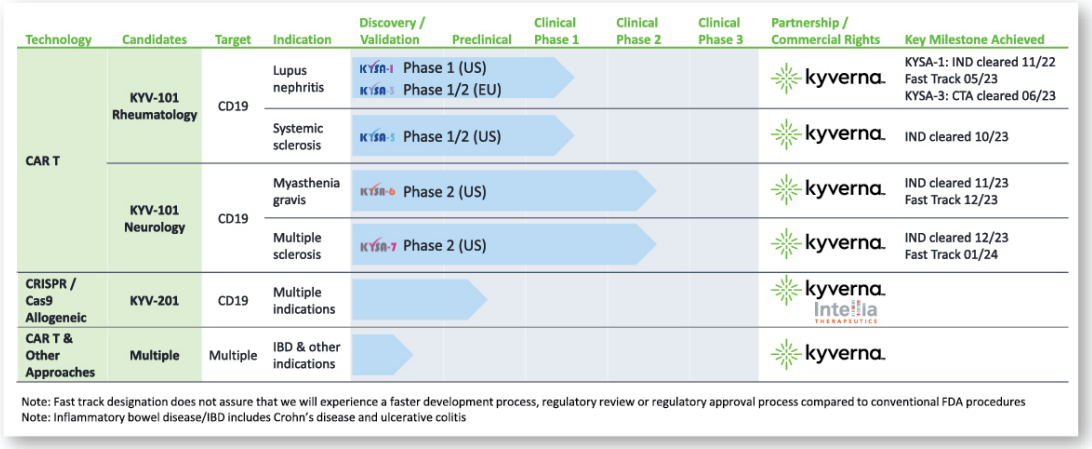
- **Role of Tumor Burden**. There is an emerging appreciation of the importance of the tumor burden on the severity of CRS. Patients with relapsed or refractory B-cell acute lymphoblastic leukemia, or B-ALL, with lower tumor burden had lower CRS severity when treated with CD19 CAR T cells compared to those with high tumor burden. We believe this suggests that patients with no tumors may have inherently lower risks of developing serious CRS. Emerging data from published case studies of CD19 CAR T-cell treatment of patients with SLE, SSc and antisynthetase syndrome were observed to have improved tolerability compared to the experience of CD19 CAR T-cell therapies in oncology, and no cases of CRS at a level of Grade 3 or above were reported in the autoimmune patients in such case studies.

Potential to Overcome Manufacturing Constraints of CAR T-cell Therapy

Challenges in the manufacturing of CAR T cells have limited the number of oncology patients who have been able to be treated with cell therapies. The manufacturing of autologous CAR T cells typically takes two to three weeks, but due to shortages in manufacturing capacity and complex logistics, the process can take several months. As the number of patients treated with CAR T cells is rapidly increasing, worldwide capacity to manufacture these therapies has increased and the processes to manufacture these therapies have continued to evolve and become more automated.

The turnaround time from retrieval of the starting cells from patients, a process referred to as apheresis, to the infusion of CAR T cells in patients is critically important for those oncology patients with progressive disease who may have exhausted other treatment options. Most autoimmune diseases, by contrast, are chronic conditions that, despite their seriousness, are less likely to significantly progress while CAR T-cell therapies are manufactured, thereby reducing the critical nature of the turnaround time.

Our Pipeline



Note: Fast track designation does not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures
Note: Inflammatory bowel disease/IBD includes Crohn's disease and ulcerative colitis

KYV-101, an Autologous CD19 CAR T-cell Product Candidate for Rheumatology and Neurology Indications

We are developing KYV-101, a fully human CD19 CAR T-cell therapy created using a CAR designed by the NIH to improve tolerability through the use of a fully human CD19 binding domain and optimized hinge and transmembrane domains. We intend to develop KYV-101 in two broad areas of autoimmune disease: rheumatology and neurology. Development of KYV-101 in rheumatology is anchored by two ongoing clinical trials in lupus nephritis, and we are preparing for additional clinical trials of KYV-101 in SSc. We intend to initially focus our neurology development on MS and MG, indications where clinical experience from individual patients treated with KYV-101 have been reported by independent physicians in named patient settings. Apart from our clinical trials, we

also continue to provide access to KYV-101 to patients with autoimmune diseases by supplying KYV-101 to third-party investigator-initiated clinical trials and in named patient settings.

Lupus Nephritis Background

Lupus nephritis is a type of kidney disease that frequently develops in patients with SLE and is a major cause of morbidity and mortality in SLE. SLE is an autoimmune disease that arises when the immune system develops antibodies against common antigens such as double-stranded DNA, or dsDNA, or components of the cell nucleus. About half of adult patients with SLE will develop kidney disease. In lupus nephritis, immune complexes containing autoantibodies, their antigens and other components of the immune system impair the ability of the kidneys to properly filter the blood and regulate fluid levels, leading to excess excretion of serum proteins. This leads to symptoms such as swelling and weight gain due to fluid retention, increased blood pressure and foamy urine due to excess protein. Most patients have protein in their urine, or proteinuria, at the time of diagnosis. These patients can also have signs of blood leakage into the urine and decreased levels of serum albumin.

The treatment goal in the management of lupus nephritis is to minimize the development of permanent kidney damage typically through the use of immunosuppressants such as glucocorticoids, mycophenolate mofetil and cyclophosphamide to reduce the immune complex driven inflammation. Anti-hypertensive agents such as angiotensin-converting enzyme inhibitors and angiotensin 2 receptors blockers are routinely used to directly reduce urinary protein excretion. Patients who do not respond to initial immunotherapies can be treated with calcineurin inhibitors, including voclosporin, marketed as Lupkynis® by Aurinia Pharmaceuticals. However, in a 52-week Phase 3 trial, only 41% of patients achieved complete renal response at week 52 when voclosporin was added on top of standard of care therapy compared to 23% on standard of care only.

Because autoreactive B cells are a driver of immune complex formation, B-cell targeted therapies are also used to treat patients with lupus nephritis. Rituximab, an anti-CD20 antibody, has been used off-label for over a decade to treat lupus nephritis. Belimumab, marketed as Benlysta® by GSK, was the first therapy to be approved by the FDA to specifically treat lupus nephritis. It functions by blocking the differentiation of B cells into antibody-producing plasma cells. However, only 30% patients treated with a combination of Benlysta® and standard of care therapies achieved complete renal responses after two years of treatment.

Current treatment strategies remain unsatisfactory in terms of achieving a complete renal response, preventing relapses, avoiding chronic kidney disease, and avoiding progression to end-stage kidney disease.

Many patients fail to achieve complete remissions within six months of initiation of approved therapies, resulting in the use of sequential treatments or combination therapies to achieve disease control. Lupus nephritis can progress aggressively, requiring prompt treatment to avoid permanent kidney damage which can arise following a single disease flare. Up to 20% of patients will ultimately develop end-stage kidney disease within the first decade after diagnosis.

Long-term high-dose immunosuppression for the treatment of lupus nephritis is associated with significant treatment toxicity. High-dose glucocorticoids have been shown to lead to neuropsychiatric toxicities, infections, and increased body mass index in lupus nephritis patients. Cyclophosphamide treatment is associated with infertility, urotoxicity and oncogenicity. These toxicities remain when patients are treated with biologics, as these agents are typically added on top of standard of care.

Treatment of lupus nephritis is estimated to cost up to $40,000 a year and these costs escalate to between $115,000 and $200,000 a year for those patients who go on to develop end-stage kidney disease. Lifetime costs for patients on current standard of care are approximately $900,000.

There are an estimated 160,000 SLE patients in the United States, the European Union and Japan that are diagnosed with lupus nephritis. We estimate that there are up to 40,000 lupus nephritis patients in the United States that are refractory to current therapies.

KYV-101, Designed for Reduced Cytokines and an Improved Therapeutic Profile

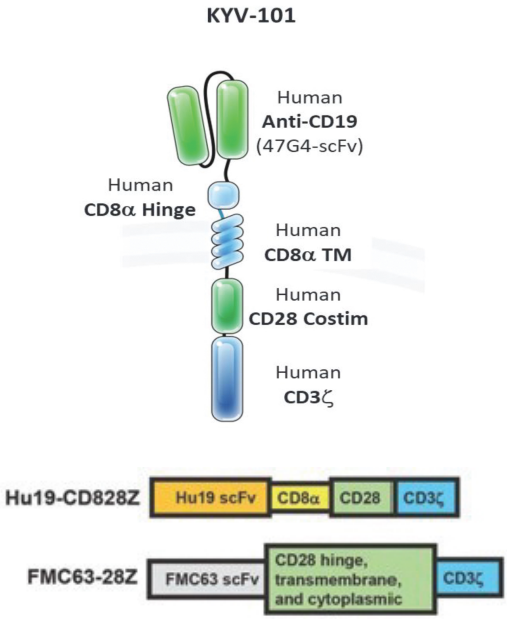
KYV-101 is created using a CAR, referred to as Hu19-CD828Z, that contains a fully human anti-CD19 single-chain fragment variable, or scFV, domain. By contrast, all four of the currently approved CD19 CAR T-cell therapies, Kymriah®, Yescarta®, Tecartus® and Breyanzi® incorporate the scFv portion of murine antibodies as their antigen-recognition domains. These murine domains lead to anti-murine immune responses in treated patients, which results in increased clearance of therapeutic CAR T cells, limiting their expansion and persistence. This anti-murine immune response can lower the efficacy of CAR T cells upon reinfusion should patients require retreatment.

We believe anti-murine antibodies may be a more significant problem in the treatment of autoimmune diseases than cancer treatment, potentially due to the hyperactivation of immune cells. In a study published by Combier et al. in *The Journal of Rheumatology* in June 2020, over 40% of patients with systemic autoimmune diseases treated with rituximab, a murine-based monoclonal antibody, had anti-drug antibodies, compared to 8.6% of rituximab-treated rheumatoid arthritis patients. The presence of anti-drug antibodies led to negative impacts on treatment of patients with SLE, including infusion-related reactions and increased persistence of autoantibodies.

We believe that the creation of KYV-101 with Hu19-CD828Z, which contains a fully human scFv domain, has the potential to reduce the likelihood of the development of anti-CAR antibodies, preserving the possibility of retreatment. Autoimmune diseases are often lifelong chronic conditions, raising the possibility that some patients may experience relapse and require retreatment, even after achieving a meaningful clinical response. It is also well-established that there are genetic drivers of autoimmune disease, predisposing some individuals to develop multiple autoimmune diseases, which may require treatment at different times.

In addition to a fully human scFv domain, Hu19-CD828Z was also designed with a human CD8α hinge and transmembrane domain, a human CD28 costimulatory domain, and a human CD3ζ activation domain. In a study published by Alabanza et al. in *Molecular Therapy* in July 2017, this combination was observed to reduce the levels of cytokine release *in vitro* in a systematic comparison of CARs created with alternate domain structures, including the FMC63-CD28Z CAR used to create Yescarta®. Importantly, the reduction in cytokine production was not correlated with a diminution in the cytotoxicity of CAR T cells against tumor cells in *in vivo* tumor models in mice.

The following illustrations show the structure of Hu19-CD828Z, the same CAR used by us to create KYV-101, and a comparison of Hu19-CD828Z to the FMC63-CD28Z CAR:

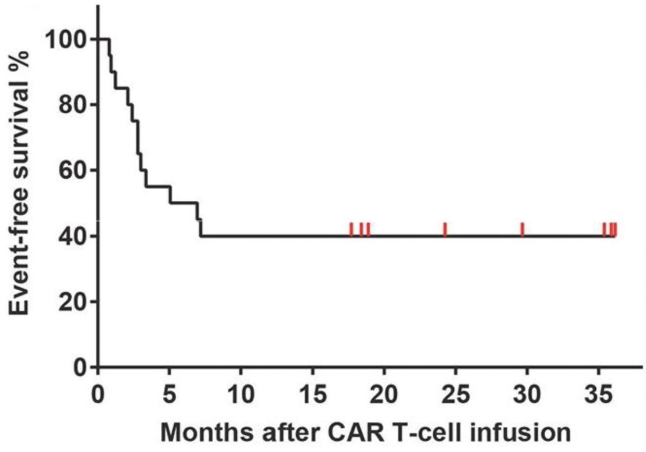


Clinical Results of Hu19-CD828Z in Oncology

A Phase 1 trial was conducted by the NIH using CAR T cells created with the Hu19-CD828Z CAR, the same CAR used by us to create KYV-101. In this trial, published in *Nature Medicine* in 2020, 20 patients with B-cell lymphoma that had failed a median of four prior lines of therapy were treated with Hu19-CD828Z CAR T cells.

The overall remission rate was 70%, with 55% of patients obtaining complete responses, or CRs. Eight of 20 patients were in ongoing CRs at the time of the last follow-up. Ongoing CRs at the time of publication of the results had durations of response ranging from 17 to 35 months. Median event-free survival for all patients was six months.

The following graph sets forth the event-free survival rate of the 20 B-cell lymphoma patients treated with Hu19-CD828Z CAR T cells:

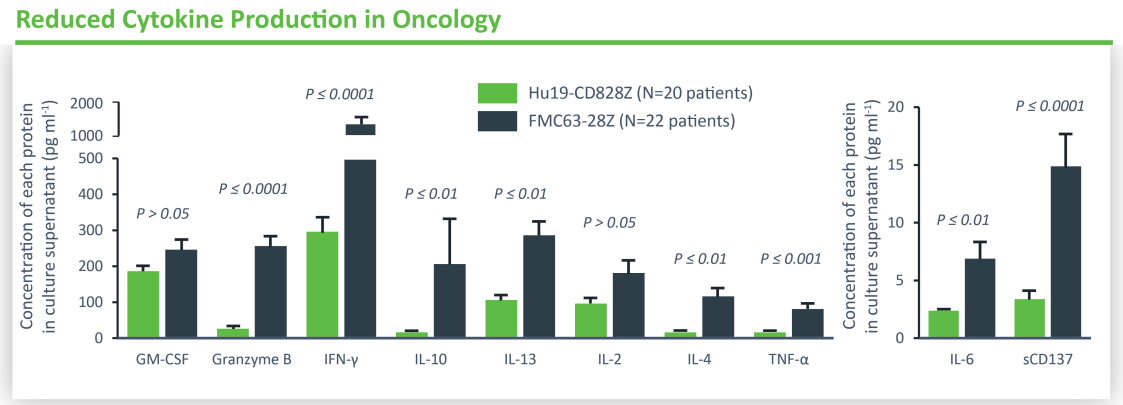


The antitumor results observed with Hu19-CD828Z CAR T cells were comparable to those previously reported in the ZUMA-7 trial of Yescarta®, but there were marked differences in the adverse event profiles for these two CAR T cells.

Patients treated with Hu-19-CD828Z CAR T cells were observed to have significantly lower levels of inflammatory cytokines, such as TNFα and IL-6 than observed at that clinical site with FMC63-28Z CAR T cells. These observations were not based on a single trial of both types of CAR T cells using a standardized protocol and patient population; consequently, the value of such a comparison of alternative therapies is limited.

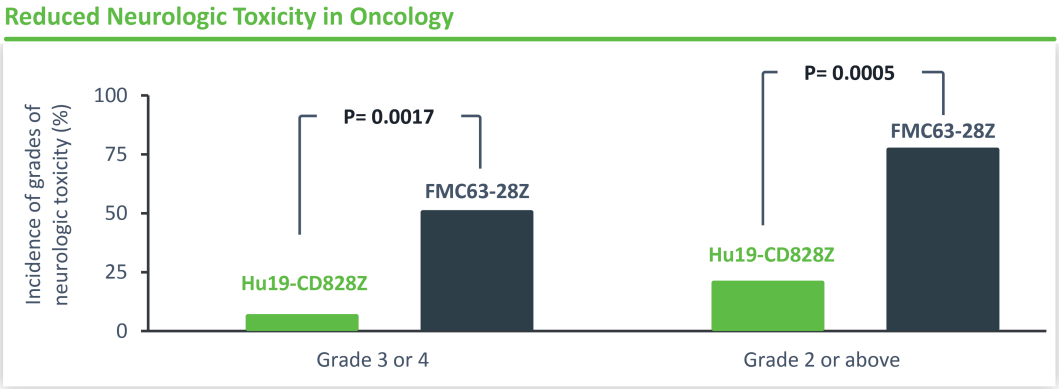
However, we believe that the published comparison of clinical results observed from Hu-19-CD828Z CAR T cell treatment and FMC63-28Z CAR T cell treatment in a highly respected, peer-reviewed journal support our rationale for advancing the Hu19-CD828Z CAR in our clinical development.

The following graph shows the reduced levels of inflammatory cytokines observed in oncology patients treated with Hu19-CD828Z CAR T cells in the NIH Phase 1 trial, compared to those observed in patients treated with FMC63-28Z CAR T cells at the same clinic:



Treatment with CAR T cells has also been associated with the development of immune effector cell-associated neurotoxicity syndrome, or ICANS. ICANS can range in seriousness from Grades 1 and 2 toxicities, characterized by mild disorientation of moderately impaired consciousness, to Grades 3 and 4 toxicities, characterized by seizures and life-threatening complications. In the NIH Phase 1 trial, treatment with Hu19-CD828Z CAR T cells resulted in a significantly lower rate of both mild and severe neurotoxicity than previously observed in patients treated with FMC63-CD28Z CAR T cells at the same clinic.

The following graph shows the reduced rates of neurotoxicity observed in patients treated with Hu19-CD828Z CAR T cells, compared to patients treated with FMC63-28Z CAR T cells:



In this initial clinical trial of Hu19-CD828Z CAR T cells, it was observed that treatment with these cells resulted in lower rates of, and less severe, CRS and neurotoxicity than observed at the same treatment center in a similar trial of FMC63-CD28z CAR T cells, subsequently approved as Yescarta®, while still leading to similar rates of durable antitumor responses. We believe that this favorable profile has the potential to be critical for the application of CAR T-cell therapies in indications such as autoimmune diseases, where there may be lower tolerance for treatment-related serious, and potentially fatal, adverse events.

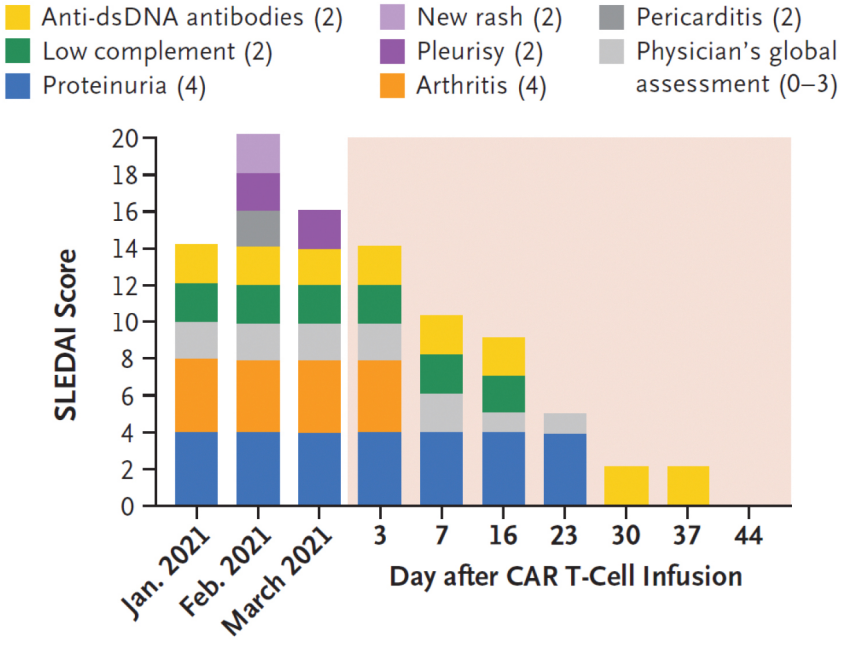
The combination of patient cells, our autologous CAR T-cell manufacturing process, and the underlying Hu19-CD828Z CAR licensed from the NIH results in the product candidate KYV-101 expressing the

Hu19-CD828Z CAR. While we do not intend to demonstrate comparability between KYV-101 and the NIH product candidate containing the same underlying CAR, we believe that the differentiated properties of the underlying CAR construct in KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies. While we may not be able to use the results from the NIH product candidate in our application for marketing approval to the FDA or other foreign regulatory agencies, we believe that these results reported in a peer-reviewed journal support the differentiated properties of the underlying CAR construct in KYV-101.

Existing CD19 CAR T Clinical Data

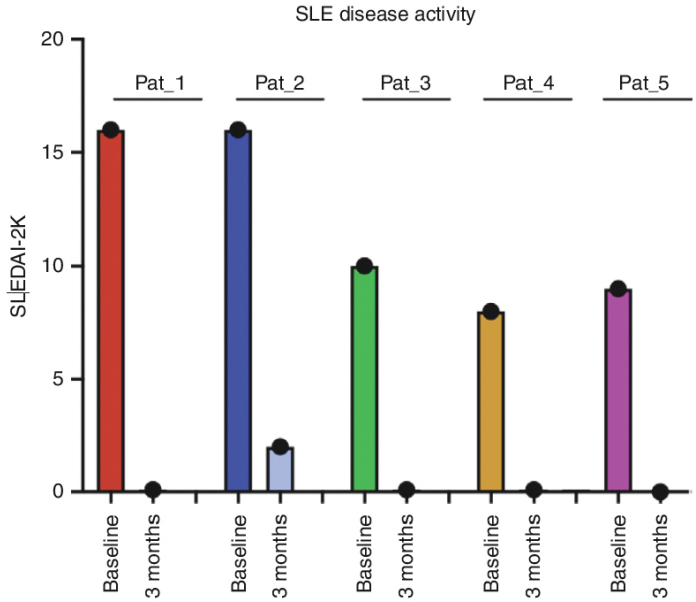
We believe a number of published case study reports describing the use of CD19 CAR T cells for the treatment of autoimmune diseases provide evidence of the potential for KYV-101. A 2021 publication in the *New England Journal of Medicine* presented the case of a 20-year-old woman with severe and refractory SLE with lupus nephritis who had been treated with glucocorticoids, mycophenolate mofetil, cyclophosphamide, tacrolimus, rituximab and belimumab, yet her symptoms and autoimmune disease were not suppressed. Rapid remission of symptoms and autoantibody levels as measured by the Systemic Lupus Erythematosus Disease Activity Index, or SLEDAI, Score, were observed in this patient following a single treatment with autologous CD19 CAR T cells. Levels of proteinuria decreased from above 2000 mg of protein per gram of creatine to less than 250 mg of protein per gram of creatine. This patient has been in remission for at least 600 days. Importantly, this long-term remission was sustained without the use of corticosteroids or other immunosuppressive medications – avoiding the requirement for more potent immunosuppressants and their associated toxicities.

The following graph shows a rapid reduction in symptoms and autoantibody levels following CAR T-cell therapy observed in a patient with severe SLE and lupus nephritis refractory to other therapies:



A subsequent publication in 2022 in *Nature Medicine* provides further support for the potential of CD19 CAR T cells for the treatment of SLE with lupus nephritis. All five patients presented in this publication treated with CD19 CAR T cells experienced improvements in SLEDAI-2K scores with scores of zero observed in four patients by three months post treatment and a score of two in one patient due to residual low-level proteinuria, which was likely due to previously accumulated kidney damage.

The following graph illustrates the improvement of SLE signs and symptoms observed in five patients treated with CD19 CAR T cells in the *Nature Medicine* case reports:



Several important observations from this publication provide insight into the potential value of CD19 CAR T-cell therapy.

- **Elimination of autoantibodies**. Autoantibodies against common antigens in SLE, such as dsDNA, disappeared from the five patients, as well as autoantibodies against other antigens.
- **Immune system reset**. CAR T cells were observed to expand *in vivo* following treatment, and B cells were rapidly and deeply depleted upon initiation of treatment, but all five patients experienced B-cell reconstitution after an average time of 110 days with no relapse of SLE.
- **Preservation of vaccination responses**. No substantial decline in immune responses against common vaccines, including measles, rubella, mumps, varicella zoster, hepatitis B, tetanus, diphtheria and pneumococci, were detected compared to baseline.
- **Treatment was well tolerated**. Either no CRS or only mild CRS was reported for all five patients. Fever (CRS Grade 1) occurred in three of five patients, which was successfully treated, and body temperature and heart rate at ten days post-treatment were generally consistent with baseline levels. No cases of ICANS or treatment-related infections were reported.

The rapid depletion of B cells upon initiation of treatment in these patients and subsequently observed naïve B-cell reconstitution suggest that CD19 CAR T-cell therapy could potentially be used to reset the immune system. We believe that the ability to reset the immune system with a single, well-tolerated treatment could provide the opportunity to improve the patient experience for those suffering from lupus nephritis, offering potential long-term benefits without the costs, inconveniences and toxicities associated with repeat treatments of existing therapies.

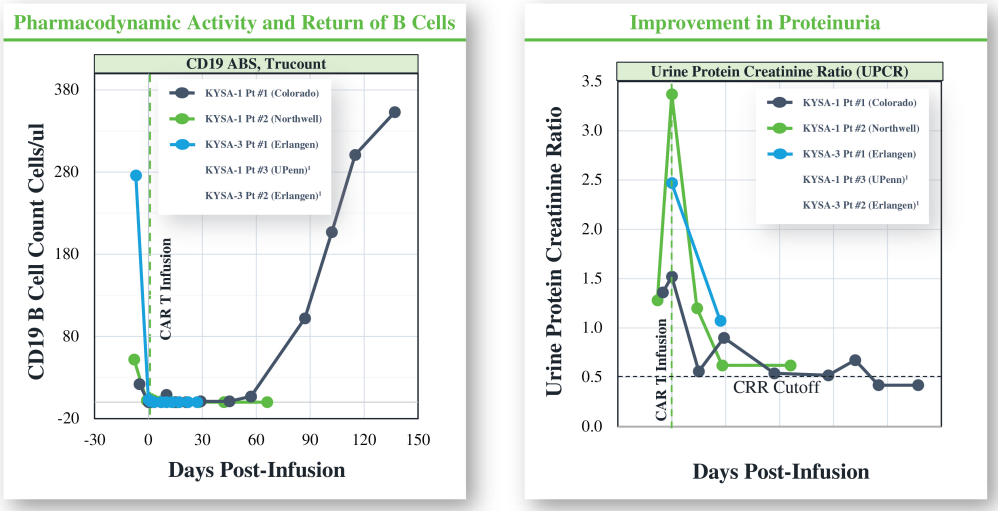
KYV-101 Clinical Development in Lupus Nephritis

KYV-101 is an autologous CAR T cell generated using the same underlying Hu19-CD828Z CAR used by the NIH in CAR T cells to treat oncology patients. We have initiated two clinical trials of KYV-101 in patients with lupus nephritis, or LN. KYSA-1 is an open-label, multicenter, U.S.-based trial in which we intend to enroll 12 adult patients with refractory lupus nephritis. The primary endpoints of KYSA-1 are the incidence of adverse events and laboratory abnormalities and the frequency of dose-limiting toxicities. Secondary endpoints of KYSA-1 include

characterizing pharmacokinetics and pharmacodynamics, evaluating disease-related biomarkers, evaluating efficacy including Complete Renal Response, or CRR, and time to CRR, and evaluating immunogenicity. KYSA-3 is a similar trial based in Germany where we aim to enroll six to 12 patients in the Phase 1 portion of the trial and up to 20 patients in the Phase 2 portion. The Phase 1 primary endpoints of KYSA-3 are the incidence of adverse events and laboratory abnormalities and the frequency of dose-limiting toxicities; the Phase 2 primary endpoints are the incidence of adverse events and laboratory abnormalities and the CRR rate. Secondary endpoints include evaluating disease-related biomarkers, efficacy, including CRR and time to CRR, and immunogenicity. Both trials are currently enrolling patients: we dosed our first patient in the KYSA-1 trial in July 2023 and we dosed our first patient in the KYSA-3 trial in November 2023.

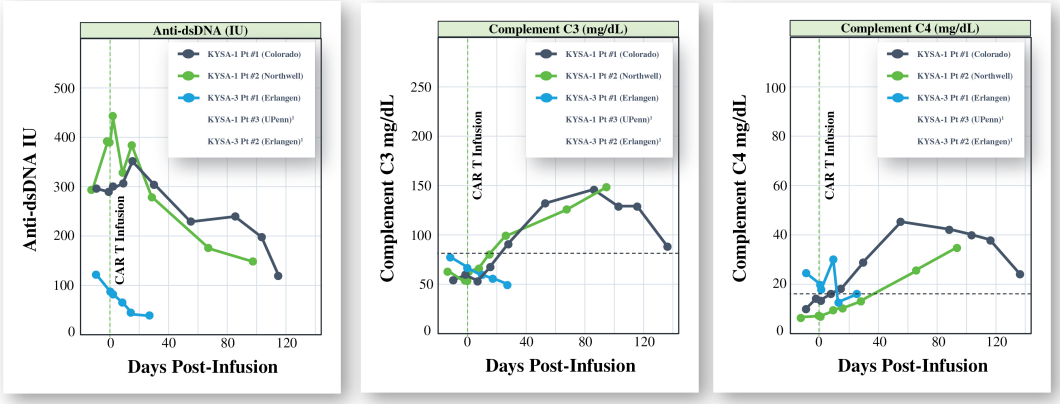
We chose LN as the initial indication for our clinical development program because of the well-defined patient population and the ability to select objective clinical endpoints to support regulatory approval. While there is significant overlap between SLE and LN patients given that 50% to 75% of SLE patients develop LN during the course of the disease, SLE and its associated SLEDAI-2K scores have historically been known to experience variability in its physician-assessed measures. On the other hand, proteinuria, elevated levels of protein released in urine, serves as a biological marker of LN disease activity and potential renal damage, and provides a more objective clinical endpoint through which we can measure the potential clinical benefits of KYV-101. During the treatment of LN, physicians can screen for proteinuria through Urinary Protein-Creatinine Ratio, or UPCR, in a spot urine sample to score renal activity. Resolution of proteinuria, measured through UPCR, is therefore used as a key component in the quantitative and objective composite endpoint, CRR, which we use as an endpoint for KYSA-1 and KYSA-3. CRR has been accepted as a registration-enabling endpoint for LN clinical trials.

In early results available as of December 31, 2023, from the first two adult patients enrolled in our KYSA-1 LN trial and from the first adult patient enrolled in our KYSA-3 LN trial, we observed improvement in UPCR as detailed in the below figure. As a baseline, patient 1 in our KYSA-1 LN trial, diagnosed with SLE nine years prior, had Class IV LN with persistent proteinuria despite treatment with mycophenolate mofetil, cyclophosphamide, tacrolimus, sirolimus, rituximab, belimumab and glucocorticoids. After KYV-101 treatment therapy, patient 1 discontinued immunosuppressive therapy except 10 mg prednisone, which was discontinued on day 31. Patient 2 in our KYSA-1 LN trial, who had SLE for two years prior to treatment, had failed numerous immunosuppressive therapies for persistently active Class IV LN. Treatment with KYV-101 was well tolerated, with Grade 1 CRS on days 5 and 6 for patient 1, and days 10 and 11 for patient 2, which responded to acetaminophen. No ICANS or other serious adverse events were observed. As expected, we observed prolonged CD19+ B-cell depletion following KYV-101 treatment, whereas levels of neutrophils, hemoglobin and platelets were normalized within several weeks. By day 56, evidence of B-cell recovery was observed in patient 1. For patient 1, UPCR improved from 1.5 at baseline to 0.5 by day 56 and improved to below 0.5 by day 120 without glucocorticoids or immunosuppressive therapy. For patient 2, UPCR improved from 3.4 at baseline to 0.6 by around day 30. For patient 1 on the KYSA-3 LN trial, we observed effective CD19+ B-cell depletion following KYV-101 treatment, and UPCR improved from 2.5 at baseline to 1.1 by day 27.



Note: data available as of 12/31/2023; [1]KYSA-1 Pt #3 and KYSA-3 Pt#2 enrolled and apheresed but not yet dosed as of 12/31/2023

The following figure shows anti-dsDNA and complement levels (C3 and C4) which are additional biomarkers used clinically to assess disease activity in lupus. Increase in anti-dsDNA antibodies and a decrease in complement levels may be associated with higher disease activity.



Note: data available as of 12/31/2023; [1]KYSA-1 Pt #3 and KYSA-3 Pt#2 enrolled and apheresed but not yet dosed as of 12/31/2023

We believe that in addition to the potential to deliver therapeutic benefits, safety and tolerability are critical factors for the application of CAR T cells to treat chronic diseases such as autoimmune diseases. As of December 31, 2023, three LN patients have been treated with KYV-101 as part of KYSA-1 or KYSA-3. Serious grade CRS and ICANS have not been observed in these patients through that date, consistent with the NIH Phase 1 observations from oncology patients treated with CAR T cells created with the same CAR, as described above under "*Potential to overcome CRS challenges of CAR T therapy*".

Clinical Applications of KYV-101 in Other Indications

We intend in the near term to also pursue clinical trials of KYV-101 in systemic sclerosis, myasthenia gravis, and multiple sclerosis.

Systemic Sclerosis (SSc) Disease Overview

SSc is a chronic, systemic autoimmune disease with three types of manifestations: vascular injury, immune abnormality characterized by autoantibodies and fibrosis. SSc can affect multiple internal organs in the body, including the lungs, heart, kidneys, joints, muscles, esophagus, stomach and intestines.

One of the most common and earliest symptoms of SSc is the so-called Raynaud phenomenon, which involves decreased blood flow to the extremities in response to cold temperatures. This can lead to temporary finger discoloration, numbness and pain and is also associated with the development of finger ulcers. Other symptoms of SSc include muscle and joint pain, skin tightening and dilated blood vessels that can be seen through the skin. Scarring of internal organs can also lead to gastrointestinal, pulmonary, cardiac and renal disease. Up to 90% of SSc patients develop interstitial lung disease, or ILD, a loss of lung capacity due to fibrosis. A less common but life-threatening complication of SSc is pulmonary arterial hypertension, or PAH, which has emerged as a leading cause of morbidity and mortality. Patients with ILD who develop PAH have a one-year mortality rate of over 60%.

The prevalence of SSc in Europe, the United States and Japan is approximately 200,000. Currently, there are no FDA-approved disease modifying therapies specifically labeled to treat SSc, although therapies have been approved for various organ-specific complications such as ILD and PAH. Immunosuppressants with significant toxicities are commonly used to treat SSc; however, there is a general absence of clinical data to support their use.

B Cell-Directed Therapeutic Approaches

Because SSc is believed to be driven by B cells, it has been proposed that rituximab, an anti-CD20 monoclonal antibody, may provide therapeutic benefit. However, clinical results of rituximab in SSc patients have been mixed, with some reports claiming significant benefits and others reporting that the clinical effect achieved with rituximab was not significantly better than with standard of care. The use of CD19 CAR T cells has been proposed as an alternative, based on the hypothesis that the weak activity of anti-CD20 monoclonal antibody treatments is due to insufficient depletion of B cells.

In one case report, a patient with SSc having interstitial pneumonia as the main manifestation continued to progress while on glucocorticoid and cyclophosphamide treatment. Treatment with CD19 CAR T cells led to a reduction in cough and improvement in interstitial pneumonia. In another published case report, a patient with treatment-refractory SSc with skin, lung and heart fibrosis and carpal arthritis was treated with CD19 CAR T cells. By three months after treatment, levels of autoantibodies were no longer detectable and lung fibrosis and function remained stable, with cardiac fibrosis and function remaining stable at six months after treatment. Carpal arthritis improved by three months and tender joint counts improved from 22 at baseline to three.

KYV-101 Clinical Development in SSc

We received FDA clearance for an IND for the treatment of SSc with KYV-101 in October 2023, and we are initiating our planned KYSA-5 Phase 1/2 open-label, multicenter, U.S.-based trial to evaluate KYV-101 in adult patients with SSc. We intend to enroll approximately six patients in the Phase 1 portion of the trial and up to 15 patients in the Phase 2 portion of the trial. Phase 1 primary endpoints will be incidence of adverse events and laboratory abnormalities. Phase 2 primary endpoints will be incidence of adverse events and laboratory abnormalities and the Revised Composite Response Index in Systemic Sclerosis, or rCRISS, response rate at 52 weeks. Secondary endpoints include evaluating other efficacy scores, disease related biomarkers, and immunogenicity.

Myasthenia Gravis (MG) Disease Background

MG is an autoimmune disorder associated with muscle weakness. MG patients develop antibodies that lead to an immunological attack on critical signaling proteins at the junction between nerve and muscle cells, thereby inhibiting the ability of nerves to communicate properly with muscles. This leads to muscle weakness in tissues throughout the body, potentially manifesting in partial paralysis of eye movements, problems in chewing and swallowing, respiratory problems, speech difficulties and weakness in skeletal muscles. The symptoms of the disease can be transient and in the early stages of the disease can remit spontaneously. However, as the disease

progresses, symptom-free periods become less frequent and disease exacerbations can last for months. Disease symptoms reach their maximum levels within two to three years in approximately 80% of patients. Up to 20% of MG patients experience respiratory crisis at least once in their lives. During the crisis phase, decline in respiratory function can become life-threatening. Patients in crisis often require intubation and mechanical ventilation. The prevalence of MG is estimated to be 1 in 5,000, with up to 60,000 cases in the United States.

Over 80% of patients with MG have antibodies to the acetylcholine receptor, or AchR, which is the receptor for the neurotransmitter acetylcholine. The presence of these autoimmune antibodies blocks the signaling from neurons to muscles, which results in outward signs of muscle weakness. The pathology in MG arises not only from the interruption of signal transduction, but also from the physical destruction of the post-synaptic membrane through activation of the complement system, which can lead to complement-driven lysis of the post-synaptic membrane.

Current Treatment Paradigm

Early-stage MG is symptomatically treated by the use of acetylcholinesterase inhibitors such as pyridostigmine, which block the breakdown of acetylcholine, thereby increasing its concentration. This compensates for some of the loss of receptors due to the autoimmune antibodies targeting AchR. As the disease progresses, patients are typically treated with immunomodulating agents such as glucocorticoids, mycophenolate and cyclosporine, each of which is associated with significant side effects and in some cases lead to disease exacerbation.

Physicians direct patients with more advanced disease and patients in crisis to therapies that reduce circulating IgG antibodies. Published studies have shown that decreases in circulating IgG antibody levels are correlated with increased relief of symptoms and decreases in the length of hospital stays.

One method for reducing levels of circulating antibodies is to block the antibody recycling pathway. Antibodies that recognize receptors on the surface of cells are often internalized by these cells into vesicles called endosomes. However, a specific receptor, FcRn, can recognize IgG antibodies and recycle them back out of the cell, thus prolonging their half-life and in the process increasing the overall levels of circulating IgG antibodies. Blockage of this pathway with efgartigimod alpha, marketed as Vyvgart® by Argenx, has been found to result in decreases in circulating antibody levels of up to 70%. Treatment with efgartigimod led to significant improvements in patients as measured by both the Myasthenia Gravis-Specific Activities of Daily Living scale and the Quantitative Myasthenia Gravis score, which measures muscle weakness. However, long-term maintenance of this response has been found to require multiple repeat treatments per year.

In another frequently used approach, physicians will administer high levels of IgG antibodies derived from pooled human blood or intravenous immunoglobulin or IVIg. IVIg provides therapeutic benefit through multiple potential mechanisms, including the saturation of the FcRn receptor, which leads to increased degradation of the endogenous autoimmune antibodies. IVIg treatment for MG requires infusions of immunoglobulin isolated from thousands of patients and these infusions are usually repeated daily to obtain significant reductions in symptoms. The large volumes of intravenous fluid associated with the administration of IVIg can lead to pulmonary edema and kidney problems in elderly patients.

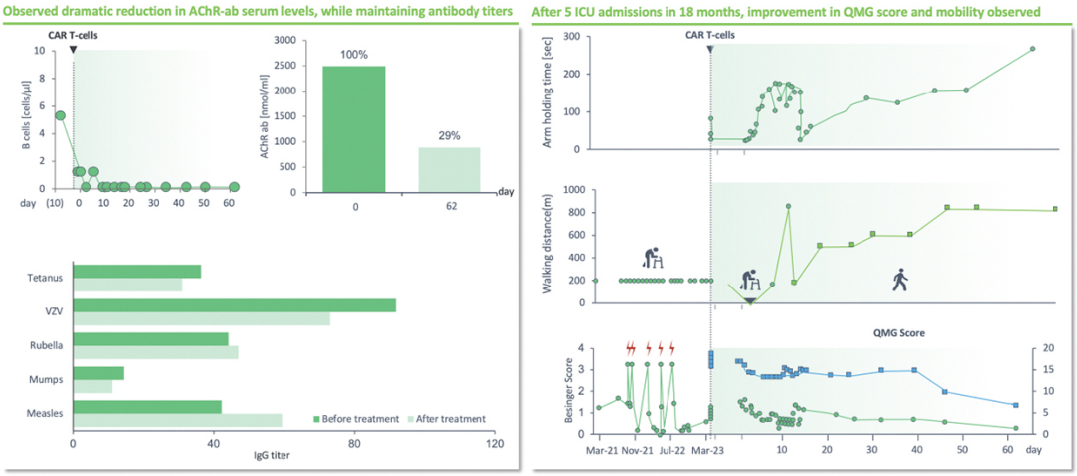
Other treatments, such as eculizumab and ravulizumab, marketed as Soliris® and Ultomiris® by Alexion, respectively, block complement activation and have been approved by the FDA for the treatment of MG and other autoimmune diseases. However, as with efgartigimod, long-term responses require repeat treatments.

We believe that targeted destruction of autoantibody-producing B cells offers the potential to lead to rapid reductions in autoantibody levels and through the ability to reset the immune system provide durable benefits without the need for regular retreatments.

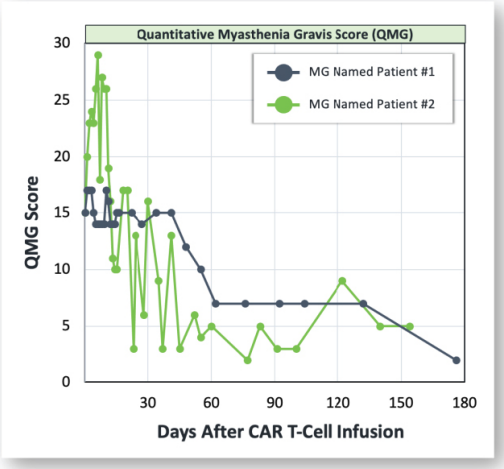
Named Patient Case Reports of KYV-101 for Treatment of MG

The results of the first MG patient treated with KYV-101 on a named patient basis have been published in *Lancet Neurology*. The patient was refractory to other treatments and had severe and highly refractory disease, with

difficulties swallowing and breathing, the inability to walk without assistive devices and several prior myasthenic crises, resulting in five ICU admissions requiring invasive ventilation in the past 18 months. Following KYV-101 infusion, the patient was not observed to experience any adverse events related to KYV-101 treatment. A 70% reduction in pathogenic autoantibodies was reported at day 62 while protective vaccination IgG titers were maintained. Following treatment with KYV-101, the patient was observed to have improved muscle strength based on enhanced walking ability without any supportive measures, reduction of the clinical multiparameter Besinger disease activity score, and reduction of the quantitative MG (QMG) scores, as shown in the below graphs.



The results from a second MG patient treated with KYV-101 on a named patient basis were accepted for presentation as a late-breaking abstract at the 96th Congress of the German Society of Neurology in November 2023, and at the American Academy of Neurology conference in April 2024. Treatment with KYV-101 in this patient was well tolerated, with low-grade CAR T-cell adverse events, including moderate flu-like symptoms consistent with Grade 1-2 CRS readily managed with standard agents and Grade 1 ICANS. After treatment with KYV-101, successful depletion of B cells, reduction in autoantibody levels and recovery of muscle strength were observed. The abstract reports that within two months of treatment with KYV-101 the patient moved from wheelchair dependence to bicycling and at four months of treatment with KYV-101 started mountain touring. The graph below shows the reduction in QMG score observed in the first two MG patients treated with KYV-101 in a named patient treatment across two separate clinical sites:



In total, six MG patients have been treated with KYV-101 on a named patient basis as of December 31, 2023. While we do not expect to be able to use the results from these case reports in our application for marketing approval to the FDA or other foreign regulatory agencies, we believe that these results reported in a peer-reviewed journal and academic conferences address our mission to prioritize patient needs while providing us insight to help de-risk future Kyverna-sponsored clinical trials.

KYV-101 Clinical Development in MG

We received FDA clearance for an IND for the treatment of MG with KYV-101, and are initiating our planned KYSA-6 Phase 2 open-label, multicenter, U.S.-based trial in which we intend to enroll approximately 20 adult patients with MG. Primary endpoints will be incidence and severity of adverse events and laboratory abnormalities and myasthenia gravis activities of daily living score, or MG-ADL, at 24 weeks. Secondary endpoints include evaluating other efficacy scores and disease related biomarkers.

Multiple Sclerosis (MS) Disease Overview

MS is a chronic disorder of the central nervous system characterized by inflammation-driven neurodegeneration. MS is associated with symptoms that include blurred vision, slurred speech, tremors, numbness, extreme fatigue, and problems with memory and concentration. Most MS patients experience muscle weakness in their extremities and difficulty with coordination and balance. These symptoms may be severe enough to impair walking or even standing. Although MS is not considered to be a fatal disease, it can lead to significant morbidity, including paralysis.

MS is the most common progressive neurologic disease of young adults worldwide. According to the National Multiple Sclerosis Society, over 2.8 million people worldwide and nearly one million people in the United States are living with MS. We estimate that there are over 1.5 million patients diagnosed with MS in the United States, the European Union and Japan.

A common pathology in MS patients is immune-mediated destruction of the myelin sheath that surrounds and protects nerve cells. While MS is generally thought to be an autoimmune disease, its exact cause is unknown. The FDA has approved over 25 therapies for MS that reduce the immune system attack, decrease the rate of relapses and delay progression of disability. However, to our knowledge, none of the approved therapies are able to reset the immune system to stop disease progression. Initial MS therapy typically involved anti-inflammatory drugs such as corticosteroids that are effective in suppressing inflammatory exacerbations during relapses, but do not alter the long-term outcome of the disease. Most patients are treated with injectable anti-inflammatory treatments such beta interferon that can slow disease progression but are associated with significant side effects. More potent anti-inflammatory drugs such as natalizumab, marketed as Tysabri© by Biogen, have been approved to treat MS, but are associated with life-threatening complications.

We believe the FDA approval in 2017 of ocrelizumab, an anti-CD20 monoclonal antibody marketed as Ocrevus® by Genentech, provides strong support for the importance of B cells in driving the frequency of relapses and disease progression in MS. However, approximately 18% of ocrelizumab-treated patients still experience relapses and 10% of patients experience disease progression.

We believe that CD19 CAR T cells, such as those delivered as part of KYV-101, have the potential to improve patient responses in MS through their ability to deeply penetrate tissues than monoclonal antibodies, increasing the potential to reset the immune system and eliminate pathogenic B cells. A recent publication by Drs. Sasha Gupta and Scott Zamvil of the University of California San Francisco and colleagues describes results from a mouse model that provide further support for the potential benefits of complete B-cell depletion using CD19 CAR T cells in MS.

As of December 31, 2023, two MS patients have been treated with KYV-101 on a named patient basis, and these patients experienced no ICANS and only one patient experienced Grade 1 CRS. In addition, in September 2023, Stanford received IND clearance for an investigator-initiated trial of KYV-101 in MS.

KYV-101 Clinical Development in MS

We received FDA clearance for an IND for the treatment of MS with KYV-101 in December 2023, and we are initiating our planned KYSA-7 Phase 2 open-label, multicenter, U.S.-based trial in which we intend to enroll approximately 120 adult patients with MS. The primary endpoint will be Confirmed Disability Progression, and secondary endpoints include measures of safety, additional efficacy assessments, and disease related biomarkers.

Summary of KYV-101 Clinical Development and Named Patient Treatments

As of December 31, 2023, 14 patients have been dosed with KYV-101, three of which were in Kyverna-sponsored clinical trials, as shown below. Of those 14 patients, 13 have reached day 28 follow-up. The following table sets forth the number of patients currently in progress for treatment with KYV-101 across Kyverna-sponsored clinical trials, investigator-initiated trials and named patient activities.

# of Patients	Identified	Consented	Apheresed	Dosed	28d Follow-up Complete
Total	29	29	22	14	13
Company-sponsored clinical trials	5	5	5	3	3
Investigator-initiated and named patient	24	24	17	11	10

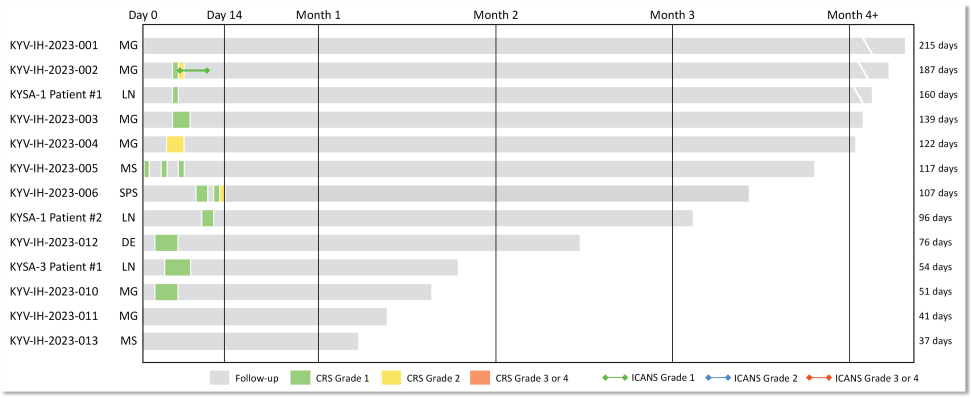
Note: As of Dec. 31, 2023

The following table sets forth reports of CRS and ICANS after treatment with CD19 CAR T-cell therapy with KYV-101 in Kyverna-sponsored clinical trials, investigator-initiated trials and named patient activities across six centers for the first 13 patients with 28 day follow-up, compared to published case reports in 15 patients with autoimmune diseases treated at a single center with a CD19 CAR T-cell therapy and three published pivotal clinical trials in oncology patients that led to the approval of CAR T-cell therapies for oncology indications. The CAR in KYV-101 contains a fully human binder whereas the other CD19 CAR T-cell therapies reported in the following table contain murine binders.

Source	Indication	N	Any Grade CRS	Any Grade ICANS	CRS Grade ≥3	ICANS Grade ≥3
KYV-101 experience	MG, LN, MS, SPS, DE	13	10	1	0	0
Schett Group case series	SLE, IIM, SSc	15	9	1	0	0
ZUMA-1 (axi-cel)	DLBCL 3L	101	94	65	13	28
TRANSCEND (liso-cel)	DLBCL 3L	268	122	95	11	32
JULIET (tisa-cel)	DLBCL 3L	115	85	69	26	22

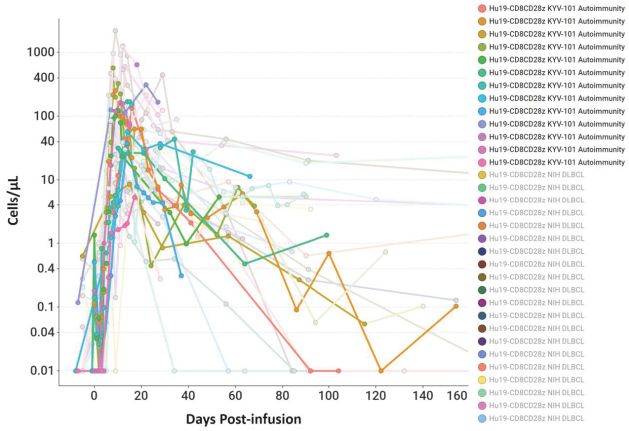
Based on these reports and results, patients with autoimmune diseases have been observed to tolerate treatment with CAR T-cell therapies without experiencing the Grade 3 and above CRS and ICANS adverse events seen in the oncology trials. These limited observations are derived from separate clinical settings, and with respect to the autoimmune data are based primarily on information from case reports rather than clinical trials. They do not represent head-to-head comparisons of CD19 CAR T-cell treatment in autoimmune indications as compared to oncology indications. Although there is insufficient evidence to claim that CAR T-cell therapy is better tolerated in the treatment of autoimmune disease than oncology, there is no data to suggest that there is a high risk of developing serious grade CRS and ICANS in autoimmune disease. Future clinical trials may not confirm the clinical safety observations discussed in these case reports and studies.

In addition, the following table sets forth CAR T-related safety events and follow-up as of December 31, 2023, for the first thirteen autoimmune patients treated with KYV-101 across six separate sites, either as part of our sponsored KYSA-1 trial, our sponsored KYSA-3 trial, or in an investigator-initiated trial or named patient setting.



CAR related safety events, if encountered, were low grade and readily manageable. There were no serious CRS or ICANS toxicities observed in such patients after being dosed with KYV-101 for the treatment of MG (six patients), lupus nephritis (three patients), MS (two patients), stiff person syndrome, or SPS, and anti-DAGLA encephalitis, or DE. As of December 31, 2023, time since infusion for the first MG patient treated with KYV-101 in a named patient setting was 215 days (approximately seven months) and time since infusion for the first LN patient treated with KYV-101 in the KYSA-1 Phase 1 trial was 160 days (approximately five months). Future clinical results, including in our clinical development program for KYV-101, may not confirm the safety observations discussed in the early clinical data from our trials, investigator-initiated trials and named patient activities.

Our early clinical experience with KYV-101 with regard to dosing and the kinetics of CAR T-cell expansion has benefited from data obtained from an NIH Phase 1 trial of an additional 20 oncology patients who were treated with CAR T cells created using the identical CAR as used in KYV-101. We have not observed any clinically meaningful differences in the kinetics or the extent of CAR T-cell expansion with KYV-101 compared to the results reported with these prior CAR T cells containing the identical CAR. The following chart sets forth cell expansion of CAR T cells with the same Hu19-CD828z CAR across 28 patients, with 20 DLBCL patients treated with the NIH CAR T cells in the NIH Phase 1 trial and the first eight autoimmune patients treated with KYV-101 in KYSA-1 or in an investigator-initiated trial or named patient setting:



Manufacturing Capabilities and Industrialization of Autologous CAR T-cell Therapies

We are developing a robust manufacturing process for KYV-101, and we have partnered with WuXi, an experienced contract development and manufacturing organization, to generate KYV-101 for our near-term Kyverna-sponsored clinical trials, investigator initiated trials and named patient activities.

In parallel, we are developing Ingenui-T, a manufacturing process designed to improve patient experience and manufacturing capabilities through partnerships with world-class organizations in cell therapy manufacturing, including ElevateBio, LLC. Ingenui-T represents an industrialization of CAR T-cell therapy manufacturing by adapting industry-leading CAR T manufacturing processes to the needs of autoimmune disease patients. We believe that innovations associated with Ingenui-T will improve manufacturing throughput and quality control and have the potential to achieve industry-leading cost of goods.

Given the reduced criticality of turnaround time in many autoimmune diseases as compared to oncology, we believe that in developing CAR T-cell therapies designed specifically for autoimmunity, we can focus on reducing cost of goods and improving patient experience. Our Ingenui-T process is evaluating potential transformational changes in the manufacturing and administration of CAR T-cell therapies including the process of isolating the starting immune cells from patients, the introduction of the CAR construct, and the expansion of modified cells. We believe that through Ingenui-T we will be able to generate CAR T cells that provide the potential to further optimize the patient experience through modification of the treatment protocols used before and after administration of CAR T cells.

KYV-201, an Allogeneic CD19 CAR T-cell Product Candidate

Over the longer term, we believe that some patients will benefit from an off-the-shelf CD19 CAR T-cell therapy manufactured from healthy donors. To that end, we established a partnership with Intellia to create allogeneic T-cell therapies. Through this partnership, we are developing KYV-201, an allogeneic version of KYV-101 that combines Intellia's world-leading expertise in gene editing with both our Hu19-CD828Z CAR construct and our broad network of clinical collaborators.

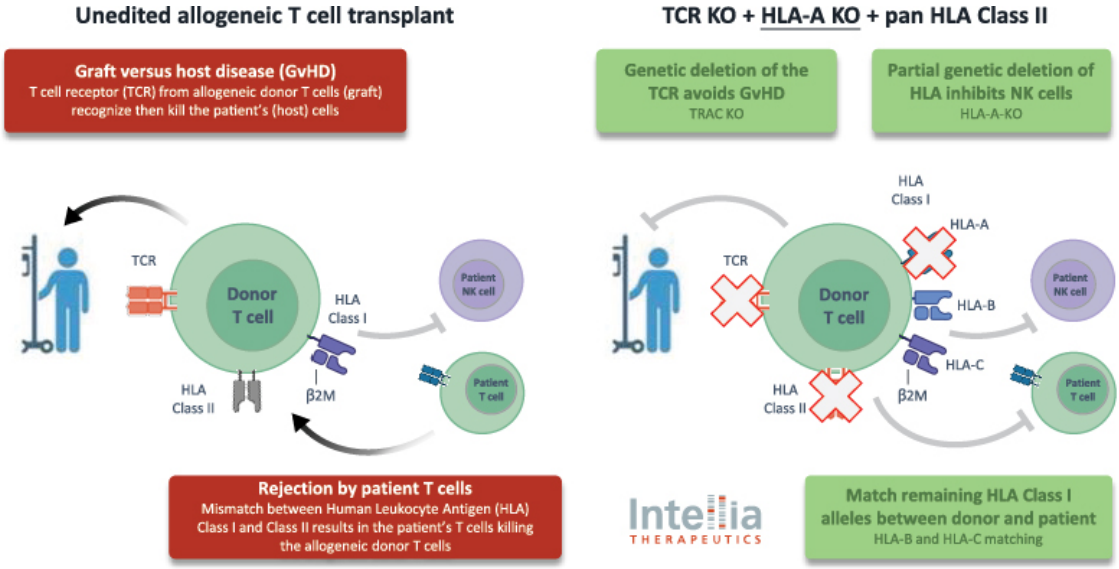
Developing allogeneic CAR T cells has long been a desire in the field of oncology. However, the clinical results obtained to date in oncology have failed to demonstrate equivalence or superiority of allogeneic CAR T cells, which tend to have a short lifespan due to immunological rejection, compared to autologous therapies. Because of these shortcomings compared to autologous therapies and their well-established regulatory pathway, clinical development of CAR T-cell therapies has been primarily focused on autologous T cells.

We believe a potential advantage of using allogeneic CAR T cells in autoimmune disease as compared to oncology is that a deep, but transient, suppression of B cells in autoimmune disease may be sufficient to reset the immune system and provide long-term durable responses, rather than requiring prolonged suppression of B cells and correspondingly, a prolonged presence of CAR T cells. Whereas the lack of long-term persistence of allogeneic CAR T cells in oncology patients may be a detriment in oncology treatment, we believe it may have little or no negative impact on outcomes in the treatment of autoimmune diseases.

The key to developing allogeneic T cells is twofold: one, to eliminate the ability of the graft cells to attack normal host cells; and, two, to limit the ability of allogeneic T cells to be eliminated by the host immune system before the cells complete their intended therapeutic purpose. Addressing these potential challenges requires overcoming the immune response in two directions. The body's T cells recognize newcomer cells as foreign if antigens presented to the T-cell receptor, or TCR, have not previously been seen during the T cell maturation process. Allogeneic donor cells, having gone through this maturation process in another individual, can potentially – and damagingly – recognize normal host cells as foreign leading to the development of graft versus host disease, or GvHD. Conversely, the host T cells can potentially recognize the donor T cells as foreign because of differences in individual-person-specific HLA antigens from those expressed on host cells.

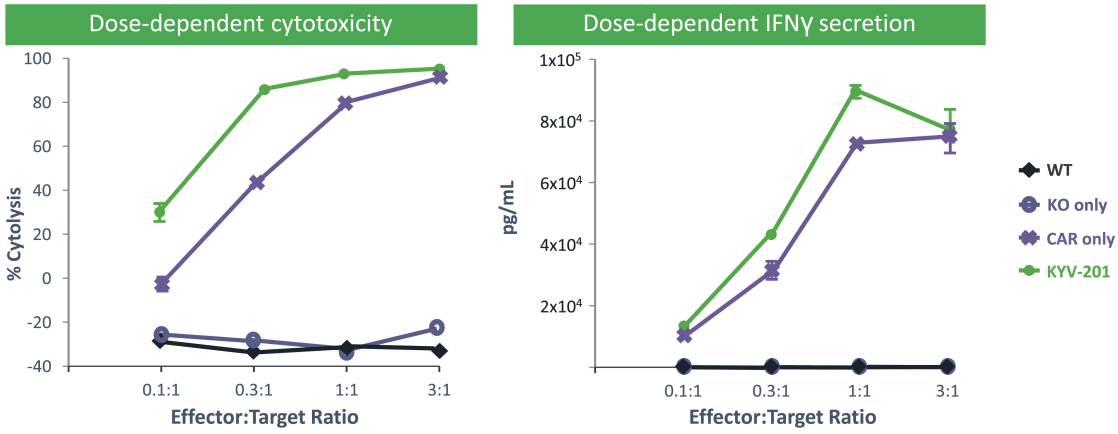
We believe the Intellia technology can address both of these challenges through gene editing. The Intellia approach to preventing GvHD is straightforward: Intellia uses gene editing to eliminate expression of the TCR on donor cells. Preventing the host cells from recognizing donor cells as foreign requires another level of sophistication. Editing out of the HLA antigens could, in principle, make donor cells unrecognizable to the host's T cells, but it has been shown that the lack of HLA expression is not the ideal solution since eliminating HLA completely triggers host NK cells to recognize and subsequently kill off the donor cells. Instead of completely removing HLA antigens via gene editing, the Intellia approach rather uses gene editing to create a partial knockout of HLA alleles, such that NK cell targeting is avoided, but also to retain enough expression of certain HLA antigens on the donor cells to allow the cells to be recognized as at least a partial match by the host cells and hence not killed off.

The following illustration describes how eliminating the expression of the TCR and most of the HLA antigens on donor T cells can provide the opportunity to develop allogeneic CAR T cells:



We believe that this approach has the potential to generate allogeneic CAR T cells that can deliver therapeutic benefits to patients with prevalent autoimmune diseases. In preclinical studies, we have observed that the *in vitro* cytotoxicity and cytokine expression levels of CAR T cells containing the gene edits that are to be incorporated into KYV-201 are roughly equivalent to those obtained using similarly constructed CAR T cells without these gene edits, which we believe suggests that the gene editing process does not adversely affect the target-specific activity of these CAR T cells.

The following graphs illustrate that CAR T cells containing KYV-201 gene edits had similar *in vitro* potency as CAR T cells created without these gene edits:



24h incubation with NALMS target cells
Representative of 3 donors
WT = Mock (unedited), untransducted
KO only = HLA-A / CIITA / TRAC KO
CAR only = CAR LV
KYV-201 = HLA-A / CIITA / TRAC KO + CAR LV

Research-Stage Programs

We believe that treatment of the wide spectrum of autoimmune diseases will over the long run require more than the ability to target B cells with CD19 CAR T-cell therapies. Our research-stage programs are focused on developing product candidates to treat other autoimmune diseases such as inflammatory bowel disease, or IBD, which includes Crohn's disease and ulcerative colitis. These programs include a suite of capabilities related to T-regs developed through our completed research collaboration with Gilead Sciences, Inc., or Gilead, and novel humanized CAR constructs developed by us for use in autoimmunity. T-regs are a subset of CD4+ T cells that maintain tolerance in the periphery through multiple mechanisms involving both soluble mediators and direct cell-cell interactions. Clinical use of polyclonal, non-engineered T-regs has not yielded optimal therapeutic effects to date in autoimmune disease settings. However, we believe the use of antigen-specific T-regs, possibly through use of a CAR, holds promise by enhancing homing to antigen-specific effector T cells or sites of inflammation. Published reports in multiple pre-clinical animal models of autoimmunity have demonstrated that antigen-specific T-regs are significantly more effective than polyclonal T-regs. We are in the process of preparing a publication that addresses the therapeutic use of T-regs using a CAR and our differentiated approach in this modality.

Our Collaboration and License Agreements

Patent License Agreements with the National Institutes of Health

In May 2021, we entered into two patent license agreements, or the NIH Agreements, with the National Institutes of Health, or the NIH, pursuant to which we obtained exclusive, worldwide licenses to certain patents to use a novel, fully human anti-CD19 CAR in our autologous and allogeneic CAR T-cell products for the treatment of patients with autoimmune disease. We paid 50% of the upfront consideration of $3.3 million for acquired licenses in July 2021 and the remaining 50% in May 2022 in accordance with the terms of the NIH Agreements.

Commencing in January 2023 and subsequently on January 1 of each calendar year thereafter until the NIH Agreements terminate, we are required to make minimum annual royalty payments of $0.2 million, which, commencing January 1, 2024, may be credited against any earned royalties due based on a low single-digit percentage of net sales made in a respective year. In addition, benchmark royalties following the completion of certain regulatory-and clinical-related benchmarks are due to the NIH, with the minimum cumulative royalty due for the first product reaching FDA approval or foreign-equivalent approval totaling approximately $5.7 million for the autologous patent license agreement and approximately $1.7 million for the allogeneic patent license agreement. Additional benchmark royalties would be payable for a subsequent indication under each NIH Agreement. If we enter into a sublicensing agreement, we are required to pay the NIH a sublicense royalty as a percentage of the fair market value of any consideration received for each sublicense granted. The sublicensing percentage starts at a high teens to low twenties percentage if clinical trials for the product candidate have not yet begun and decreases to a mid-single-digit percentage if the product candidate receives FDA approval or foreign-equivalent approval.

Unless terminated sooner, the NIH Agreements remain in effect until the last licensed patent rights granted pursuant to the respective agreement expire. We have a unilateral right to terminate the agreements or any licenses in any country or territory upon 60 days' notice to the NIH. The NIH may terminate the agreements for our uncured material breach, insolvency or bankruptcy, subject to certain notice and cure periods. The NIH also has the right to terminate or modify the NIH Agreements as necessary to meet requirements for public use specified by federal regulations issued after the date of the applicable license, subject to certain notice, cure and appeal periods.

Under the NIH Agreements, we have agreed to indemnify the NIH from and against all liability, demands, damages, expenses and losses, including but not limited to death, personal injury, illness or property damage in connection with or arising out of the use by us or the design, manufacture, distribution or use of any of the licensed products or licensed processes or materials under the NIH Agreements.

Intellia License and Collaboration Agreement

In December 2021, we entered into a License and Collaboration Agreement, or the Intellia Agreement, with Intellia Therapeutics, Inc., a clinical-stage biotechnology company focused on developing novel therapeutics

leveraging CRISPR-based technologies, or Intellia, to research and develop an allogeneic CD19-directed CAR cell therapy product, or the CRISPR Product, suitable for validation through pre-clinical and clinical proof-of-concept clinical trials, including the performance of activities as agreed in the collaboration plan. Pursuant to the Intellia Agreement, Intellia granted us an exclusive, worldwide, sublicensable in multiple tiers, royalty bearing license under certain of Intellia's intellectual property to research, develop, sell and otherwise exploit the CRISPR Product. We are performing the majority of the work under the collaboration plan.

As a consideration for the licenses granted to us pursuant to the Intellia Agreement, we issued to Intellia 3,739,515 shares of our Series B Preferred Stock at a price of $1.8719 per share, which was the price paid by other investors in our Series B Preferred Stock financing, for consideration of $7.0 million. Intellia also purchased 1,602,649 shares of Series B Preferred Stock at a price of $1.8719 per share under the Series B Preferred Stock Purchase Agreement in cash for total proceeds to us of $3.0 million. We are also obligated to make aggregate milestone payments to Intellia of up to $64.5 million upon the achievement of specified development and regulatory milestones and are obligated to pay to Intellia low to mid-single-digit royalties as a percentage of annual worldwide sales, subject to certain adjustments, and additional potential royalties and milestones to Intellia's licensors. The royalties are payable on a country-by-country basis, commencing upon the first commercial sale of the CRISPR Product in the applicable country and expiring upon the later of (i) 12 years after the first commercial sale or (ii) the expiration of the last-to-expire valid patent claim.

Under the Intellia Agreement, Intellia owns rights, title and interests in and to any intellectual property developed in the course of performance under the Intellia Agreement that is not specifically directed to the CRISPR Product. We granted to Intellia certain non-exclusive, royalty-free, fully paid-up, worldwide licenses under our intellectual property solely to perform the activities designated to Intellia under the collaboration, and to research, develop or otherwise exploit any human therapeutic product that is developed or commercialized by Intellia, utilizes or incorporates Intellia intellectual property and that is not the CRISPR Product or any product directed to CD19 or any other B-cell antigen.

In addition, we granted Intellia an exclusive option, or the Intellia Option, to enter into a co-development and co-commercialization agreement with us for the CRISPR Product, or the Co-Co Agreement, for a fee payable to us. If Intellia exercises the Intellia Option, we and Intellia would share equally the regulatory and clinical development expenses associated with obtaining approval of the CRISPR Product in the United States and would also share equally all net profits and losses from commercialization of the CRISPR Product in the United States. If Intellia exercises the Intellia Option, no milestone payments will be due and payable from that time forward and we will only pay royalties on sales outside of the United States. In addition, upon exercise of the Intellia Option, following regulatory approval of the CRISPR Product, Intellia will have exclusive commercialization rights for the CRISPR Product for U.S. administration, subject to our rights to co-promote the CRISPR Product in the United States, and we will retain the sole and exclusive rights to research, develop, or otherwise exploit the CRISPR Product for rest-of-world administration and shall have sole decision-making authority in relation thereto, subject to the parties' obligations to cooperate regarding certain development, regulatory and commercialization strategies.

During the term of the Co-Co Agreement, subject to certain exceptions, neither party will clinically develop or commercialize a cell therapy product directed to CD19 other than the CRISPR Product for use in the treatment or prevention of certain indications set forth in the Intellia Agreement and any additional indication that the parties mutually agree to include (any such product, a Competitive Product); provided, however, that (i) any products for use in any indications that are the subject of a development program or third-party collaboration as of the effective date of the Co-Co Agreement shall not be considered Competitive Products and (ii) any products for use in any additional indications that are the subject of a development program or third-party collaboration as of the date that such additional indications are included in the global development plan shall not be considered Competitive Products.

The Intellia Agreement terminates on a country-by-country basis upon the expiration of the last valid claim within Intellia's patent rights covering the CRISPR Product within such country, unless the agreement is earlier terminated in its entirety by either party for insolvency, by either party for material breach of contract, by Intellia if we participate in legal action or proceeding challenging the validity or enforceability of Intellia's patents, or by the execution of the Co-Co Agreement. We may terminate the Intellia Agreement in its entirety, or on a country-by-country basis, by providing a written notice after the expiration or termination of the Intellia Option. Following the expiration of the term for a given country, the licenses granted to us in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free licenses.

Under the Intellia Agreement, we and Intellia have agreed, subject to certain exceptions, to indemnify each other against any third-party liabilities arising out of (i) any breach of our respective representations, warranties and obligations thereunder, (ii) our respective gross negligence or willful misconduct, or (iii) the research, development or manufacture of the CRISPR Product. We have also agreed, subject to certain exceptions, to indemnify Intellia against any third-party liabilities arising out of the commercialization of the CRISPR Product by us.

Manufacturing

Manufacturing of both autologous and allogeneic cell therapies requires multiple components and is complex, and there are many similarities in the processes for both kinds of therapies. We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently contract with third-party contract manufacturing organizations, or CMOs, for the manufacture of any product candidates that we may develop for preclinical and clinical study, and for and critical materials required to be incorporated into the product.

Under our Master Services Agreement with WuXi ATU Advanced Therapies Inc., dated March 2022, or the WuXi Agreement, WuXi provides us with certain customized cell manufacturing, release and testing services for our KYV-101 product candidate. Pursuant to our Licence and Supply Agreement with Oxford Biomedica (UK) Limited, or Oxford, dated September 2023, or the Oxford Agreement, Oxford is undertaking lentiviral vector process development services with the intention of providing lentiviral vector for clinical and commercial use in our product candidates. We believe we currently have sufficient clinical-grade vector in inventory to move forward with our anticipated clinical trials.

We are also developing Ingenui-T, a manufacturing process designed to improve patient experience and manufacturing capabilities through partnerships with world-class organizations in cell therapy manufacturing. Under our Development and Manufacturing Services Agreement with ElevateBio Base Camp, Inc., or ElevateBio, dated July 2023, or the ElevateBio Agreement, ElevateBio is undertaking process development services for the development of a low-cost, fully closed manufacturing process for our CAR T-cell products.

We expect to rely on our CMOs for the manufacturing of our product candidates to expedite readiness for future clinical trials, and most of these CMOs have capabilities for commercial manufacturing. All of our manufacturing operations performed by our CMOs are subject to the requirements of current Good Manufacturing Practices, or cGMPs, and, if applicable, the FDA's current good tissue practice, or cGTP, requirements for the use of human cellular and tissue products, as described in regulations from the FDA, the Code of Federal Regulations, and equivalent regulations in all regions where our clinical candidates are studied.

As clinical trial development progresses forward, we will continue to explore both internal capabilities as well as deepening and expanding external relationships to ensure we meet our manufacturing requirements.

Sales and Marketing

We have not yet defined our sales, marketing or product distribution strategy for our product candidates because they are still in development. Our commercial strategy may include the use of strategic partners, distributors, a contract sales force or the establishment of our own commercial sales force. We plan to further evaluate these alternatives as we approach approval for our product candidates, if any.

Competition

The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our product candidates, if approved, may address multiple markets. Ultimately, the diseases our product candidates target and for which we may receive marketing authorization will determine our competition. There are competing programs under development by other companies for our targeted indication scope, which is B-cell-driven autoimmune diseases. Many emerging and established life sciences companies have been focused on similar therapeutics, including CAR T-cell candidates for B-cell-driven autoimmune disease. Our product candidates, if approved, will have to compete with existing therapies and new therapies that may become available in the future. We face potential competition from many different sources, including larger and better-funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. In many cases, the companies with competing programs will have access to greater financial, technical, manufacturing, marketing, sales and supply resources, will have more expertise and experience than us and may be more advanced in those programs. Moreover, we may also compete with universities and other research institutions that may be active in research in our target indications and could be in direct competition with us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We believe our current and future competition can be grouped into the following broad categories:

- Companies working to develop biologics and other modalities, including large pharmaceutical and biotech companies; and
- Organizations providing stem cell transplant therapies, including hospitals and clinics.

Companies developing biologics and other modalities include Roche Holding AG (currently markets Rituxan (rituximab), which is used for a broad number of autoimmune diseases and Ocrevus (ocrelizumab), both of which target CD20 on B cells), and others who have biologics aimed at other targets relevant to autoimmune diseases, including, for example, AbbVie, Johnson & Johnson, Bristol Myers Squibb and Novartis. In terms of organizations providing stem cell transplant therapies, the procedure for stem cell transplants is non-proprietary and is performed by medical hematologists and oncologists in hospitals and clinics throughout the world.

If we successfully obtain approval for any of our product candidates, we believe that the key competitive factors that will affect the success of these candidates will be efficacy, safety, tolerability, convenience, price and the availability of reimbursement from government and other third-party payors relative to such competing products. Our commercial opportunity could be reduced or eliminated if our competitors have products that are superior in one or more of these categories.

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our product candidates, as well as for future product candidates and novel discoveries, product development technologies and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, licensing or filing applications for U.S. and foreign patents relating to our product candidates, technology, inventions and improvements that are important to the development and implementation of our business.

Our patent portfolio is built with a goal of establishing broad protection that generally includes, for the product candidates, claims directed to compositions of matter, pharmaceutical compositions or formulations, methods of manufacturing and methods of treatment. We are seeking and maintaining patent protection in the United States and key foreign jurisdictions where we intend to market our product candidates, if they are approved. Our patent portfolio includes a combination of pending patent applications solely owned by us and patents and pending patent applications licensed from the National Institutes of Health, or the NIH. As of March 1, 2024, our patent portfolio comprises nine distinct patent families protecting our technology relating to our product candidates.

We in-license a patent family from the NIH relating to the CD19 CAR of our KYV-101 and KYV-201 product candidates. This patent family includes granted U.S. patents that include composition of matter claims. This patent family also includes patents granted in Australia, China, the European Patent Organization (validated in France, Germany, Ireland, Italy, Spain, and the United Kingdom), Hong Kong, Israel, India, Japan, Mexico, Saudi Arabia, and Singapore, and pending patent applications in Australia, Canada, the European Patent Organization, Hong Kong, Israel, India, Japan, South Korea, Mexico, New Zealand, and the United States. The granted patents and the pending patent applications in this patent family, if issued, have a nominal expiration date of 2035, without accounting for any available patent term adjustments or extensions.

With respect to the KYV-101 product candidate, we own two patent families directed to methods of treating autoimmune diseases, such as lupus nephritis, using T cells expressing a CD19 CAR. The first patent family includes a pending international PCT patent application, a pending U.S. utility patent application, and a pending patent application in Taiwan. The second patent family includes a pending international PCT patent application. Patent applications in these patent families, or patent applications claiming priority to them, if issued, would have nominal expiration dates of 2043, without accounting for any available patent term adjustments or extensions.

We also own three patent families directed to methods of treating myasthenia gravis, systemic sclerosis, and multiple sclerosis, respectively, using T cells expressing a CD19 CAR. These patent families include pending U.S. provisional patent applications. Patent applications claiming priority to the provisional patent applications in these patent families, if issued, would have nominal expiration dates of 2044, without accounting for any available patent term adjustments or extensions.

With respect to the KYV-201 product candidate, we own a patent family directed to allogeneic CD19 CAR T cells and methods of producing the allogeneic T cells. This patent family includes two pending U.S. provisional patent applications. Patent applications claiming priority to the provisional patent application, if issued, would have a nominal expiration date of 2044, without accounting for any available patent term adjustments or extensions.

With respect to manufacture of CAR T cells, we own two patent families directed to methods of producing CAR T cells using specific manufacturing processes. Both patent families include pending U.S. provisional patent applications. Patent applications claiming priority to the provisional patent applications, if issued, would have a nominal expiration date of 2044, without accounting for any available patent term adjustments or extensions.

The term of individual patents in our portfolio depends upon the legal term of patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be eligible for patent term adjustment, which permits patent term restoration as compensation for delays incurred at the United States Patent and Trademark Office, or the USPTO, during the patent prosecution process. In addition, for patents that cover an FDA-approved drug, the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. While the length of the patent term extension is related to the length of time the drug is under regulatory review, patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent per approved drug may be extended under the Hatch-Waxman Act. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our products receive FDA approval, we expect to apply for patent term extensions on patents covering those products. We plan to seek any available patent term extension to any granted patents we may be granted in any jurisdiction where such extensions are available; however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

We may also rely on trade secrets relating to our discovery programs and product candidates, and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us, and for employees and consultants to enter into invention assignment agreements with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is

to be kept confidential and not disclosed to third parties except in specific circumstances. Where applicable, the agreements provide that all inventions to which the individual contributed as an inventor shall be assigned to us, and as such, will become our property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Further, we have and will continue to pursue trademark protection for our company name and brand, as well as slogans and taglines and logos. As of March 1, 2024, we owned two registered trademarks in the United States and 15 registered trademarks in foreign jurisdictions comprising or incorporating the term "KYVERNA." As of March 1, 2024, we owned two registered trademarks in the United States and two registered trademarks in foreign jurisdictions comprising the Kyverna Compass Logo ().

Government Regulation

U.S. Regulation

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell-or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. Our products are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biological Product Development

In the United States, the FDA regulates biologics under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and the Public Health Service Act, or the PHSA, and their implementing regulations. Biologics are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may result in delays to the conduct of a study, regulatory review and approval or subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license suspension or revocation, refusal to allow an applicant to proceed with clinical trials, imposition of a clinical hold, issuance of untitled or warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits or civil or criminal investigations or penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Our drug product candidates must be approved by the FDA through the Biologics License Application, or BLA, process before they may be legally marketed in the United States. The process required by the FDA before a biologic may be marketed in the United States generally involves the following:

- completion of extensive nonclinical, sometimes referred to as preclinical, laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations and standards;
- submission to the FDA of an IND which must become effective 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 applicable IND regulations, GCPs, and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product candidate for its proposed indication;
- submission to the FDA of a BLA, which includes not only the results of the clinical trials, but also, detailed information on the chemistry, manufacture and quality controls for the product candidate and proposed labeling;
- satisfactory completion of an FDA pre-license or pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency, and, if applicable, the FDA's cGTP requirements for the use of human cell and tissue products;
- potential FDA audit of the preclinical trial sites and/or clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

The data required to support a BLA is generated in two distinct development stages: preclinical and clinical. The preclinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The conduct of the preclinical studies must comply with federal regulations, including GLPs. The sponsor must submit the results of the preclinical studies together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, as well as other information, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug product candidate at any time before or during clinical trials due to safety concerns, non-compliance or other issues affecting the integrity of the trial. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or the NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (*i.e.*, recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (*i.e.*, synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and

oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

The clinical stage of development involves the administration of the drug product candidate to healthy volunteers and patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at www.clinicaltrials.gov.

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap. Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the drug product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action tolerability, adverse effects, safety of the drug product candidate and, if possible, to gain early evidence on effectiveness. Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks and preliminary evaluation of efficacy. Phase 3 clinical trials generally involve large numbers of patients at multiple sites, in multiple countries, and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use and its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Phase 3 clinical trials may include comparisons with placebo and/or other comparator treatments. The duration of treatment is often extended to mimic the actual use of a product during marketing. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA. In certain instances, FDA may condition approval of a BLA on the sponsor's agreement to conduct additional clinical trials to further assess the biologic's safety and effectiveness after BLA approval. Such post-approval trials are sometimes referred to as Phase 4 clinical trials. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and further document clinical benefit in the case of drugs approved under Accelerated Approval regulations. Failure to exhibit due diligence with regard to conducting Phase 4 clinical trials could result in withdrawal of approval for products or other consequences.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA; written IND safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the biologic, findings from animal or *in vitro* testing that suggest a significant risk for human subjects and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA, the IRB, or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with

unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated intervals based on access to certain data from the trial and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as interim data suggesting a lack of efficacy. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate. Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug product candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug product candidate and, among other things, must develop methods for testing the identity, strength, quality, potency and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug product candidate does not undergo unacceptable deterioration over its shelf life.

BLA and FDA Review Process

Following trial completion, trial data are analyzed to assess safety and efficacy. The results of preclinical studies and clinical trials are then submitted to the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the drug product candidate and other relevant information. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive non-clinical and clinical testing. The application may include both negative or ambiguous results of preclinical and clinical trials as well as positive findings. Data may come from company-sponsored clinical trials intended to test the safety and efficacy 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 efficacy of the investigational product to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a significant user fee, which is adjusted on an annual basis. PDUFA also imposes an annual prescription drug product program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Once a BLA has been accepted for filing, which occurs, if at all, sixty days after the BLA's submission, the FDA's stated goal is to review BLAs within 10 months of the filing date for standard review or six months of the filing date for priority review, if the application is for a product intended for a serious or life-threatening condition and the product, if approved, would provide a significant improvement in safety or effectiveness. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data are insufficient for approval, and may require additional preclinical, clinical or other studies before it accepts the filing. Additionally, the review process is often significantly extended by FDA requests for additional information or clarification.

After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed drug product candidate is safe and effective for its intended use, and whether the drug product candidate is being manufactured in accordance with cGMP to assure and preserve the drug product candidate's identity, strength, quality, purity and potency. The FDA may refer applications for novel drug product candidates or drug product candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and 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 will conduct its own analysis of the clinical trial data, which could result in extensive discussions between the FDA and us during the review process. The review and evaluation of a BLA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

Before approving a BLA, the FDA will conduct a pre-license or pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMPs and, if applicable, cGTP requirements. The FDA will not approve the product 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. In addition, before approving a BLA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an 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 Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, withdraw the application or request a hearing. Even if such data and information is submitted, the FDA may ultimately decide that the BLA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than we interpret the same data.

If applicable, the FDA also will not approve the product if we are not in compliance with cGTPs, which are requirements found in FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the cGTP requirements is to ensure that cell- and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

There is no assurance that the FDA will ultimately approve a product for marketing in the United States, and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific populations, severities of allergies, and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Furthermore, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the BLA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-market testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess the product's safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized, including long-term follow up for certain cellular products. The FDA may also place other conditions on approvals including the requirement for a Risk Evaluation and Mitigation Strategy, or REMS, to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve the BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or based on the results of post-market studies or surveillance programs. Additionally, post-approval, many types of changes to the approved product, such as adding new indications, changing manufacturing processes and adding labeling claims, are subject to further testing requirements and FDA review and approval. Such post-approval requirements can be costly and time-consuming and can affect the potential market and profitability of the product.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 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 this type of disease or condition will be recovered from sales of the product.

Orphan drug designation must be requested before submitting an NDA or BLA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug or biologic for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity on the basis of greater effectiveness or safety or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If we pursue marketing approval for an indication broader than the orphan drug designation we have received, we may not be entitled to orphan drug exclusivity. Orphan drug status in the European Union has similar, but not identical, requirements and benefits.

In *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the court disagreed with the FDA's longstanding position that the orphan drug exclusivity only applies to the approved use or indication within an eligible disease. This decision created uncertainty in the application of the orphan drug exclusivity. In January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

Expedited Development and Review Programs

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied.

The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product concurrently with, or at any time after, submission of an IND, and the FDA must determine if the product qualifies for fast track designation within 60 days of receipt of the sponsor's request. Under the fast track designation, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review, or review within a six-month timeframe from the date a complete BLA is accepted for filing, if it has the potential to provide a significant improvement in safety and effectiveness compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review.

Additionally, a product may be eligible for accelerated approval. An investigational drug may obtain accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Breakthrough Designation

A product can be designated as a breakthrough therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A sponsor may request that a drug product candidate be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the drug product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor's request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable, involving senior managers and experienced review staff in a cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable.

Accelerated Approval for Regenerative Medicine Advanced Therapies

FDA's regenerative medicine advanced therapy, or RMAT, program is intended to facilitate efficient development and expedite review of regenerative medicine advanced therapies, which are intended to treat, modify, reverse or cure a serious or life-threatening disease or condition. A drug sponsor may request that FDA designate a drug as an RMAT concurrently with or at any time after submission of an IND. FDA has 60 calendar days to determine whether the drug meets the criteria, including whether there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs for a serious or life-threatening disease or condition. A BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. An RMAT that is granted accelerated approval and is subject to post approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post approval monitoring of all patients treated with such therapy prior to its approval.

Pediatric Trials

Under the Pediatric Research Equity Act, a BLA or supplement to a BLA must contain data to assess the safety and efficacy of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDCA requires that a sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or as may

be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials and/or other clinical development programs. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. Furthermore, with some exceptions, requirements under the Pediatric Research Equity Act generally do not apply to a biologic for an indication for which orphan designation has been granted.

Post-Marketing Requirements

Following approval of a new product, a manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the applicable regulatory authorities of adverse experiences with the product, providing the regulatory authorities with updated safety and efficacy information, product sampling, distribution, and tracking and tracing requirements and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs and biologics for off-label uses, manufacturers may not market or promote such off-label uses.

Modifications or enhancements to the product or its labeling or manufacturing changes are often subject to the approval of the FDA and other regulators, which may or may not be received or may result in a lengthy review process. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. cGMP regulations require, among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Manufacturers are also subject to record requests from FDA that demonstrate cGMP compliance through data and other information. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. These regulations also impose certain organizational, procedural and documentation requirements with respect to manufacturing and quality assurance activities. BLA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These firms and, where applicable, their suppliers are subject to inspections by the FDA at any time, and the discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market.

The FDA also may require post-approval testing, sometimes referred to as Phase 4 testing, REMS and post-marketing surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings

and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Other Regulatory Matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS (*e.g.*, the Office of Inspector General and Office for Civil Rights), the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments. In the United States, sales, marketing and scientific/educational programs must also comply with federal and state fraud and abuse laws, data privacy and security laws, transparency laws and pricing and reimbursement requirements in connection with governmental payor programs, among others. The handling of any controlled substances must comply with the U.S. Controlled Substances Act and Controlled Substances Import and Export Act. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of product approvals or refusal to allow a firm to enter into supply contracts, including government contracts. In addition, even if a firm complies with FDA and other requirements, new information regarding the safety or efficacy of a product could lead the FDA to modify or withdraw product approval. Prohibitions or restrictions on sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

U.S. Patent Term Restoration and Marketing Exclusivity

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

An abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product was created by the Biologics Price Competition and Innovation Act of

2009, or BPCI Act, which was part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA. This amendment to the PHSA attempts to minimize duplicative animal or human testing. Biosimilarity, which requires that the biological product be highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there be no clinically meaningful differences between the product and the reference product in terms of safety, purity and potency, is generally shown through a combination of analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a biological product be biosimilar to the reference product and that the product can be expected to produce the same clinical results as the reference product in any given patient, and for products administered multiple times, that the product and the reference product 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 biological product. However, complexities associated with the larger, and often more complex, structure of biological products as compared to small molecule drugs, as well as the processes by which such products are manufactured, pose significant hurdles to implementation that are still being refined by the FDA.

A reference biological product is granted twelve years of 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 first licensure. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. This does not include a supplement for the biological product or a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest or other related entity) for a change that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength, unless that change is a modification to the structure of the biological product and such modification changes its safety, purity or potency. Whether a subsequent application, if approved, warrants exclusivity as the "first licensure" of a biological product is determined on a case-by-case basis with data submitted by the sponsor.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which attaches to the twelve-year exclusivity period for reference biologics, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Pricing and Reimbursement

United States

Sales of our products will depend, in part, on the extent to which our products, if approved, will be covered and reimbursed by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a third-party payor will provide coverage for a drug product, including a biologic, typically is separate from the process for setting the price of a drug product or for establishing the reimbursement rate that a payor will pay for the drug product once coverage is approved. Third-party payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the approved drugs for a particular indication.

In order to secure coverage and reimbursement for any drug product candidate that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the drug product candidate, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Whether or not we conduct such studies, our drug product candidates may not be considered medically necessary or cost-effective. A third-party payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Third party reimbursement may not be sufficient to enable us to maintain price levels high enough to realize an appropriate return on our investment in product development. In the United States, the principal decisions about reimbursement for new drug products are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Additionally, one third-party payor's decision to cover a particular product or service does not ensure that other payors will also

provide coverage for the product or service, and the level of coverage and reimbursement can differ significantly from payor to payor. As a result, the coverage determination process will often require us to provide scientific and clinical support for the use of our products to each payor separately and can be a time-consuming process, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs, including biologics, have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In many countries, the prices of drug products are subject to varying price control mechanisms as part of national health systems. In general, the prices of drug products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for drug products, but monitor and control company profits. Accordingly, in markets outside the United States, the reimbursement for drug products may be reduced compared with the United States. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug product candidate or a decision by a third-party payor to not cover our drug product candidate could reduce physician usage of the drug product candidate and have a material adverse effect on our sales, results of operations and financial condition.

Outside of the United States, the pricing of pharmaceutical products is subject to governmental control in many countries. For example, 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 approved. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of pharmaceutical products will likely continue as countries attempt to manage healthcare expenditures. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations in the United States and our current and future arrangements with clinical investigators, healthcare providers, consultants, third-party payors and patients may expose us to broadly applicable federal and state 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 drugs for which we obtain marketing approval. In the United States, these laws include: the federal Anti-Kickback Statute, the False Claims Act, and the Health Insurance Portability and Accountability Act of 1996, or HIPAA.

The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration, directly or indirectly, in cash or in kind, that is intended to induce or reward referrals, including the purchase, recommendation, order or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam

actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products and the sale and marketing of our product candidates, are subject to scrutiny under this law.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Additionally, we may be subject to data privacy and security regulations by both the federal government and states in which we conduct our business. For example, HIPAA created new federal criminal statutes that prohibit among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include certain health care providers, health plans and healthcare clearinghouses, that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information and other personal data in certain circumstances, some of which are more stringent or otherwise different than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Further, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often

not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

We may become subject to federal government price reporting laws, which would require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs, as well as federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Similar federal, state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services. Such laws are generally broad and are enforced by various state agencies and private actions. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant federal government compliance guidance, and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures.

In order to distribute products commercially, we must comply with federal and state laws relating to drug supply chain traceability and that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Federal laws require the implementation of systems to provide, capture, and maintain information about transactions involving drug products distributed within the United States and the trading partners who engaged in such transactions. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. 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, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, individual imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities can be time-and resource-consuming, and can divert a company's attention from the business.

Current and Future Legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare and containing or lowering the cost of healthcare.

For example, in 2010, the ACA was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA:

- made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on average manufacturer price, or AMP, on most branded prescription drugs and adding a new rebate calculation for "line extensions" (*i.e.*, new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP;
- imposed a requirement on manufacturers of branded drugs to provide a 70% point-of-sale discount as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D;
- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs; and
- established a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted:

- The Budget Control Act of 2011 and subsequent legislation, among other things, created measures for spending reductions by Congress that include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through the first half of 2032. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021 and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- The American Taxpayer Relief Act of 2012, which, among other things, further 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.
- On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain IND products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for drugs. President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

The Inflation Reduction Act of 2022, or IRA, includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access, marketing cost disclosure, transparency measures and other measures designed to encourage importation from other countries and bulk purchasing. In January 2024, FDA authorized Florida's Agency for Health Care Administration's drug importation program, which is the first step toward Florida facilitating importation of certain prescription drugs from Canada. Authorization of other state programs may follow. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities 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. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

The Foreign Corrupt Practices Act

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

Europe / Rest of World Government Regulation

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions that we may in the future select, which may govern, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we would need to obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit an MAA. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCPs and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

European Union General Data Protection Regulation

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation, or GDPR. The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, including, for example, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention of information, increased requirements pertaining to special categories of data, such as health data and additional obligations when we contract with third-party processors in connection with the processing of the personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to the United States and other third countries. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data.

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules.

Human Capital Resources

As of March 1, 2024, we had 96 employees, all of whom were full-time. Of those, 76 were engaged in research and development activities. All of our employees are located in the United States. We do not have any employees that are represented by a labor union or covered under a collective bargaining agreement. We consider our relationship with our employees to be good.

Our future success depends on our ability to attract, develop and retain key personnel, maintain our culture and ensure diversity and inclusion in our board of directors, management and broader workforce. Our human resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and prospective employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. As these areas directly impact our ability to compete and innovate, they are key focus areas for our board of directors and senior executives.

Properties and Facilities

Our corporate headquarters are located in Emeryville, California, where we house our administrative, manufacturing and R&D activities. We currently lease approximately 68,000 square feet of space as our primary headquarters in Emeryville, California. One of the leases expires in January 2027, with an option for us to extend the term until January 2030. Another lease of approximately 35,000 square feet expires in February 2027 and does not have an option to extend the lease term. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Corporate Information

We were incorporated in Delaware in June 2018 under the name BAIT Therapeutics, Inc., and changed our name to Kyverna Therapeutics, Inc. in October 2019. Our principal executive offices are located at 5980 Horton St., STE 550, Emeryville, CA 94608, and our telephone number is (510) 925-2492.

Available Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission, or the SEC, and all amendments to these filings, can be obtained free of charge from our website following our filing of any of these reports with the SEC. Our website address is *https://kyvernatx.com/.* We do not incorporate the information on, or accessible through, our website into this Annual Report on Form 10-K, and you should not consider any information on, or accessible through, our website as 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. The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

Item 1A. Risk Factors.

You should carefully consider and read the following risk factors, as well as the financial and other information contained in this Annual Report on Form 10-K, including in Part II, Item 7 titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and in our financial statements and related notes included in Part II, Item 8 of this Annual Report on Form 10-K. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations or prospects and cause the value of our stock to decline, which could cause you to lose all or part of your investment. The risks described below are not the only ones facing us. Additional risks and uncertainties of which we are unaware, or that we currently deem immaterial, also may become important factors that affect us.

Risk Factor Summary

Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks that we face, follows this summary. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties:

- We have limited operating history, have incurred substantial net losses and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- Our business depends entirely on the success of our product candidates and we cannot guarantee that any or all of our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Results of any patient who receives our product candidate in an investigator-initiated trial or on a named patient basis should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for purposes of obtaining regulatory approval.
- We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be

able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

- We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business. In addition, if we lose key management or other scientific or clinical personnel, or if we fail to recruit additional highly skilled personnel, our business, results of operations and financial condition could be adversely affected.
- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.
- If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, results of operations and financial condition.
- We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.
- Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could cause us to suspend or discontinue clinical trials, abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, results of operations and financial condition.
- We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.
- We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.
- We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which could adversely affect our business, results of operations and financial condition.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- We may not be successful in obtaining or maintaining necessary rights to develop current and any future product candidates on acceptable terms.
- The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.
- On November 28, 2023, the FDA issued a statement that it is investigating serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies, such as KYV-101, and in January 2024, the FDA notified the manufacturers of the six FDA-approved BCMA-directed and CD19-directed chimeric CAR genetically modified autologous T-cell therapies that their products' safety information must be updated to include a boxed warning that T-cell malignancies have occurred following treatment with BCMA-directed and

CD19-directed genetically modified autologous T-cell immunotherapies. The FDA's investigation may impact the FDA's review of product candidates that we are developing, or that we may seek to develop in the future, which may, among other things, result in additional regulatory scrutiny of our product candidates, delay the timing for receiving any regulatory approvals, require us to include a boxed warning on any of our product candidates that receive regulatory approval or impose additional post-approval requirements on any of our product candidates that receive regulatory approval.

- Our principal stockholders and management own a significant percentage of our common stock and will be able to control matters subject to stockholder approval.
- Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.

Risks Related to Our Business, Limited Operating History and Financial Position

We have limited operating history, have incurred substantial net losses and anticipate that we will continue to incur net losses for the foreseeable future. We have no products approved for commercial sale, have never generated any revenue from product sales and may never be profitable.

We are a clinical stage biotechnology company with a limited operating history. We were formed in 2018 and we have devoted substantially all of our efforts and financial resources to organizing and staffing our company, business planning, raising capital, discovering product candidates and securing related intellectual property rights, and conducting research and development activities for our product candidates, including KYV-101 and KYV-201. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success, and viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing program candidates. Investment in biotechnology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have not yet demonstrated the ability to progress any product candidate through clinical trials, we have no products approved for commercial sale and we have not generated any revenue from product sales to date. We continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and we have incurred net losses since our inception through December 31, 2023. For the years ended December 31, 2023 and 2022, we reported a net loss of $60.4 million and $28.9 million, respectively. As of December 31, 2023, we had an accumulated deficit of $136.0 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of our product candidates, and seek regulatory approvals for our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct further clinical trials for KYV-101 and KYV-201 and our other product candidates;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;

- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and regulatory approval for our product candidates, including as a result of macroeconomic conditions, geopolitical conflicts or other factors; and
- incur additional costs associated with operating as a public company.

To become and remain profitable, we and any current or potential future collaborators must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials, obtaining marketing approval for product candidates, manufacturing, marketing and selling products if we obtain marketing approval, obtaining market acceptance for such products and satisfying any post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we 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 the price or of common stock, 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 you to lose all or part of your investment.

Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We also may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' (deficit) equity and working capital.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since our inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of, and seek regulatory approval for, KYV-101, KYV-201 and any future product candidates.

Because the design and outcome of our planned and anticipated preclinical studies and clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidates we develop. If we are required by the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority to perform clinical trials or preclinical studies in addition to those that we currently anticipate, our expenses could increase. In addition, if we obtain regulatory approval to market any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Other unanticipated costs may also arise.

We will incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations.

Until such time as we can generate significant revenue from sales of our product candidates, if ever, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities.

Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Our business depends entirely on the success of our product candidates and we cannot guarantee that any or all of our product candidates will successfully complete development, receive regulatory approval, or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our product candidates, each of which is still in clinical development, and expect that we will continue to invest heavily in these product candidates, as well as in any future product candidates we may develop. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts and further investment before we can generate any revenue from product sales. We currently generate no revenue and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected adverse events or failure to achieve primary endpoints in clinical trials.

Even if our product candidates are successful in clinical trials, we will not be permitted to market or promote any of our product candidates until we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations and prospects.

We cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of our investigational new drug applications, or INDs, or other submissions, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical trial design. Such changes could delay approval or necessitate withdrawal of our INDs or other submissions.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing;
- manufacture product candidates through contract manufacturing organizations, or CMOs, in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- price our products competitively such that third-party and government reimbursement permits broad product adoption;

- demonstrate the superiority of our products compared to the standard of care, as well as other therapies in development;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- effectively commercialize any of our products that receive regulatory approval;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing organizations on commercially reasonable terms;
- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our products;
- maintain compliance with applicable laws, regulations, and guidance specific to commercialization including interactions with healthcare professionals, patient advocacy groups, and communication of healthcare economic information to payors and formularies;
- achieve market acceptance of our products by patients, the medical community and third-party payors;
- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and
- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time and resources to new compliance initiatives.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Stock Market LLC, or Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could significantly harm our business, financial condition, results of operations and prospects. We plan to hire additional financial reporting, internal controls and other finance personnel or consultants in order to develop and implement appropriate internal controls and reporting procedures, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business, financial condition, results of operations and prospects may be significantly harmed.

We have identified material weaknesses in our internal control over financial reporting. If we fail to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

In connection with the preparation of our financial statements for the year ended December 31, 2023, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We did not appropriately design and maintain entity-level controls impacting the control environment, risk assessment, control activities, information and communication and monitoring activities to prevent or detect material misstatements to the financial statements. These material weaknesses related to (i) an insufficient number of qualified resources to ensure adequate oversight and accountability over the performance of controls, including retention of control evidence, (ii) ineffective identification and assessment of risks impacting internal control over financial reporting, and (iii) insufficient evaluation and determination as to whether the components of internal controls were present and functioning based upon evidence maintained for management review controls and activity level controls across substantially all financial statement areas.

These material weaknesses contributed to the following additional material weakness: we did not design and maintain effective (i) general controls over information systems that support the financial reporting process, (ii) controls over the completeness and accuracy of information used in the operation of control activities across substantially all financial statement areas, and (iii) management review controls at a sufficient level of precision to detect a material misstatement across substantially all financial statement areas that involve complex and judgmental areas of accounting and disclosure.

These material weaknesses could result in a misstatement of substantially all of our accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

We plan to implement formal risk assessment processes and procedures and design sufficient controls to remediate these weaknesses. We intend to hire additional experienced accounting and financial reporting personnel, formalize design and implementation of internal controls over the financial reporting process, including general controls over information systems. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. We expect to implement new procedures and controls and take efforts to address each of the identified weaknesses during fiscal years 2024 and 2025, and anticipate that the full remediation of the material weaknesses identified will extend beyond December 31, 2024. These remediation measures will be time consuming and require financial and operational resources.

After the closing of our initial public offering in February 2024, or the IPO, we became subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or the SEC.

We are required, pursuant to Section 404 of the Sarbanes Oxley Act to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting for the fiscal year ending December 31, 2024. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting and will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control

over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of any of our product candidates will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and ease of administration of our product candidates;
- the prevalence and severity of side effects and adverse events associated with our product candidates, and how the safety and tolerability profile of our product candidates compares to those of existing therapies, or those under development;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA with respect to such product candidates or to which we agree as part of a mandatory risk evaluation and mitigation strategy, or REMS, or voluntary risk management plan;
- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;

- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates and as our product candidates are used in named patient programs, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in FDA, the European Medicines Agency, or the EMA, or other investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We believe we may face greater risks with respect to our product candidates than many other biotechnology candidates because our product candidates are being developed to address conditions for which many prior products and product technologies have been unsuccessful. In addition, the patient population that our product candidates are seeking to target are often heavily immunosuppressed and may be more likely to experience serious adverse events with potential treatments and have higher morbidity rates generally than other patient populations. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business. In addition, if we lose key management or other scientific or clinical personnel, or if we fail to recruit additional highly skilled personnel, our business, results of operations and financial condition could be adversely affected.

As of March 1, 2024, we had 96 full-time employees. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in manufacturing, marketing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage

additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

In addition, our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our Chief Executive Officer, Peter Maag, Ph.D., and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the greater San Francisco Bay Area. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could adversely affect our business, results of operations and financial condition.

We are exposed to the risk of fraud or other misconduct by our employees, contractors or partners. Misconduct by these parties could include failures to comply with FDA regulations or comparable foreign regulations, to provide accurate information to the FDA or comparable foreign authorities, to comply with federal, state or foreign healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us, or failure to comply with comparable foreign requirements. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental 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 resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign equivalents, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our potential sublicensees' exercise of rights under the agreement. With respect to our commercial agreements, we indemnify our vendors from any third-party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

Our ability to use our net operating loss, or NOL, carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2023, we had federal NOL carryforwards of $48.8 million and state NOL carryforwards of $103.2 million. Under the Internal Revenue Code of 1986, as amended, or the Code, our U.S. federal net operating losses will not expire and may be carried forward indefinitely but the deductibility of federal net operating losses is limited to no more than 80% of current year taxable income (with certain adjustments). In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We completed a Section 382 study as of December 31, 2023 and determined that an ownership change had occurred as of such date and we expect approximately $2.0 million of federal net operating losses and $1.9 million California net operating losses to expire unused due to Section 382 limitations. Furthermore, there may be additional ownership changes in the future, including in connection with the IPO or as a result of subsequent changes in our stock ownership, some of which may be outside of our control. As a result, if we undergo an ownership change, and our ability to use our pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes is limited, it would harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations, or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. For example, the Tax Cuts and JOBS Act, the Coronavirus Aid, Relief, and Economic Security Act, and the Inflation Reduction Act, or the IRA, enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation. For example, the IRA includes provisions that will impact the U.S. federal income taxation of certain corporations, including imposing a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that would be imposed on the corporation repurchasing such stock. In addition, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted or otherwise become subject to changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

Our operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire and earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as a flood, wildfire, explosion, earthquake, extreme weather condition, epidemic or pandemic, power outage, telecommunications failure or other natural or manmade accidents or incidents that result in us being unable to fully

utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party CMOs and contract research organizations, or CROs, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we and our CMOs and CROs have in place may prove inadequate in the event of a serious disaster or similar event. In the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance we currently carry will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs or CROs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our clinical development programs and the diseases our product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. Following the COVID-19 pandemic and in connection with geopolitical conflicts, global economic and business activities continue to face widespread uncertainties. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, the failures of Silicon Valley Bank, Signature Bank and First Republic Bank in the first half of 2023 resulted in significant disruption in the financial services industry. If any of the banks which hold our cash deposits were to be placed into receivership, we may be unable to access our cash, cash equivalents and available-for-sale marketable securities, which would adversely affect our business. In addition, if any of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to fulfill their obligations to us could be adversely affected.

We or our directors or officers may be subject to securities litigation, which is expensive and could divert management attention.

We may be the target of securities litigation in the future, including based on volatility in the market price of our stock. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies. The market price of our common stock is likely to be volatile. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. In addition, certain of our directors and officers are involved in ongoing securities or other lawsuits in the context of their roles with other public companies, and our directors or officers may in the future become involved in such litigation. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive, time-consuming, damage our reputation and divert our management's and board of directors' attention from other business concerns, which could seriously harm our business.

Risks Related to Research, Development and Commercialization

We have never successfully completed any large-scale or pivotal clinical trials, and we may be unable to do so for any product candidates we develop.

We have not yet demonstrated our ability to successfully complete any large-scale or pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Although our key employees have significant experience in leading clinical development programs, our experience conducting clinical trials with our product candidates is limited. Developing cell therapies, in particular autologous cell therapies, is a complex and resource-intensive process requiring a team of scientists, clinicians, and technical and regulatory experts. We may not be able to file INDs for any of our other product candidates on the timelines we expect, if at all. For example, we cannot be certain that the IND-enabling studies for our product candidates will be completed in a timely manner or be successful or that the manufacturing process will be validated in a timely manner. Even if we submit an IND for a product candidate, the FDA may not clear the IND and allow us to begin clinical trials in a timely manner or at all. The timing of submissions of INDs for our product candidates will be dependent on further preclinical and manufacturing success. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing requirements; or
- be required to have the product removed from the market after obtaining marketing approval.

Results of any patient who receives our product candidate in an investigator-initiated trial or on a named patient basis should not be viewed as representative of how the product candidate will perform in our clinical trials and may not be able to be used to establish safety or efficacy for regulatory approval.

We supply our investigational product candidate, KYV-101, in investigator-initiated trials and on a named patient basis to patients who have exhausted other treatment options and for whom there is a strong scientific rationale to support the use of an unapproved product candidate. The investigator-initiated trials we supply to are located in the United States, and the independent investigators of such trials file INDs for the treatment of multiple or individual patients with KYV-101. We also currently supply KYV-101 for use in single named patients in Germany, through a European distributor. In Germany, these single-patient efforts are termed "Individueller Heilversuch," or single-patient treatment healing attempts, and occur outside of a controlled clinical trial setting and are not part of a compassionate use program or a codified German regulatory path. These investigator-initiated trials and the provision of KYV-101 on a named patient basis are not a substitute for, or intended to replace, our clinical trials. The primary goal of these healing attempts is not to assess the effectiveness of a potential therapy, but rather to provide the individual patient with the best possible treatment option, as determined by the patient's physician. We evaluate whether to grant such access or similar access in other foreign countries to KYV-101 outside of our sponsored clinical trials on a case-by-case basis.

We do not control the design, administration or timing of investigator-initiated trials. In addition, named patient treatments are carried out by independent physicians in a manner that the physician determines to be appropriate, which may be inconsistent from patient to patient and may not be conducted in strict compliance with good clinical practices, or GCPs, which can lead to a treatment effect that may differ from that in our controlled clinical trials. In addition, we rely on each investigator and physician to ensure their own compliance with clinical and regulatory requirements in using our product candidate for investigator-initiated trials and named patient activities, and we could be subject to liability if they are out of compliance. Individual patient results from named patient settings, including, but not limited to, data, experiences, images or videos, are observational, patient-specific and reported by the patients' respective physicians. Because of our lack of control over the settings in which these patients are given KYV-101, we cannot assure you that any positive results from such named patient activities are attributable to KYV-101, or that administration of KYV-101 to other patients will have similar positive results. Patient data from these trials and named patient activities are not designed to be aggregated or reported as results and may be highly variable.

Before we can seek regulatory approval for any of our product candidates, we must demonstrate in well-controlled clinical trials statistically significant evidence that the product candidate is both safe and effective for the indication for which we are seeking approval. The results of investigator-initiated trials and named patient activities may not be used to establish safety or efficacy for purposes of obtaining regulatory approval.

In contrast, such trials and named patient activities could potentially identify significant concerns with respect to our product candidates that could impact our findings or clinical trials, and adversely affect our ability to obtain marketing approval from the FDA or other applicable regulatory authorities. To the extent the results of investigator-initiated trials or named patient activities are inconsistent with, or different from, the results of our sponsored trials or raise concerns regarding our product candidates, the FDA or a foreign regulatory authority may question the well-controlled results of the company-sponsored trial, or subject such results to greater scrutiny than it otherwise would. In these circumstances, the FDA or such foreign regulatory authorities may require us to obtain and submit additional clinical data, which could delay clinical development or marketing approval of our product candidates. In addition, the risk for serious adverse events in the patient population of such trials and named patient activities is high. Adverse events, if attributed to our product candidate, could have a negative impact on the safety profile of our product candidates, and in turn cause significant delays or an inability to obtain regulatory approval or successfully commercialize our drug candidates.

Furthermore, there is no guarantee that we will be able to continue to receive or publicize observational data through investigator-initiated trials or named patient activities using our product candidates. Our supply capabilities may limit the number of patients who are able to enroll in these trials or the number of named patients that can be treated, and we may in the future need to restructure or pause such supply in order to enroll sufficient numbers of patients in our sponsored clinical trials, which could prompt adverse publicity or other disruptions. In addition, there is no clear regulatory framework under which we may supply our unapproved investigational product candidate in named patient settings, particularly for multiple named patients, outside of a clinical trial or a compassionate use program that is registered with applicable regulatory authorities. Our single-patient healing attempts are not part of a clinical trial or a compassionate use program that is registered with German regulatory authorities. As a result, if such supply, or our use of data from named patient activities, is found to contravene regulatory requirements, we could potentially be subjected to liability, fines or other consequences, which could be further exacerbated if such patients experience adverse safety events. Furthermore, if we supply our unapproved investigational product candidate to a named patient who would have qualified for enrollment in our KYSA-3 clinical trial in Germany, we may be subject to additional penalties. We also rely on each investigator and physician to ensure their own compliance with clinical and regulatory requirements in using our product candidate for investigator-initiated trials and named patient activities, and could be subject to liability if they are out of compliance.

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

All of our product candidates are either in preclinical or clinical development and their risk of failure is high. Some of the product candidates and technologies we are developing are novel and unproven, which makes it difficult to accurately predict the challenges we may face with respect to our product candidates as they proceed through development. We believe we may face greater risks with respect to our product candidates than many other biotechnology candidates because our product candidates are being developed to address conditions for which many prior products and product technologies have been unsuccessful. In addition, the patient population that our product candidates are seeking to target are often heavily immunosuppressed and may be more likely to experience serious adverse events with potential treatments and have higher morbidity rates generally than other patient populations. It is also impossible to predict whether our clinical trials will continue and when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of such product candidates. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a similar foreign regulatory authority.

Even after we make our submission, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional trials or amend our protocols or impose stricter conditions on the commencement of clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely in part on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or our collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive marketing approval or commercialize our current and any future product candidates, including:

- regulators, such as the FDA or comparable foreign regulatory agencies, Institutional Review Boards, or IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials may be greater than we anticipate, or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a Biologic License Application, or BLA, or new drug application, or NDA;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates; and
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs.

We may in the future experience participant withdrawals or discontinuations from our trials. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the IRBs of the institutions in which such trials are being conducted, the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board, or DSMB, for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our CROs to perform in accordance with GCP requirements, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also conduct preclinical and clinical research in collaboration with academic, pharmaceutical and biotechnology entities in which we combine our development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

If we encounter difficulties enrolling patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected, which could adversely affect our business, results of operations and financial condition.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients who remain in a trial until its conclusion. We may not be able to initiate, continue or complete clinical trials that may be required by the FDA or comparable foreign regulatory authorities to obtain regulatory approval for any of our product candidates if we are unable to locate, enroll and retain a sufficient number of eligible patients to participate in these clinical trials. Patient enrollment, a significant factor in the timing to conduct and complete clinical trials, is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies; and
- other factors outside of our control, such as the effects of global economic conditions and volatility in the credit and financial markets, inflationary pressures, the Russian invasion of Ukraine, the Israel-Hamas war and other geopolitical conditions.

We also may encounter difficulties in identifying and enrolling patients with a stage of disease appropriate for ongoing or future clinical trials. In addition, the process of finding and diagnosing patients may prove costly. Other pharmaceutical companies with more resources and greater experience in drug development and commercialization are targeting similar treatments, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is also limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites, and may delay or make it more difficult to fully enroll our clinical trials. We also rely on CROs and clinical trial sites to enroll subjects in our clinical trials and, while we have agreements governing their services, we will have limited influence over their actual performance.

These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient 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 publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim 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 patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

Others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically a significant volume of data and other information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

Because we have limited financial and managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future 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 such product candidate.

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

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates. In December 2021, we entered into a License and Collaboration Agreement, or the Intellia Agreement, with Intellia Therapeutics, Inc., a clinical-stage biotechnology company focused on developing novel therapeutics leveraging CRISPR-based technologies, or Intellia, to research and develop an allogeneic cell therapy product, or the CRISPR Product Candidate. Collaborations are complex and time-consuming to negotiate and document. 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.

We face competition from entities that have made substantial investments into the rapid development of novel treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, hospitals and clinics, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data emerge.

Our current product candidates, initially under development for treatment of various immunological indications, if approved, would face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing KYV-101 for the treatment of B-cell-driven autoimmune diseases. Many emerging and established life sciences companies have been focused on similar therapeutics, including CAR T-cell candidates for B-cell-driven autoimmune diseases. If approved, KYV-101 would compete with currently approved therapeutics, including Rituxan and Ocrevus, both from Roche Holding AG, and

generic immunosuppressive or biosimilar drugs, such as mycophenolate mofetil, glucocorticoids, azathioprine, cyclophosphamide, and IVIG, among others we anticipate will receive approvals in the near term. There are also a number of product candidates in clinical development by third parties that are intended to treat some B-cell-driven autoimmune diseases, such as obinutuzumab (targeting CD20 on B cells), which is also from Genentech/Roche Holding AG.

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provides a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates demonstrate meaningful improvements in these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we do not achieve our projected development goals in the timeframes we announce and expect, the commercialization of our programs may be delayed and our expenses may increase and, as a result, our stock price may decline.

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials, as well as the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our programs may be delayed or never achieved and, as a result, our stock price may decline. Additionally, delays relative to our projected timelines are likely to cause overall expenses to increase, which may require us to raise additional capital sooner than expected and prior to achieving targeted development milestones.

Use of our product candidates could be associated with side effects, adverse events or other properties or safety risks, which could cause us to suspend or discontinue clinical trials, abandon a product candidate, delay or preclude approval, prevent market acceptance, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, results of operations and financial condition.

Before obtaining regulatory approvals for the commercial sale of any of our products, we must demonstrate through lengthy, complex and expensive preclinical studies and clinical trials that our current product candidates, including our lead product candidates, and any future product candidate are both safe, pure and potent, or effective for use in such product candidate's target indication. Clinical testing is expensive, can take many years to complete and its outcome is inherently uncertain. In addition, some of the product candidates and technologies we are developing are novel and unproven, which makes it impossible to predict whether our clinical trials will continue. The patient population that our product candidates are seeking to target also are often heavily immunosuppressed and may be more likely to experience serious adverse events with potential treatments and have higher morbidity rates generally than other patient populations. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to generate desired safety and efficacy data despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved and there can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of our current product candidates or any of our future product candidates or ultimately their approval. We do not expect to be able to use the results from any investigator initiated trials or named patient activities conducted with our product candidates in any regulatory submission for marketing approval.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. In addition, negative results from investigator initiated trials as well as named patient activities involving our product candidates could cause similar issues. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, results of operations and financial condition significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies, clinical trials or investigator initiated trials, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, results of operations and financial condition significantly.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, in any investigator initiated trials conducted with our product candidates, or in our named patient activities, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable foreign regulatory authorities or an IRB or ethics committee may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, results of operations and financial condition.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. Such delayed side effects might be observed during the long-term follow-up FDA has insisted upon for certain gene therapy products. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product from the marketplace, if approved;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

Changes in product candidate manufacturing, formulation or analytical methods may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and future commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation or analytical methods, are altered throughout the development process in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials or utilizing different analytical methods. Such changes also may require additional testing, or notification to, or authorization 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. If we or our CMOs are not able to successfully manufacture our product candidates in sufficient

quality and quantity, clinical development and timelines for our product candidates and subsequent approval could be adversely impacted.

A variety of risks associated with conducting research and clinical trials abroad and marketing our product candidates internationally could materially adversely affect our business.

We plan to globally develop our product candidates. In addition, our enrollment timelines for our product candidates depend on initiating clinical trial sites outside of the United States. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- differing standards and privacy requirements for the conduct of clinical trials;
- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- challenges with obtaining any local supply of drugs or agents used with our product candidates, which are required by certain local clinical trial sites before conducting any study; and
- business interruptions resulting from health epidemics or pandemics, or natural or man-made disasters, including earthquakes, tsunamis, fires or other medical epidemics, or geo-political actions, including war and terrorism.

These and other risks associated with our collaboration with Intellia may materially adversely affect our ability to attain or maintain profitable operations.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign authority approval process, and we currently, and will need to continue to, contract with manufacturers who can meet our and all applicable FDA or comparable foreign authority requirements on an ongoing basis.

The manufacturing process for any products that we may develop is subject to the FDA or comparable foreign authority approval process, and any contractors with which we contract for manufacturing must meet all applicable FDA or comparable foreign authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or comparable foreign authority, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA or comparable foreign authority, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restriction and criminal prosecutions, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality and complying with applicable regulatory requirements. An inability to do so could have a material adverse effect on our business, financial condition and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

We rely on third party CMOs to manufacture and supply cell therapy products for our research and development purposes and for our clinical trials. Under our Master Services Agreement with WuXi ATU Advanced Therapies Inc., dated March 2022, or the WuXi Agreement, WuXi provides us certain with certain customized cell manufacturing, release and testing services for our KYV-101 product candidate. Pursuant to our Licence and Supply Agreement with Oxford Biomedica (UK) Limited, or Oxford, dated September 2023, or the Oxford Agreement, we recently engaged Oxford to undertake lentiviral vector process development services, with the intention for Oxford to ultimately manufacture and supply to us lentiviral vectors for research and development purposes and for use in connection with our clinical trials. Although we believe we currently have sufficient clinical-grade vector in inventory to move forward with our anticipated clinical trials, there is no guarantee that sufficient clinical-grade vector will be available in the quantities we require in the future or on terms that are acceptable to us. In July 2023, we entered into a Development and Manufacturing Services Agreement, or the ElevateBio Agreement, with ElevateBio Base Camp, Inc., or ElevateBio, pursuant to which ElevateBio is undertaking process development services for the development of a low-cost, fully closed manufacturing process for our CAR T-cell product candidates.

Reliance on third-party manufacturers entails exposure to risks to which we would not be subject if we manufactured the product candidate ourselves, including:

- inability to negotiate manufacturing and quality agreements with third parties under commercially reasonable terms;
- reduced day-to-day control over the manufacturing process for our product candidates as a result of using third-party manufacturers for all aspects of manufacturing activities;
- reduced control over the protection of our trade secrets and know-how from misappropriation or inadvertent disclosure;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that may be costly or damaging to us or result in delays in the development or commercialization of our product candidates;

- disruptions to the operations of our third-party manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- international or multi-national activities that are related to business activities outside of our scope, but may have an impact on a CMO's ability to conduct business in a manner consistent with governmental or our regulatory and ethical standards; and
- our ability to synchronize operations and standards to ensure that all aspects of manufacturing are consistent without deviations across facilities.

Should we continue to use CMOs, we may not succeed in maintaining our relationships with our current CMOs or establishing relationships with additional or alternative CMOs. Our product candidates may compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under current Good Manufacturing Practice, or cGMP, regulations and that are both capable of manufacturing for us and willing to do so. If our CMOs should cease manufacturing for us, we would experience delays in obtaining sufficient quantities of our product candidates for clinical trials and, if approved, commercial supply. Further, our CMOs may breach, terminate, or not renew these agreements. If we were to need to find alternative manufacturing facilities it would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. The commercial terms of any new arrangement could be less favorable than our existing arrangements and the expenses relating to the transfer of necessary technology and processes could be significant.

Moreover, if we are unable to manufacture or contract for a sufficient supply of our product candidates on acceptable terms, or if we encounter delays or difficulties in the scale-up of our manufacturing processes or our relationships with WuXi or other manufacturers, our preclinical and human clinical testing schedule would be delayed. This in turn would delay the submission of product candidates for regulatory approval and thereby delay the market introduction and subsequent sales of any products that receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations. In addition, if any of our product candidates are approved for sale, our inability to manufacture or contract for a sufficient supply of such potential future products on acceptable terms would have a material adverse effect on our business, financial condition and results of operations.

Even to the extent we use and continue to use CMOs, we are ultimately responsible for the manufacture of our products and product candidates. A failure to comply with these requirements may result in regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Risks Related to Intellectual Property

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which could adversely affect our business, results of operations and financial condition.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. For example, we have two patent license agreements, or the NIH Agreements, with the National Institutes of Health, or the NIH, pursuant to which we obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR in our autologous and allogeneic CAR T-cell products for the treatment of patients with autoimmune disease, which is the CAR we used to create our lead product candidate, KYV-101. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

Disputes also may arise between us and our licensors regarding intellectual property subject to a license 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 collaborative development relationships;
- the priority of invention of patented technology;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and future commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of and rights to use inventions and know-how resulting from the joint or individual creation or use of intellectual property by our licensors and us and our partners.

In addition, certain of our current and future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We generally also are subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described in this "Risk Factors" section. If we or our licensors fail to adequately protect this intellectual property, our business, results of operations and financial condition could be adversely affected.

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

We rely upon a combination of in-licensed patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. For example, pursuant to the NIH Agreements, we obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR in our autologous and allogeneic CAR T-cell products for the treatment of patients with autoimmune disease, which is the CAR we used to create our lead product candidate, KYV-101.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. We cannot assure you that our existing patents and any future issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into

non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our technologies or product candidates.

We are also dependent on our licensors to take necessary action to comply with patent protection requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, 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. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our or our collaborators' or licensors' pending patent applications directed to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our or our licensors' issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned and in-licensed patent applications may not result in patents being issued that protect our technologies or product candidates, effectively prevent others from commercializing our technologies or product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we will be successful in protecting our product candidates by obtaining and defending patents. For example, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own or our licensors' patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. As a result, the issuance, inventorship, scope, validity, enforceability and commercial value of our or our licensors' patent rights are highly uncertain.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our or our licensors' pending patent applications may be challenged in patent offices in the United States and abroad. Even

issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our or our licensors' pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO or our issued patents may be subject to post-grant review, or PGR, proceedings, oppositions, derivations, reexaminations, interferences, inter partes review, or IPR, proceedings or other similar proceedings, in the United States or elsewhere, challenging our or our licensors' patent rights or the patent rights of others. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned or licensed pending patent applications. 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 similar or identical technology and product candidates, or limit the duration of the patent protection of our technology and product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. An adverse result in any legal proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

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. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue, or that our issued patents or patents that issue in the future will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have pending and issued U.S. and foreign patents and patent applications in our portfolio; however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any issued patent will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications will result in issued patents with claims that cover each of our product candidates or uses thereof in the United States or in other foreign countries.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, revocation, 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 challenge may result in loss of exclusivity or in our 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 similar or identical technology and products or limit the duration of the patent protection of our technology and products. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may rely on more than one patent to provide multiple layers of patent protection for our product candidates. If the latest-expiring patent is invalidated or held unenforceable, in whole or in part, the overall protection for the product candidate may be adversely affected. For example, if the latest-expiring patent is invalidated, the overall patent term for our product candidate could be adversely affected.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products.

Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to our product candidates. Further, in cases where a particular compound of interest is in the public domain, third parties may be able to obtain patents on improvements or other inventions relating to such compound if they were to discover the same patentable inventions relating to such compounds after us but manage to file a patent application before we do. In addition, we may enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, including any polymorphs and variants, such as our employees, collaborators, consultants, advisors and other third parties; however, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to obtain patent protection. Furthermore, if third parties have filed patent applications related to our product candidates or technology, an interference proceeding in the United States can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. 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.

Given the amount of time required for the development, testing and regulatory review of new product candidates, our patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical ours. Our competitors and other third parties may also seek approval to market their own products similar to or otherwise competitive with our products. Alternatively, our competitors or other third parties may seek to market generic or biosimilar versions of any approved products and in so doing, claim that patents owned by us are invalid, unenforceable or not infringed. 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 may find 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.

Moreover, some of our patents may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

If we fail to comply with our obligations under our patent licenses with third parties, we could lose license rights that are important to our business, which could adversely affect our business, results of operations and financial condition.

We are a party to license agreements pursuant to which we in-license patent and patent applications, know-how, trade secrets and data rights for our product candidates. These include, for example, the NIH Agreements, pursuant to which we obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR in our autologous and allogeneic CAR T-cell products for the treatment of patients with autoimmune disease, and the Intellia Agreement, which provides for the research and development of the CRISPR Product Candidate. These existing licenses impose on us various diligence, milestone payment, royalty, insurance and other obligations. If we fail to comply with these obligations, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property.

We may also enter into license agreements with third parties under which we are a sub-licensee. If our sub-licensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sub-license. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may have limited control over the maintenance and prosecution of these in-licensed patents and patent applications, activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, such activities by these licensors may not have been or may not be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Our licensors may not successfully prosecute the patent applications to which we are licensed in a manner consistent with the best interests of our business. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

We cannot prevent other companies from licensing some of the same intellectual properties that we have licensed or from otherwise duplicating our business model and operations.

Since parties we have licenses with are developing therapies to similar technologies, they may make their methods and data available to third parties, who may want to enter into our line of business and compete against us. Although we currently exclusively license certain intellectual property for each of our product candidates, there can be no assurance we will not need to license other intellectual property on a non-exclusive basis in the future or that our exclusively licensed intellectual property could be used to prevent third parties from duplicating our business plan or from otherwise directly competing against us. Further, no assurance can be given that our existing exclusive rights are or will be sufficient to prevent others from competing with us and developing substantially similar products.

We may not be successful in obtaining or maintaining necessary rights to develop current and any future product candidates on acceptable terms.

Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. Our product candidates also may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and expenses and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we

are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we sometimes collaborate with academic institutions and governmental authorities to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business, results of operations and financial condition could be adversely affected.

The licensing and acquisition of third-party intellectual property rights is a highly competitive area, and companies, which may be more established or have greater resources than we do, also may be pursuing strategies to license or acquire third-party intellectual property rights that we consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

Our product candidates licensed from various third parties may be subject to retained rights.

Our licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions. In particular, under the NIH Agreements the NIH reserves, on behalf of the United States federal government and certain third parties, an irrevocable, nonexclusive, worldwide, royalty-free license to practice all of the inventions licensed under such agreements, and the NIH also reserves the right to grant third parties research licenses on reasonable terms. Under the Intellia Agreement, Intellia is granted an irrevocable, nonexclusive, worldwide, royalty-free license to fully exploit certain Intellia-developed products that are not directed to CD19 or other B-cell antigens and which are not intended for treatment or prevention of autoimmune or inflammatory diseases or conditions and not for humoral rejection for solid organ transplantation.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act, or the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates. We may infringe the intellectual property rights of others, which may prevent or delay our drug development efforts and prevent us from commercializing or increase the costs of commercializing our products.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of

our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our technologies or product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our technologies and product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

Our commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. For example, there could be issued patents of which we are not aware that our current or potential future product candidates infringe. There also could be patents that we believe we do not infringe, but that we may ultimately be found to infringe. Competitors may file continuing patent applications claiming priority to already issued patents in the form of continuation, divisional or continuation-in-part applications, in order to maintain the pendency of a patent family and attempt to cover our product candidates.

Third parties may assert that we are employing their proprietary technology without authorization and may sue us for patent or other intellectual property infringement. These lawsuits are costly and could adversely affect our business, financial condition and results of operations and divert the attention of managerial and scientific personnel. If we are sued for patent infringement, we would need to demonstrate that our product candidates, potential products or methods either do not infringe the claims of the relevant patent or that the patent claims are invalid, 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. Even if we are successful in these proceedings, 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 have a material adverse effect on us. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. If a court holds that any third-party patents are valid, enforceable and cover our products or their use, the holders of any of these patents may be able to block our ability to commercialize our products unless we acquire or obtain a license under the applicable patents or until the patents expire.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant. We may not be able to enter into licensing

arrangements or make other arrangements at a reasonable cost or on reasonable terms. Any inability to secure licenses or alternative technology could result in delays in the introduction of our products or lead to prohibition of the manufacture or sale of products by us. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially and adversely affect our business, financial condition and results of operations. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material and adverse effect on our business, financial condition and results of operations. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or one of our licensing partners 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. Our or our licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. 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 or our licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or our licensors 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 or our licensors' patent claims do not cover the invention, or decide that the other party's use of our or our licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). In addition, the U.S. Supreme Court recently has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria, which also could make it more difficult to obtain patents. An adverse outcome in a litigation or proceeding involving our or our licensors' patents could limit our ability to assert our or our licensors' 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 position, and our business, financial condition, results of operations and prospects. 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. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of

our common stock. Moreover, we cannot assure you 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.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party.

If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an inter partes review, ex parte re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings at the EPO or similar proceedings in other foreign patent offices, where either our owned or in-licensed foreign patents are challenged.

In the future, we may be involved in similar proceedings challenging the patent rights of others, and the outcome of such proceedings is highly uncertain. An adverse determination in any such proceeding may result in our inability to manufacture or commercialize products without infringing third-party patent rights. The costs of these opposition or similar proceedings could be substantial, and may result in a loss of scope of some claims or a loss of the entire patent. Even if we ultimately prevail in any such claims or proceedings, 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 claims or proceedings.

We may become subject to claims challenging the inventorship or ownership of our or our licensors' patents and other intellectual property or claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or our licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. 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 it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could adversely affect our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on products or product candidates for an adequate amount of time. If we do not obtained patent term extension for our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application 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 products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might expire before or shortly after such products or candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one or more of our or our licensors' issued U.S. patents or issued U.S. patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term, or PTE, of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under Supplemental Protection Certificate, or SPC. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded 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, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents. The Leahy-Smith Act includes a number of significant changes

to U.S. patent law. These include 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. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents and patents that we or our licensors might obtain in the future. We cannot predict how future decisions by the courts, the U.S. Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have also increased in recent years. In Europe, in June 2023, a new unitary patent system was introduced, which will significantly impact European patents, including those granted before the introduction of the system. Under the unitary patent system, after a European patent is granted, the patent proprietor can request unitary effect, thereby getting a European patent with unitary Effect, or a Unitary Patent. Each Unitary Patent is subject to the jurisdiction of the Unitary Patent Court, or UPC. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of the new unitary patent system.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We may also rely on trade secret protection as temporary protection for concepts that may be included in a future patent filing. However, trade secret protection will not protect us from innovations that a competitor develops independently of our proprietary know how. If a competitor independently develops a technology that we protect as a trade secret and files a patent application on that technology, then we may not be able to patent that technology in the future, may require a license from the competitor to use our own know-how, and if the license is not available on commercially viable terms, then we may not be able to launch our product candidate. Additionally, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets. If our trade secrets are not adequately protected, our business, financial condition, results of operations and prospects could be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared merely descriptive, generic or determined to be infringing on other marks. The use of our registered and unregistered marks is also limited by certain agreements with third parties. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. In the USPTO, cancellation proceedings may be filed against our trademarks, once registered, which may not survive such proceedings. In foreign jurisdictions, opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names.

If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain names, social media handles or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than those in the United States. Moreover, obtaining such protection in a timely manner, or at all, may be affected by factors or events beyond our control, such as a prolonged economic downturn, or global financial or political crises. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. 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 but where 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 patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do

not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. In addition, certain countries outside of the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government authorities or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Risks Related to Government Regulation

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 adversely affect our business, results of operations and financial condition.

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. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our future commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, this may not be the case and we may not eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state, federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes or our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. Although we have environmental liability insurance for our California facility as required by the related lease agreement, we do not currently carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for criminal damages and fines arising from biological or hazardous waste exposure or contamination.

We have conducted, are currently conducting, and may in the future conduct clinical trials for our product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We have conducted, are currently conducting, and may in the future conduct one or more clinical trials of our current or future product candidates outside the United States, including in Germany. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority 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 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 (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such as inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical power, must be met. 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, we would need to conduct additional trials, which could be costly and time-consuming.

Even if we receive marketing approval for our current or future product candidates in the United States, we may never receive regulatory approval to market outside of the United States.

We plan to seek regulatory approval of our current or future product candidates outside of the United States and are currently conducting certain clinical trials internationally, including in Europe. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The marketing approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of any of our product candidates in certain countries. Regulatory and marketing approval in one country does not ensure regulatory and marketing approval in another, but a failure or delay in obtaining regulatory and marketing approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

Any of our product candidates and any future product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of products. Rigorous preclinical studies, clinical trials, and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new product can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of our product candidates will obtain the regulatory approvals necessary for us to begin selling them.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors,

including the discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that any product candidates we may seek to develop in the future will never obtain regulatory approval. Neither we nor any future collaborator is permitted to market any of our product candidates in the United States until we receive regulatory approval of our product candidates through a new drug application, or NDA, or biologics license application, or BLA, from the FDA. The FDA and other regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the FDA or other regulatory authorities that any of our product candidates are safe and effective for any indication;
- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA or other regulatory authorities for approval;
- the FDA or other regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA or other regulatory authorities may not find the data from preclinical studies and clinical trials sufficient to demonstrate that the benefits of any of our product candidates outweigh their safety risks;
- the FDA or other regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials, or may not accept data generated at our clinical trial sites;
- the data collected from preclinical studies and clinical trials of any of our product candidates may not be sufficient to support the submission of an IND or other application for regulatory approval;
- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;
- the FDA may require development of a risk evaluation and mitigation strategy, or REMS, and other regulatory authorities may require a risk management plan, or RMP, as a condition of approval for new products, among other additional requirements;
- the FDA or other regulatory authorities may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;
- the FDA or other regulatory authorities may change their approval policies or adopt new regulations; and
- the FDA or other regulatory authorities may require simultaneous approval for both adults and for children and adolescents, which may delay approval, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory authorities may require that we conduct additional clinical, preclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications 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 or other regulatory authorities for obtaining approval.

In addition, the FDA or other regulatory authorities may approve a product candidate for fewer or more limited indications than we request, may impose significant limitations related to use restrictions for certain age groups, warnings, precautions or contraindications or may grant approval contingent on the performance of costly post-marketing clinical trials or risk mitigation requirements, such as the implementation of a REMS or comparable

foreign risk management approaches. The FDA or other regulatory authorities may not accept the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Further, the FDA and its foreign counterparts may respond to any BLA or NDA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of any of our product candidates or any future product candidates.

On November 28, 2023, the FDA issued a statement that it is investigating serious risk of T-cell malignancy following BCMA-directed or CD19-directed autologous chimeric antigen receptor (CAR) T cell immunotherapies, such as KYV-101. While the FDA noted that it currently believes that the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA stated that it is investigating the identified risk of T-cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action. In January 2024, the FDA notified the manufacturers of the six FDA-approved BCMA-directed and CD19-directed chimeric CAR genetically modified autologous T-cell therapies that their products' safety information must be updated to include a boxed warning that T-cell malignancies have occurred following treatment with BCMA-directed and CD19-directed genetically modified autologous T-cell immunotherapies. However, because all currently approved CAR T-cell immunotherapies are in oncology indications, there can be no assurance that the FDA will reach the same risk-benefit analysis in other indications, such as autoimmune. Given that the autoimmune diseases we are seeking to treat are different indications from the approved oncology indications, the FDA and other regulatory authorities may apply a different benefit-risk assessment threshold such that even if our product candidate demonstrated a similar safety profile as current CAR T therapies, the FDA could ultimately determine that the harmful side effects outweigh the benefits and require us to cease clinical trials or deny approval of our product candidates. The FDA's investigation may impact the FDA's review of product candidates that we are developing, or that we may seek to develop in the future, which may, among other things, result in additional regulatory scrutiny of our product candidates, delay the timing for receiving any regulatory approvals, require us to include a boxed warning on any of our product candidates that receive regulatory approval or impose additional post-approval requirements on any of our product candidates that receive regulatory approval.

Any delay or failure in obtaining required approvals could adversely affect our ability to generate revenue from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Even if we commercialize any product candidates, alone or with our partners, such product may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Current and future 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 drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay or limit our commercial launch of the product, possibly for lengthy time periods, which could negatively impact the revenue we generate from the sale of the product in that particular country. Adverse pricing limitations may hinder

our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates profitably.

The success of our product candidates, if approved, depends on the availability of coverage and adequate reimbursement from third-party payors. We cannot be certain that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will continue to be available for any product that we may develop that receives coverage and adequate reimbursement from one or more third-party payors. 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. Accordingly, coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. These groups have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, in July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a

Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. At the state level, legislatures have increasingly passed legislation and implemented 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.

Additionally, there may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a 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 only be temporary. 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.

We expect to experience pricing pressures in connection with the sale of all of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or third-party 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 both government-funded and private payors for any approved products that we 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.

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

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of pharmaceutical products. Our current and future arrangements with healthcare providers, third-party payors and customers can expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we research and, if approved, sell, market and distribute our products. In particular, the research of our product candidates, as well as the promotion, sales, marketing and business arrangements of our product candidates, is subject to extensive laws designed to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other;
- the federal civil and criminal false claims laws, including the federal False Claims Act or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other

federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government healthcare programs if they are deemed to "cause" the submission of false or fraudulent claims. In addition, 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 FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating the healthcare fraud statute under HIPAA without actual knowledge of the statute or specific intent to violate it;
- the federal Physician Payments Sunshine Act and its implementing regulations, which require some manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and local laws that require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal, state and foreign enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions, significant fines and penalties and settlements in the healthcare industry. Ensuring that business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time-and resource-consuming and may divert our management's attention from the operation of our business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other

healthcare laws and 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, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Prohibitions or restrictions on sales or withdrawal of future marketed products could adversely affect our business, results of operations and financial condition.

We may attempt to seek approval from the FDA for one or more of our product candidates through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval pathway, 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. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is permitted to require, as appropriate, that such studies be underway prior to approval or within a specified time period after the date accelerated approval is granted. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. In addition, FDORA gives the FDA increased authority to withdraw accelerated approval on an expedited basis if, for example, the sponsor fails to conduct such studies in a timely manner, such studies fail to confirm the drug's clinical benefit or the sponsor fails to send the necessary updates to the FDA. The FDA is empowered to take action against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, the FDA generally requires, unless otherwise informed by the agency, pre-approval of promotional materials for products receiving accelerated approval, which could adversely impact the timing of the commercial launch of the product.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA seeking accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates

would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may not be successful in pursuing or maintaining Fast Track or other expedited regulatory designations for our product candidates, and such designations may not actually lead to a faster development or regulatory approval process.

Although we received Fast Track designation for KYV-101 for the treatment of patients with refractory lupus nephritis in May 2023, for KYV-101 for the treatment of patients with myasthenia gravis in December 2023 and for KYV-101 for the treatment of patients with multiple sclerosis in January 2024, these designations do not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures. In addition, the FDA may withdraw a Fast Track or other accelerated review designation if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate. Access to an expedited program may expedite the development or approval process, but it does not change the standards for approval.

Furthermore, although we may pursue additional opportunities to accelerate the development of certain of our product candidates through one or more of the FDA's expedited program designations, we cannot be assured that any of our product candidates will qualify for such programs. The FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain marketing approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures

that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain marketing approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, was enacted in the United States, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program, or MDRP, are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the MDRP, extended manufacturer Medicaid rebate obligations to utilization by individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and established a new Medicare Part D coverage gap discount program. Since its enactment, there have been judicial, congressional, and executive branch challenges to the ACA, which have resulted in delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. In addition, there have been a number of health reform initiatives by the Biden administration that have impacted the ACA. For example, on August 16, 2022, President Biden signed the IRA into law, which, among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how other such challenges, and the healthcare reform measures of the Biden administration, will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, on August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013, and, due to subsequent legislative amendments to the statute, will remain in effect through 2031. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. In addition, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain IND 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 authorization under an FDA expanded access program; however, manufacturers are not obligated to provide IND products under the current federal right to try law. In certain countries outside the United States, reimbursement for products that have not yet received marketing authorization may be provided through national managed access programs.

We expect that the ACA, the IRA, and any 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Changing regulatory environments could negatively impact our business.

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting 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 for which we obtain marketing approval.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Many EU Member States periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess the therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States.

In December 2021, Regulation No. 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the European Union. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal

products, and providing the basis for cooperation at European Union level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU 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 most 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 EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the European Union could be negatively affected.

Legislators, policymakers and healthcare insurance funds in the European Union may continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we would be able to charge for product candidates that we may successfully develop and for which we may obtain regulatory approval or the level of reimbursement available for these products from governmental authorities or third-party payors. Further, an increasing number of European Union and other foreign countries use prices for medicinal products established in other countries as "reference prices" to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

Our business could be negatively impacted by environmental, social and corporate governance, or ESG, matters or our reporting of such matters.

There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. While we have internal efforts directed at ESG matters and preparations for any increased required future disclosures, we may be perceived to be not acting responsibly in connection with these matters, which could negatively impact us. Moreover, the SEC has recently proposed, and may continue to propose, certain mandated ESG reporting requirements, such as the SEC's proposed rules designed to enhance and standardize climate-related disclosures, which, if finally approved, would significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation or that harm our stock price. In addition, we currently do not report our environmental emissions, and lack of reporting could result in certain investors declining to invest in our common stock.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government authorities or government-affiliated hospitals, universities, and other organizations.

We also expect our non-U.S. activities to increase over time. We plan to engage third parties for clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals, and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. If we further expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The Foreign Corrupt Practices Act, or the FCPA, prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate and other related parties for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also

obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our research and development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks Related to Data and Privacy

If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including, but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related to our business, and other adverse consequences.

In the ordinary course of our business, we, and the third parties upon which we rely, process sensitive data and, as a result, we and the third parties upon which we rely face a variety of evolving threats which could cause security incidents.

Our internal information technology systems and those of our CROs, CMOs, clinical sites and other contractors and consultants upon which we rely are vulnerable to cyberattacks, computer viruses, bugs, worms, or other malicious codes, malware (including as a result of advanced persistent threat intrusions), and other attacks by computer hackers, cracking, application security attacks, social engineering (including through phishing attacks), supply chain attacks and vulnerabilities through our third-party service providers, denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive customer information), loss of income, significant extra expenses to restore data or systems, reputational loss and the diversion of funds. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments).

Some actors also now engage and are expected to continue to engage in cyberattacks, including without limitation nation-state actors, for geopolitical reasons and in conjunction with military conflicts and defense

activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyberattacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products, if approved. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Furthermore, future business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Additionally, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

While we take steps to detect and remediate vulnerabilities, we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit such vulnerabilities change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, encryption and authentication technology, employee email, and other functions. We also rely on third-party service providers to assist with our clinical trials, provide other products or services, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services including clinical trials.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other contractors and consultants become subject to disruptions or security incidents, 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.

If any such incidents were to occur and cause interruptions in our operations, it could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any product candidates could be delayed. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security

incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. Any such event could also result in legal claims or proceedings, liability under laws that protect the privacy of personal information and significant regulatory penalties, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates.

Failure to comply with data privacy and security laws, regulations and other obligations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, negative publicity, and/or other adverse consequences that could negatively affect our operating results and business.

We and our partners may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information, could apply to our operations or the operations of our partners. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. Depending on the facts and circumstances, we could be subject to penalties if we violate HIPAA.

Even when HIPAA does not apply, according to the Federal Trade Commission, or the FTC, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain state laws govern the privacy and security of health-related and other personal information in certain circumstances, some of which may be more stringent, broader in scope or offer greater individual rights with respect to protected health information than HIPAA, many of which may differ from each other, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the California Consumer Privacy Act, or the CCPA, which creates new individual privacy rights for California consumers (as defined in the law), including the right to opt out of certain disclosures of their information, and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act, or the CPRA, recently entered into force in California, amending the CCPA. The changes introduced by the CPRA impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt-outs for certain uses of sensitive data. The amendments ushered in by the CPRA also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required.

Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business. New consumer privacy laws entered into force in Connecticut, Colorado, Virginia and Utah in 2023. In addition, a number of other states have proposed new privacy laws, some of which are similar to the above-discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Foreign data protection laws, including the European Union's General Data Protection Regulation, or the EU GDPR, and the UK equivalent of the same, or UK GDPR, together with the EU GDPR, the GDPR, may also apply to our processing of health-related and other personal data regardless of where the processing in question is carried out.

The GDPR imposes stringent requirements for controllers and processors of personal data of individuals within the European Economic Area, or EEA, or the United Kingdom. The GDPR applies to any company established in the EEA or United Kingdom as well as to those outside the EEA or United Kingdom if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or United Kingdom or the monitoring of their behavior. The GDPR, together with national legislation, regulations and guidelines of the EEA Member States and the United Kingdom governing the processing of personal data, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. In particular, these obligations and restrictions concern the consent of the individuals to whom the personal data relates, the information provided to the individuals, the transfer of personal data out of the EEA or the United Kingdom, security breach notifications, security and confidentiality of the personal data and imposition of substantial potential fines for breaches of the data protection obligations. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (£17.5 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater. Currently, the EU GDPR and UK GDPR remain largely aligned, but the United Kingdom has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce significant changes from the EU GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EEA and the United Kingdom, and we will need to amend our processes and procedures to align with the new framework.

Implementing mechanisms to endeavor to ensure compliance with the GDPR and relevant local legislation in EEA Member States and the United Kingdom may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations, and prospects. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, and orders to cease/change our use of data, enforcement notices, or potential civil claims including class-action-type litigation. While we have taken steps to comply with the GDPR where applicable, including by reviewing our security procedures, engaging data protection personnel, and entering into data processing agreements with relevant contractors, our efforts to achieve and remain in compliance may not be fully successful.

Compliance with U.S. and foreign privacy and security laws, rules and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or, in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Each of these constantly evolving laws can be subject to varying interpretations. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and enforcement actions (which could include civil or criminal penalties), fines, private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Risks Related to Our Reliance on Third Parties

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials, as well as investigator initiated trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs, and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or

future product candidates. In addition, third parties are conducting and we expect will continue to conduct investigator initiated trials with our product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies is conducted in accordance with good laboratory practices, or GLPs, and clinical trials are conducted in accordance with GCPs. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with 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. Regulatory authorities enforce these requirements through periodic inspections (including pre-approval inspections once an NDA or BLA is submitted to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period

when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third-party contract developers and manufacturers to manufacture bulk drug substances, drug products, raw materials, samples, components, and other materials for our product candidates. For example, under the WuXi Agreement, WuXi provides us certain with certain customized cell manufacturing, release and testing services for our KYV-101 product candidate; pursuant to the Oxford Agreement, we recently engaged Oxford to undertake lentiviral vector process development services, with the intention for Oxford to ultimately manufacture and supply to us lentiviral vectors for research and development purposes and for use in connection with our clinical trials; and under the ElevateBio Agreement, ElevateBio is undertaking process development services for the development of a low-cost, fully closed manufacturing process for our CAR T-cell product candidates.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

The manufacturing process for our product candidates is subject to the FDA, EMA and foreign regulatory authority review. We, and our suppliers and manufacturers, some of which are currently our sole source of supply, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs, and, in certain cases, current good tissue practice, or cGTP, requirements. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, EMA and foreign regulatory authorities. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Moreover, we do not conduct the manufacturing process ourselves and are dependent on our CMOs for manufacturing in compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, delayed, interrupted, or more costly than anticipated, we may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party.

These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us to manufacture, or to have another third party manufacture, our product candidates. 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 applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. The delays and costs associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs and cGTPs, or maintain a compliance status acceptable to the FDA, EMA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products; and
- regulatory enforcement actions against our manufacturers or us, including fines and civil and criminal penalties, which could result in imprisonment, suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the biologic, refusal to permit the import or export of the products, requirements to cease distribution of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, or withdrawal of product approval.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants if approved, would be jeopardized.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. If we are unable to source these supplies on a timely basis, or establish longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

We depend on sole source and limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. For example, WuXi is currently our sole provider of customized cell manufacturing, release and testing services for our KYV-101 product candidate. We do not currently have long-term supply contracts with all of our CMOs and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs in the future as we advance our clinical trials or commercialization plans, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding

long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

Furthermore, any of the sole source and limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our CMOs. For example, in February 2024, a group of bipartisan U.S. lawmakers called for investigations into the Chinese biotechnology companies WuXi AppTec Co., Ltd., WuXi's parent company, and the affiliated WuXi Biologics, including calling for these companies to be added to the Department of Defense's Chinese Military Companies List (1260H list), the Department of Commerce's Bureau of Industry and Security Entity List, and the Department of Treasury's Non-SDN Chinese Military-Industrial Complex Companies List. While the Biden administration has yet to take action in response to this, adding either or both previously mentioned WuXi entities on any or all of the aforementioned lists could materially impact our relationship with WuXi and the WuXi Agreement due to those entities' affiliation with WuXi.

Establishing additional or replacement suppliers for these supplies, and obtaining regulatory clearance or approvals that may result from adding or replacing suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of sole source or limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited or sole source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

The operations of our suppliers, some of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, some of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;
- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;
- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or cGTPs or status acceptable to the FDA, EMA or foreign regulatory authorities;
- reduced protection for intellectual property rights, including trademark protection, in some countries;
- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters;
- disruptions or delays in shipments; and
- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, which may be important to our business. If we are unable to enter into new collaborations, or if these or any of our current collaborations are not successful and we fail to realize the benefits of such collaborations or licensing arrangements, our business, results of operations and financial condition could be adversely affected.

A part of our strategy is to strategically evaluate and, as we deem appropriate, enter into additional partnerships in the future, including potentially with major biotechnology or pharmaceutical companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may continue to enter into collaborations with other companies in the future to provide us with important technologies and funding for our programs and technology. Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators.

Our current collaborations and any future collaborations we enter into may pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs or license arrangements based on clinical trial or test results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may 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;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates, if approved;
- collaborators may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- collaborators with marketing, manufacturing and distribution rights to one or more of our product candidates that achieve regulatory approval, if any, may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out the marketing and distribution of such product or products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or future commercialization of product candidates, if approved, 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 seek to amend or modify the terms of any collaboration;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in such a way as to invite actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or future commercialization of any product candidate licensed to it by us; and
- collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or future commercialization of the applicable product candidates.

If our collaborations do not result in the successful discovery, development and future commercialization of product candidates, if approved, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and future commercialization described in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K also apply to the activities of our therapeutic collaborators. Additionally, if one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate partners for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully partner with our product candidates, potential partners must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies.

Collaborations are complex, expensive and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Additionally, our collaboration agreements may contain non-competition provisions that could limit our ability to enter into strategic collaborations with future collaborators or restrict our ability to commercialize products on our own, if approved.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization, if approved, or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or future commercialization activities at our own expense. If we elect to increase our expenditures to fund development or future commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations or do not have sufficient funds or expertise to undertake the necessary development and future commercialization activities, we may not be able to further develop our product candidates, bring them to market, if approved, and generate revenue from sales of drugs or continue to develop our technology, and our business, results of operations and financial condition could be adversely affected. Even if we are successful in our efforts to establish new strategic partnerships, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of any approved product are disappointing. Any delay in entering into new strategic partnership agreements related to our product candidates could delay the development and future commercialization of our product candidates, if approved, and reduce their competitiveness even if they reach the market.

Risks Related to Ownership of Our Common Stock

Our stock price may be volatile.

The market price of our common stock is likely to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or our collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or our competitors;
- announcements relating to strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- expiration of market standoff or lock-up agreements;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of healthcare payment systems;
- litigation or arbitration;
- pandemics, natural disasters or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this section titled “Risk Factors.”

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

When the market price of a stock has been volatile, as our stock price may be, holders of that stock have occasionally brought securities class action litigation claims against the company that issued the stock. If any of our stockholders were to bring a lawsuit of this type against us, even if the lawsuit were without merit, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates or future development programs;
- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;
- the timing of payments we may make or receive under existing license and collaboration arrangements or the termination or modification thereof;
- our execution of any strategic transactions, including acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

The market opportunities for our product candidates and forecasts of market growth may not be accurate, and the actual market for our products may be smaller than we estimate, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our estimates of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. Even if the markets in which we compete meet our size estimates and growth forecasts, our business may not grow at similar rates, or at all. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States, other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access

to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

The future issuance of equity or of debt securities that are convertible into equity would dilute our share capital.

We may choose to raise additional capital in the future, depending on market conditions, strategic considerations and operational requirements. To the extent that additional capital is raised through the issuance of shares or other securities convertible into shares, our stockholders will be diluted. Future issuances of our common stock or other equity securities, or the perception that such sales may occur, could adversely affect the trading price of our common stock and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or other equity securities or the availability of common stock for future sales will have on the trading price of our common stock.

Pursuant to our 2024 Equity Incentive Plan, or our 2024 Plan, our management is authorized to grant stock options to our employees, directors and consultants. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under our 2024 Plan is 4,215,000 shares. Additionally, the number of shares of our common stock reserved for issuance under the 2024 Plan will automatically increase on January 1st of each year, beginning on January 1, 2025 and continuing through and including January 1, 2034, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

We may acquire other businesses, form joint ventures or make investments in other companies or technologies that could negatively affect our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of assets or licenses of assets, including preclinical, clinical or commercial stage products or product candidates, businesses, strategic alliances, joint ventures and collaborations, to expand our existing technologies and operations.

Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;

- the assumption of additional indebtedness, contractual obligations or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In the future, we may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions also could result in the incurrence of debt, contingent liabilities or future write-offs of intangible assets or goodwill, any of which could have a negative impact on our cash flows, financial condition and results of operations. Integration of an acquired company also may disrupt ongoing operations and require management resources that we would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could harm our financial condition and results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis or at all, and we may not realize the anticipated benefits of any acquisition, license, strategic alliance or joint venture.

To finance such a transaction, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant amortization expense. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for these activities through public or private financings or through the issuance of debt. Additional funds may not be available on terms that are favorable to the Company, or at all, and any debt financing may involve covenants limiting or restricting our ability to take certain actions.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity securities.

Only the 16,675,000 shares of our common stock sold in the IPO (unless they were purchased by one of our affiliates) are freely tradable, without restriction, in the public market following the IPO. However, our directors and executive officers and holders of substantially all of our outstanding securities have entered into lock-up agreements with the underwriters for the IPO pursuant to which they may not, with certain exceptions, through August 5, 2024, offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of the representatives of the underwriters. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock-up agreements expire, an additional 26,319,350 shares of our common stock will be eligible for sale in the public market; however, shares held by directors, executive officers and other affiliates will continue to be subject to volume limitations under Rule 144 under the Securities Act.

In addition, the shares of our common stock that are subject to outstanding options under our equity incentive plans are eligible for sale in the public market after this offering, to the extent permitted by the provisions of various vesting schedules, the lock-up agreements (and the exceptions thereto) and Rule 144 and Rule 701 under the Securities Act. If these additional shares of our common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 25,171,265 shares of our outstanding common stock, or approximately 58.4% of our total outstanding common stock as of March 1, 2024, will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could adversely affect the trading price of our common stock.

Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, when conflicts arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, members of our board of directors that are representatives of the principal stockholders may not be disinterested.

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

As of March 1, 2024, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 48.8% of our outstanding common stock. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We are an "emerging growth company" and a "smaller reporting company" and our election of reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our other periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements. We could be an emerging growth company for up to five years following the completion of the IPO, although circumstances could cause us to lose that status earlier, including if we are deemed to be a "large accelerated filer," which occurs when the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30, or if we have total annual gross revenue of $1.235 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than $1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we could still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section

404 and reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10-K and our other periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards until such time as those standards apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards, and therefore we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of our board of directors will be elected at one time;
- authorize our board of directors to issue one or more new series of preferred stock without stockholder approval and create, subject to applicable law, one or more series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our amended and restated bylaws;

- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our capital stock;
- require the approval of not less than 66-2/3% of all outstanding shares of our capital stock to amend our amended and restated bylaws and specific provisions of our amended and restated certificate of incorporation; and
- specify the jurisdictions in which certain stockholder litigation may be brought.

In addition, Section 203 of General Corporation Law of the State of Delaware, or the DGCL, may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

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

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction) shall be the sole and exclusive forum, in all cases subject to the court's having jurisdiction over indispensable parties named as defendants, for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a breach of fiduciary duty owed to us or our stockholders by any director, officer or other employee; (iii) any action asserting a claim against us or any director, officer or other employee arising pursuant to the DGCL; (iv) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws; or (v) any other action asserting a claim that is governed by the internal affairs doctrine. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the exclusive forum provision does not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated 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 harm our business, financial condition and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

The trading market for our common stock will be influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

Techniques employed by short sellers may drive down the market price of our common stock.

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Cyber Risk Management and Strategy

We, under the oversight of the Audit Committee of our board of directors, have implemented and maintain an enterprise risk management process, which includes periodic assessments of various risk categories, including cyber risks, across our Company. Our process for assessing, identifying, and managing risks from cybersecurity threats is informed by industry standards and supported by cybersecurity technologies, including third-party security solutions, monitoring, and alerting tools, designed to monitor, identify, and address cybersecurity risks.

We leverage a managed security service provider and also engage with other third-party providers and consultants to support our cyber risk management efforts, including through periodic security testing. We have a process to assess and review the cybersecurity practices of information technology third-party vendors and service providers, including through review of applicable certifications, security reports, and vendor questionnaires and contractual requirements, as appropriate.

Governance Related to Cybersecurity Risks

Our cyber risk management program and related operations and processes are directed by our Head of IT in consultation with the legal team and our third-party security advisor. Currently, our Head of IT role is held by an individual who has over 20 years of information technology experience. The Head of IT reports to our Chief Financial Officer.

Our Head of IT meets with our Chief Financial Officer periodically to discuss and review our cybersecurity risk management processes and to address matters related to potential cybersecurity and information technology risks, with input from our third-party technology providers, as appropriate. In addition, our Head of IT has regular meetings with our managed security service provider to inform our cyber risk management processes and reporting to management. Our Head of IT, working with our Chief Financial Officer, provides periodic reports on cybersecurity and information technology matters to our Audit Committee, which assists our board of directors in reviewing and overseeing our risk management process, including cybersecurity risks.

Our Chief Financial Officer and our Audit Committee periodically report on cybersecurity risk management to the full board of directors. Our board of directors, as a whole and through its committees, has responsibility for the periodic review and oversight of information technology risks, including cybersecurity risks.

Our enterprise risk management program is overseen by a risk management committee comprised of senior management across key functional areas inclusive of cybersecurity and information technology matters. This committee, working with our Chief Financial Officer, provides periodic reports and updates, as needed, to our board of directors or our Audit Committee. In collecting information on enterprise risk, cybersecurity is included as a designated risk category, and the results of our enterprise risk assessment processes, including risks related to cybersecurity, are also discussed with the Audit Committee and among senior management on a periodic basis.

Material Affects of Cybersecurity Incidents

Except as disclosed in Part I, Item 1A, "Risk Factors" of this Annual Report on Form 10-K, including, without limitation, the risk factor under the heading "*If our internal information technology systems, or those used by our CROs, CMOs, clinical sites or other contractors or consultants upon which we rely, are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including, but not limited to, operational or service interruption, harm to our reputation, litigation, fines, penalties and liability, compromise of sensitive information related to our business, and other adverse consequences*", risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have not materially affected and are not reasonably likely to materially affect our company, including our business strategy, results of operations, or financial condition.

Item 2. Properties.

Our corporate headquarters are located in Emeryville, California, where we house our administrative, manufacturing and R&D activities. We currently lease approximately 68,000 square feet of space as our primary headquarters in Emeryville, California. One of the leases expires in January 2027, with an option for us to extend the term until January 2030. Another lease of approximately 35,000 square feet expires in February 2027 and does not have an option to extend the lease term. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm 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.

Our common stock has been listed on the Nasdaq Global Select Market under the symbol "KYTX" since February 8, 2024. Prior to this date, there was no public market for our common stock.

Holders of Common Stock

As of March 1, 2024, there were approximately 69 holders of record of our common stock. The approximate number of holders is based upon the actual number of holders registered in our records at such date and excludes holders in "street name" or persons, partnerships, associations, corporations, or other entities identified in security positions listings maintained by depository trust companies.

Stock Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide a performance graph.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities

On February 12, 2024, upon the closing of our initial public offering, or the IPO, all of our outstanding shares of redeemable convertible preferred stock automatically converted into 25,171,265 shares of our common stock. The issuance of such common stock upon conversion of the redeemable convertible preferred stock was exempt from the registration requirements of the Securities Act of 1933, as amended, or the Securities Act, pursuant to Section 3(a)(9) thereof, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange.

Between October 1, 2023 and December 29, 2023, we issued to certain of our employees and directors options to purchase an aggregate of 1,762,161 shares of our common stock at a weighted average exercise price of $4.94 per share. On February 7, 2024, we issued to certain of our employees options to purchase an aggregate of 239,914 shares of our common stock at an exercise price per share equal to $22.00. From October 1, 2023 through February 4, 2024, we issued to certain of our employees, consultants and directors an aggregate of 117,689 shares of our common stock at a per share price ranging from $0.32 to $4.42 per share pursuant to exercises of options. The offers, sales and issuances of the securities described in this paragraph were deemed to be exempt from registration either under Rule 701 promulgated under the Securities Act, or Rule 701, in that the transactions were under compensatory benefit plans and contracts relating to compensation, or under Section 4(a)(2) of the Securities Act in that the transactions were between an issuer and members of its senior executive management and did not involve any public offering within the meaning of Section 4(a)(2). The recipients of such securities were our employees, directors or consultants and received the securities under the Amended and Restated 2019 Stock Plan, or the 2019 Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about our company. We filed a registration statement on Form S-8 under the Securities Act on February 8, 2024 to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

Use of Proceeds from Initial Public Offering

On February 12, 2024, we closed the IPO, pursuant to which we issued and sold 16,675,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 2,175,000 additional shares, at an initial public offering price of $22.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-276523), which was declared effective by the SEC on February 7, 2024. Following the sale of the above shares, the offering terminated. J.P. Morgan, Morgan Stanley, Leerink Partners and Wells Fargo Securities acted as joint book-running managers.

We received aggregate gross proceeds from the IPO of $366.9 million, or aggregate net proceeds of $336.2 million, inclusive of the full exercise by the underwriters of their option to purchase additional shares, after deducting underwriting discounts and commissions and estimated other offering costs. None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to (i) our directors or officers or their associates, (ii) persons owning 10% or more of our common stock or (iii) any of our affiliates.

There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on February 8, 2024.

Purchases of Equity Securities by the Issuer and Affiliated Purchases

None.

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 related notes and other financial information included in Part II, Item 8 of this Annual Report. Some of the information contained in this discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Overview

We are a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases. Our goal is to bring disease-modifying therapeutic benefits to patients suffering from autoimmune diseases through our patient-centered approach, our broad platform, our insights into treating immune disorders and the learnings from successful application of cell therapy in other areas of medicine. Our cell therapy approach to the treatment of autoimmune diseases is supported by the scientific publication of multiple autoimmune case studies using CD19 CAR T-cell treatment as well as early clinical data from our ongoing trials illustrating the disease-modifying potential of these therapies. This validation provides us with a clear path to continue advancing our lead product candidate, KYV-101, through clinical development across two broad areas of autoimmune disease: rheumatology and neurology.

Since our inception in June 2018, we have devoted substantially all of our resources to performing research and development, enabling manufacturing activities in support of our product development efforts, hiring personnel, acquiring and developing our technology and product candidates, performing business planning, developing and establishing our intellectual property portfolio, raising capital and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales.

We have incurred significant losses and negative cash flows from operations since our inception. We have funded our operations primarily from sales of our redeemable convertible preferred stock, issuances of convertible notes and revenue from our collaboration agreement with Gilead Sciences, Inc., or Gilead, which terminated effective as of January 22, 2024. Our net losses were $60.4 million and $28.9 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $136.0 million. On February 12, 2024, we closed an initial public offering, or the IPO, of 16,675,000 shares of our common stock at a price to the public of $22.00 per share, including the exercise in full by the underwriters of their option to purchase 2,175,000 additional shares of our common stock and received gross proceeds of $366.9 million. Net proceeds were approximately $336.2 million, after deducting underwriting discounts and commissions and estimated other offering costs. Management has determined that our cash and cash equivalents and available-for-sale marketable securities of $57.5 million as of December 31, 2023, together with the IPO proceeds, will be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. We plan to monitor expenses and raise additional capital through a combination of public and private equity and debt financings, strategic alliances and licensing arrangements. Our ability to access capital when needed is not assured and if capital is not available to us when, and in the amounts, needed, we could be required to delay, scale back or abandon some or all of our development programs and other operations, which could materially harm our business, financial condition and results of operations.

We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon the successful development, approval and commercialization of our product candidates and upon the receipt of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. We may never achieve profitability, and unless we do and until then, we will need to continue to raise additional capital.

We expect our expenses will increase substantially in connection with our ongoing and planned activities, as we:

- continue to progress the development of our product candidates, including KYV-101 in multiple clinical trials in parallel and KYV-201 into the clinic;
- explore additional indications for our existing product candidates;
- procure manufacturing of clinical supply for our product candidates;
- acquire, discover, validate and develop additional product candidates;
- attract, hire and retain additional personnel;
- implement operational, financial and management systems;
- pursue regulatory approval for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval and related commercial manufacturing build-out;
- obtain, maintain, expand and protect our portfolio of intellectual property rights; and
- operate as a public company.

We do not currently own or operate any manufacturing facilities. We rely on contract manufacturing organizations, or CMOs, to produce our drug candidates in accordance with the U.S. Food and Drug Administration's, or the FDA's, current Good Manufacturing Practices regulations for use in our clinical studies. In March 2022, we entered into a master services agreement with WuXi ATU Advanced Therapies, Inc., or WuXi. WuXi's facility in Philadelphia, Pennsylvania, provides us with certain customized cell manufacturing, release and testing services for our KYV-101 product candidate. Pursuant to our Licence and Supply Agreement with Oxford Biomedica (UK) Limited, or Oxford, dated September 2023, we recently engaged Oxford to undertake lentiviral vector process development services, with the intention for Oxford to ultimately manufacture and supply to us lentiviral vectors for research and development purposes and for use in connection with our clinical trials. In July 2023, we entered into a Development and Manufacturing Services Agreement with ElevateBio Base Camp, Inc., or ElevateBio, pursuant to which ElevateBio is undertaking process development services for the development of a low-cost, fully closed manufacturing process for our CAR T-cell product candidates.

Given our stage of development, we do not yet have a marketing or sales organization or commercial infrastructure. Accordingly, if we obtain regulatory approval for any of our product candidates, we also expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability, if at all. Even if we are able to generate revenue from the sale of our product candidates, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

Reverse Stock Split

On January 30, 2023, we effected a reverse stock split of the shares of our outstanding common stock at a ratio of 1-for-4.5511, or the Reverse Stock Split. Unless otherwise indicated, all references to shares of common stock, options to purchase common stock, share data, per share data and related information contained in this Annual Report on Form 10-K, including this Management's Discussion and Analysis, have been adjusted to reflect the effect of the Reverse Stock Split.

Macroeconomic Trends

We may be affected by worldwide economic conditions and challenges, such as the effects of the ongoing geopolitical conflicts in Ukraine, the Israel-Hamas war, tensions in United States-China relations, disruptions in the banking industry and inflationary trends. The fiscal years 2023 and 2022 were marked by significant market uncertainty and increasing inflationary pressures. These market dynamics continue into 2024, and these and similar adverse market conditions may negatively impact our business, financial position and results of operations. For further discussion of the potential impacts of macroeconomic events on us, refer to the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

License and Collaboration Agreements

Patent License Agreements with the National Institutes of Health

In May 2021, we entered into two patent license agreements, or the NIH Agreements, with the National Institutes of Health, or the NIH, pursuant to which we obtained exclusive, worldwide licenses to certain patents to use a novel, fully human anti-CD19 CAR in our autologous and allogeneic CAR T-cell products for the treatment of patients with autoimmune disease. We paid 50% of the upfront consideration of $3.3 million for acquired licenses in July 2021 and the remaining 50% in May 2022 in accordance with the terms of the NIH Agreements.

Commencing in January 2023 and subsequently on January 1 of each calendar year thereafter until the NIH Agreements terminate, we are required to make minimum annual royalty payments of $0.2 million, which, commencing January 1, 2024, may be credited against any earned royalties due based on a low single-digit percentage of net sales made in a respective year. In addition, benchmark royalties following the completion of certain regulatory-and clinical-related benchmarks are due to the NIH, with the minimum cumulative royalty due for the first product reaching FDA approval or foreign-equivalent approval totaling approximately $5.7 million for the autologous patent license agreement and approximately $1.7 million for the allogeneic patent license agreement. Additional benchmark royalties would be payable for a subsequent indication under each NIH Agreement. If we enter into a sublicensing agreement, we are required to pay the NIH a sublicense royalty as a percentage of the fair market value of any consideration received for each sublicense granted. The sublicensing percentage starts at a high teens to low twenties percentage if clinical trials for the product candidate have not yet begun and decreases to a mid-single-digit percentage if the product candidate receives FDA approval or foreign-equivalent approval.

Unless terminated sooner, the NIH Agreements remain in effect until the last licensed patent rights granted pursuant to the respective agreement expire.

We accounted for the acquisition of the licenses, including patent rights and know-how, as an asset acquisition. As the acquired technology did not have an alternative use for accounting purposes, we recorded the consideration of $3.3 million as a research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2021. We recognized $0.2 million as research and development expense related to minimum annual royalty payments for the year ended December 31, 2023. No benchmark royalties were probable or payable as of December 31, 2023 and 2022.

Intellia License and Collaboration Agreement

In December 2021, we entered into a License and Collaboration Agreement, or the Intellia Agreement, with Intellia Therapeutics, Inc., or Intellia, to research and develop an allogeneic CD19-directed CAR cell therapy product, or the CRISPR Product, suitable for validation through pre-clinical and clinical proof-of-concept clinical trials, including the performance of activities as agreed in the collaboration plan. Pursuant to the Intellia Agreement, Intellia granted us an exclusive, worldwide, sublicensable in multiple tiers, royalty bearing license under certain of Intellia's intellectual property to research, develop, sell and otherwise exploit the CRISPR Product. We are performing the majority of the work under the collaboration plan.

As a consideration for the licenses granted to us pursuant to the Intellia Agreement, we issued to Intellia 3,739,515 shares of our Series B Preferred Stock at a price of $1.8719 per share, which was the price paid by other investors in our Series B Preferred Stock financing, for consideration of $7.0 million. Intellia also purchased

1,602,649 shares of Series B Preferred Stock at a price of $1.8719 per share under the Series B Preferred Stock Purchase Agreement in cash for total proceeds to us of $3.0 million. We are also obligated to make aggregate milestone payments to Intellia of up to $64.5 million upon the achievement of specified development and regulatory milestones and are obligated to pay to Intellia low to mid-single-digit royalties as a percentage of annual worldwide sales, subject to certain adjustments, and additional potential royalties and milestones to Intellia's licensors. The royalties are payable on a country-by-country basis, commencing upon the first commercial sale of the CRISPR Product in the applicable country and expiring upon the later of (i) 12 years after the first commercial sale or (ii) the expiration of the last-to-expire valid patent claim.

Under the Intellia Agreement, Intellia owns rights, title and interests in and to any intellectual property developed in the course of performance under the Intellia Agreement that is not specifically directed to the CRISPR Product. We granted to Intellia certain non-exclusive, royalty-free, fully paid-up, worldwide licenses under our intellectual property solely to perform the activities designated to Intellia under the collaboration, and to research, develop or otherwise exploit any human therapeutic product that is developed or commercialized by Intellia, utilizes or incorporates Intellia intellectual property and that is not the CRISPR Product or any product directed to CD19 or any other B-cell antigen.

In addition, we granted Intellia an exclusive option, or the Intellia Option, to enter into a co-development and co-commercialization agreement with us for the CRISPR Product, or the Co-Co Agreement, for a fee payable to us. If Intellia exercises the Intellia Option, we and Intellia would share equally the regulatory and clinical development expenses associated with obtaining approval of the CRISPR Product in the United States and would also share equally all net profits and losses from commercialization of the CRISPR Product in the United States. If Intellia exercises the Intellia Option, no milestone payments will be due and payable from that time forward and we will only pay royalties on sales outside of the United States. In addition, upon exercise of the Intellia Option, following regulatory approval of the CRISPR Product, Intellia will have exclusive commercialization rights for the CRISPR Product for U.S. administration, subject to our rights to co-promote the CRISPR Product in the United States, and we will retain the sole and exclusive rights to research, develop, or otherwise exploit the CRISPR Product for rest-of-world administration and shall have sole decision-making authority in relation thereto, subject to the parties' obligations to cooperate regarding certain development, regulatory and commercialization strategies.

During the term of the Co-Co Agreement, subject to certain exceptions, neither party will clinically develop or commercialize a cell therapy product directed to CD19 other than the CRISPR Product for use in the treatment or prevention of certain indications set forth in the Intellia Agreement and any additional indication that the parties mutually agree to include (any such product, a Competitive Product); provided, however, that (i) any products for use in any indications that are the subject of a development program or third-party collaboration as of the effective date of the Co-Co Agreement shall not be considered Competitive Products and (ii) any products for use in any additional indications that are the subject of a development program or third-party collaboration as of the date that such additional indications are included in the global development plan shall not be considered Competitive Products.

The Intellia Agreement terminates on a country-by-country basis upon the expiration of the last valid claim within Intellia's patent rights covering the CRISPR Product within such country, unless the agreement is earlier terminated in its entirety by either party for insolvency, by either party for material breach of contract, by Intellia if we participate in legal action or proceeding challenging the validity or enforceability of Intellia's patents, or by the execution of the Co-Co Agreement. We may terminate the Intellia Agreement in its entirety, or on a country-by-country basis, by providing a written notice after the expiration or termination of the Intellia Option. Following the expiration of the term for a given country, the licenses granted to us in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free licenses.

No milestone payments were probable or payable as of December 31, 2023 and 2022.

As of December 31, 2023, Intellia owned less than 5% of our outstanding equity. As of December 31, 2022, Intellia owned more than 5% and less than 10% of our outstanding equity.

Gilead Collaboration, Option and License Agreement

In January 2020, we entered into a Collaboration, Option and License Agreement, or the Gilead Agreement, with Gilead. Simultaneously with the entry into the Gilead Agreement, we entered into (i) a License Agreement, or the Kite Agreement, with Kite Pharma, Inc., or Kite, an affiliate of Gilead, and (ii) a stock purchase agreement, pursuant to which we issued to Gilead an aggregate of 6,890,744 shares of our Series A-2 Preferred Stock, of which 4,042,066 shares were issued as consideration under the Kite Agreement.

Pursuant to the Gilead Agreement, we and Gilead collaborated to develop potential cell-based therapy products using the SynNotch Technology and the SynNotch intellectual property related thereto, controlled by Gilead through Kite, for the treatment, diagnosis or prevention of autoimmune, inflammatory, or allogeneic stem cell transplant inflammatory diseases (excluding post-transplant infectious diseases), subject to certain exceptions. The Gilead Agreement initially involved the research and development of cell-based products for the treatment, diagnosis or prevention of two indications under two research programs and non-exclusive research licenses, specifically, Crohn's disease, or Program A, and Ulcerative colitis, or Program B. Upon execution of the Gilead Agreement, Gilead paid us a one-time, non-refundable and non-creditable payment of $17.5 million.

Pursuant to the Gilead Agreement, we also granted Gilead, on a research program-by-program basis, an exclusive option, exercisable at any time during the Option Period for such program, to obtain an exclusive license under such program's intellectual property to develop, manufacture, and commercialize optioned products belonging to such program for a specified fee and on the terms and conditions set out in the Gilead Agreement. For purposes of the foregoing, an Option Period meant, on a program-by-program basis, the period commencing on the date of execution of the Gilead Agreement and ending upon the earlier of (i) the expiration of the review period for such program and (ii) the ten-year anniversary of the date of execution of the Gilead Agreement.

On November 30, 2022, after the completion of research activities under Program A and Program B, Gilead provided us with notice that Program A and Program B were terminated. There are currently no other active programs under the Gilead Agreement.

On October 24, 2023, after agreement by both parties that the Gilead Agreement had no active programs, Gilead provided us with 90 days' written notice to terminate the Gilead Agreement, and such termination became effective as of January 22, 2024.

We concluded that the Gilead Agreement was in the scope of revenue recognition guidance. We estimated the transaction price as $17.5 million, which was allocated to two performance obligations, Program A and Program B, based on the relative fair value of each program. Other milestone payments were constrained and not included in the transaction price as they were considered not probable as of December 31, 2022. We recognized collaboration revenue based on the measure of progress using an estimated cost-based input method. For the years ended December 31, 2023 and 2022, we recognized zero and $7.0 million as collaboration revenue, respectively, under the Gilead Agreement.

As of each period ended December 31, 2023 and 2022, Gilead owned more than 10% and less than 15% of our outstanding equity.

Kite License Agreement

Concurrently with the Gilead Agreement, we entered into the Kite Agreement. Pursuant to the Kite Agreement, Kite granted to us a ten-year, co-exclusive license for the SynNotch technology primarily used in our own internal research and development programs for the treatment, diagnosis or prevention of autoimmune, inflammatory or allogeneic stem cell transplant inflammatory diseases (excluding post-transplant infectious diseases). Upon expiration of the ten-year co-exclusive license term, the license will become a non-exclusive license through expiration of the related patents.

Kite had licensed certain of the SynNotch technology included in the Kite Agreement pursuant to that certain Amended and Restated Exclusive License Agreement, between The Regents of the University of California and Kite (as successor to Cell Design Labs, Inc.), or the UCSF License Agreement. We are responsible for all costs and

payments arising under the UCSF License Agreement and as a result of activities under the Kite Agreement, including earned royalties based on a low single-digit percentage of net sales, milestone payments in an aggregate amount of up to $10.8 million and accrued interest payables. Pursuant to the Kite Agreement, we are also obligated to pay mid-teen-and mid-single-digit percentages of annual maintenance fees, minimum annual royalties and patent prosecution costs payable under the UCSF License Agreement during the co-exclusive term and non-exclusive term, respectively. We were also obligated to pay a $6.3 million sublicensing fee under the UCSF License Agreement, which we agreed to offset with future milestone payments payable by Gilead under the Gilead Agreement.

Unless terminated earlier, the Kite Agreement will expire upon the expiration of all licensed patents and Kite improvement patents therein. We have the right to terminate the Kite Agreement at will, in our sole discretion, in its entirety upon 90 days' written notice to Kite. In addition, either party may terminate the Kite Agreement for uncured material breach by the other party, or upon the occurrence of insolvency-related events of the other party.

As a consideration for the license, we issued to Gilead an aggregate of 4,042,066 shares of our Series A-2 Preferred Stock at a price per share of $0.8776, which was the purchase price paid by other investors in the Series A-2 Preferred Stock financing, for a total of $3.5 million.

The acquisition of the co-exclusive license under the Kite Agreement, including patent rights and know-how, was accounted for as an asset acquisition. As the acquired technology did not have an alternative use for accounting purposes, the consideration of $3.5 million was recorded as a research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2020. The sublicensing fee payable of $6.3 million was recognized as research and development expenses in the statement of operations and comprehensive loss for the year ended December 31, 2020.

As of December 31, 2023 and 2022, we recognized the total sublicensing fee of $6.3 million as current accrued license expense – related party, of which $2.5 million became payable as a result of the qualified financing. We expect to pay such amount of $2.5 million by mid-2024. The remaining $3.8 million was available to be offset against future milestones payable by Gilead under the Gilead Agreement; however, due to the termination of the Gilead Agreement, there are no future milestones payable to offset the sublicensing fee, and the payment schedule for the remaining $3.8 million of the sublicensing fee has not been agreed to by us and Gilead.

We only paid minimal costs related to annual maintenance fees, patent prosecutions costs and minimal annual royalties for the years ended December 31, 2023 and 2022 under the Kite Agreement. No milestone payments were due or payable under the Kite Agreement as of December 31, 2023 and 2022.

Components of Operating Results

Collaboration Revenue – Related Party

We have not had any product candidates approved for commercialization, we have not generated any revenue from product sales and we do not expect to generate any revenue from the sale of products for the foreseeable future. Our ability to generate product revenues will depend on the successful development and eventual commercialization of any product candidates that we identify. If we fail to complete the development of any future product candidates in a timely manner or fail to obtain regulatory approval for such product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

To date, all of our revenue consisted of collaboration revenue earned under the Gilead Agreement. This agreement included the following types of promised goods or services: (i) grants of licenses, (ii) performance of research and development services and (iii) participation in a joint steering committee. Our collaboration revenue under the Gilead Agreement was zero and $7.0 million for the years ended December 31, 2023 and 2022, respectively. No collaboration revenue was recognized after November 2022, when the current programs under the Gilead Agreement were terminated.

For additional information about our revenue recognition policy related to our collaboration agreements, refer to Note 2 in our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

Research and Development Expenses

The largest component of our total operating expenses since inception has been research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist primarily of compensation and benefits for research and development employees, including: stock-based compensation; expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites that conduct preclinical and clinical studies; costs of acquiring and manufacturing clinical study materials and other supplies; payments under licensing and research and development agreements; other outside services and consulting costs; and facilities, information technology and overhead expenses. Research and development costs are expensed as incurred.

External research and development costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses, milestone payments and annual license maintenance fees under our licensing agreements;
- costs incurred under agreements with third-party CROs, CMOs and other third parties that conduct preclinical and clinical activities on our behalf and manufacture our product candidates;
- consulting fees associated with our research and development activities; and
- other costs associated with our research and development programs, including laboratory materials and supplies.

Internal research and development costs include:

- employee-related costs, including salaries, benefits, travel and meals expenses, and stock-based compensation expense for our research and development personnel; and
- allocated facilities and overhead costs, including software and other miscellaneous expenses incurred in connection with our research and development programs.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through preclinical studies and clinical trials, pursue regulatory approval of our product candidates and expand our pipeline of product candidates. The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, early clinical data, investment in our clinical programs, competition, manufacturing capability and commercial viability. We may never receive regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved.

General and Administrative Expenses

General and administrative expenses consist primarily of payroll and personnel-related expenses, including: salaries, employee benefit costs and stock-based compensation expense; professional fees for legal, consulting, accounting and tax services; allocated overheads, including rent, equipment, information technology costs and utilities; and other general operating expenses not otherwise classified as research and development expenses.

We anticipate that our general and administrative expenses will increase following our IPO, as a result of increased personnel costs, including salaries, benefits and stock-based compensation expense, patent costs for our product candidates, expanded infrastructure and higher consulting, legal and accounting services associated with maintaining compliance with stock exchange listing and requirements of the Securities and Exchange Commission,

or the SEC, investor relations costs and director and officer insurance premiums associated with being a public company.

Interest Income

Interest income consists primarily of interest and accretion of premiums and discounts on our investments in available-for-sale marketable securities.

Interest Expense

Interest expense consists primarily of interest expense related to our lab equipment finance leases.

Other Expense, Net

Other expense, net primarily consists of settlement and revaluation of transactions and accounts payable in foreign currency.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,		Change	
	2023	2022	$	%
	(in thousands, except percentages)			
Revenue				
Collaboration revenue - related party	$ -	$ 7,025	$ (7,025)	-100%
Operating expenses				
Research and development	49,923	28,402	21,521	76%
General and administrative	12,483	8,007	4,476	56%
Total operating expenses	62,406	36,409	25,997	71%
Loss from operations	(62,406)	(29,384)	(33,022)	112%
Interest income	2,282	565	1,717	304%
Interest expense	(187)	(65)	(122)	188%
Other expense, net	(55)	(9)	(46)	511%
Total other income, net	2,040	491	1,549	315%
Net loss	(60,366)	(28,893)	(31,473)	109%

Collaboration Revenue

Collaboration revenue decreased by $7.0 million, or 100%, from $7.0 million for the year ended December 31, 2022 to zero for the year ended December 31, 2023. The decrease was related to the completion of research activities under the Gilead Agreement in November 2022. In November 2022, after the completion of research activities and recognition of all deferred revenue as collaboration revenue, the two programs under the Gilead Agreement were terminated, and rights were returned to us. On October 24, 2023, after agreement by both parties that the Gilead Agreement had no active programs, Gilead provided us with 90 days' written notice to terminate the Gilead Agreement, and such termination became effective as of January 22, 2024. We do not expect any future collaboration revenue until we enter into another collaboration revenue agreement.

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented:

	Year Ended December 31,		Change	
	2023	2022	$	%
	(in thousands, except percentages)			
External costs:				
License fees, milestone payments and annual maintenance fees related to acquired technologies	$ 248	$ 150	$ 98	65%
CRO, CMO, professional consulting and other third-party preclinical studies and clinical trials costs	21,468	7,225	14,243	197%
Other research and development costs, including laboratory materials and supplies	5,288	5,113	175	3%
Internal costs:				
Personnel-related	16,800	11,028	5,772	52%
Facilities and overhead	6,119	4,886	1,233	25%
Total research and development expenses	$ 49,923	$ 28,402	$ 21,521	76%

Research and development expenses increased by $21.5 million, or 76%, from $28.4 million for the year ended December 31, 2022 to $49.9 million for the year ended December 31, 2023. License fees for the year ended December 31, 2023 mainly included expenses related to the minimum annual royalties of $0.2 million payable to the NIH. In 2023, CRO, CMO and other third-party preclinical studies and clinical trial expenses increased by $14.2 million and other research and development costs, including laboratory materials and supplies, increased by $0.2 million as compared to 2022 as we continued progress in our pre-clinical studies and clinical trials.

In 2023, personnel-related research and development costs increased by $5.8 million as a result of hiring personnel in our research and development organization during the year. This increase included an increase of $0.4 million in stock-based compensation expense. Facilities and overhead costs increased by $1.2 million for 2023, mainly due to a $0.5 million increase in rent expense as we continued to invest in our research organization and expanded our leased facilities, an increase of $0.4 million in conference expenses and an increase of $0.2 million in allocated personnel-related costs.

The following table summarizes our external costs by program for the periods presented:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
KYV-101	$ 18,267	$ 6,707
KYV-201	4,509	363
Other programs and research and development activities	4,228	5,418
Total external research and development expenses	$ 27,004	$ 12,488

In 2023, KYV-101 program expenses increased by $11.6 million, primarily attributable to a $9.5 million increase in CRO, CMO and other clinical trials costs as we continued to advance KYV-101 through clinical development across two broad areas of autoimmune disease: rheumatology and neurology. KYV-101 program expenses in 2023 also include $1.6 million of external expense related to the development of our Ingenui-T manufacturing process. KYV-201 expenses for 2023 increased by $4.1 million, including a $2.7 million increase in CRO, CMO and other third-party preclinical studies and a $1.2 million increase in other research and development costs, including laboratory materials and supplies, as we continued to advance KYV-201 through preclinical development. Other programs and research and development activities decreased by $1.2 million for the year ended December 31, 2023 compared to the year ended December 31, 2022 and include expenses related to our preclinical

research activities, including reagents, lab supplies, outsourced research and development and professional consulting services.

General and Administrative Expenses

General and administrative expenses increased $4.5 million, or 56%, to $12.5 million for the year ended December 31, 2023 from $8.0 million for the year ended December 31, 2022. The increase in general and administrative expenses was primarily attributable to a $2.6 million increase in salaries and benefits, including an increase of $0.9 million in stock-based compensation expense, an increase of $1.7 million in professional services costs related to legal, accounting and consulting services, and a $0.2 million increase in facilities and overhead costs.

Interest Income

Interest income increased $1.7 million, from $0.6 million for the year ended December 31, 2022 to $2.3 million for the year ended December 31, 2023. The increase relates to increased amounts invested in available-for-sale marketable securities and an increase in interest rates on these securities during the year ended December 31, 2023 compared to year ended December 31, 2022.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. Through December 31, 2023, we have primarily funded our operations from sales of shares of our redeemable convertible preferred stock of $168.0 million, issuances of convertible notes of $2.0 million and an upfront payment of $17.5 million under the Gilead Agreement. As of December 31, 2023, we had $57.5 million in cash, cash equivalents and available-for-sale marketable securities.

On February 12, 2024, we closed an initial public offering, or the IPO, of 16,675,000 shares of our common stock at a price to the public of $22.00 per share, including the exercise in full by the underwriters of their option to purchase 2,175,000 additional shares of our common stock. We received aggregate gross proceeds from the IPO of $366.9 million, or aggregate net proceeds of approximately $336.2 million, after deducting underwriting discounts and commissions and estimated other offering costs.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates and incur costs associated with the potential commercialization of our product candidates, if approved. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We have incurred significant losses and negative cash flows from operations since our inception. As of December 31, 2023, we had an accumulated deficit of $136.0 million. Based on the current cash forecast, management has determined that our cash and cash equivalents and available-for-sale marketable securities of $57.5 million as of December 31, 2023, together with the IPO proceeds, will be sufficient to fund our planned operations for at least one year from the issuance date of the financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. This forecast of cash resources and planned operations involves risks and uncertainties, and the actual amount of expenses could vary materially as a result of a number of factors.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Our future funding requirements will depend on many factors, including, but not limited to, the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates, including any requirement to conduct more studies or generate additional data beyond that which we currently expect would be required to support a Biologic License Application;
- the cost of manufacturing clinical and commercial supplies, as well as scale-up of our current and future product candidates;
- the potential increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to maintain existing, and establish new, strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;
- the costs associated with being a public company; and
- the impact of inflation, as well as other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Furthermore, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates, or we may have to grant licenses on terms that may not be favorable to us. If we

are unable to raise capital as and when needed or on attractive terms, we may have to significantly delay, reduce or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Cash Flows

The following table summarizes our primary sources and uses of cash for the periods presented:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (52,410)	$ (36,113)
Net cash used in investing activities	(8,785)	(14,097)
Net cash provided by financing activities	58,118	11,880
Net decrease in cash and cash equivalents	$ (3,077)	$ (38,330)

Operating Activities

Net cash used in operating activities was $52.4 million and $36.1 million for the years ended December 31, 2023 and 2022, respectively.

Cash used in operating activities for the year ended December 31, 2023, was primarily due to our net loss of $60.4 million, decreased by other non-cash charges of $4.5 million and decreased by a net reduction of $3.4 million in our net operating assets and liabilities. Non-cash changes primarily consisted of $2.2 million stock-based compensation expense, $1.7 million depreciation and amortization expense and a $1.7 million non-cash lease expense, partially offset by $1.1 million accretion of discount on available-for-sale marketable securities. The change in our net operating assets and liabilities was primarily due to an increase in accounts payable of $4.1 million, a $2.7 million increase in other current liabilities and a $1.4 million increase in accrued compensation, offset by an increase in other non-current assets of $1.8 million, a decrease in operating lease liabilities of $1.7 million and an increase in prepaid expenses and other current assets of $1.2 million.

Cash used in operating activities for the year ended December 31, 2022, was primarily due to our net loss of $28.9 million, decreased by non-cash charges of $3.1 million and increased by a net reduction of $10.3 million in our net operating assets and liabilities. The non-cash charges primarily consisted of a $1.4 million non-cash lease expense, a $1.1 million depreciation and amortization expense and a $0.9 million stock-based compensation expense, partially offset by $0.3 million of income related to the accretion of discounts on available-for-sale marketable securities. The change in our net operating assets and liabilities was primarily due to a decrease in deferred revenue of $7.0 million related to recognition of collaboration revenue under the Gilead Agreement, a decrease in accrued license expenses of $1.6 million, a decrease in operating lease liabilities of $1.1 million, an increase in prepaid expenses and other current assets of $0.9 million and an increase in other long-term assets of $0.6 million, offset by a $0.7 million increase in accounts payable and a $0.3 million increase in accrued compensation.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2023, was $8.8 million, which consisted of $54.8 million of purchases of available-for-sale marketable securities and $0.6 million of purchases of property and equipment, offset by $46.7 million in proceeds from maturities and sales of available-for-sale marketable securities.

Net cash used in investing activities for the year ended December 31, 2022, was $14.1 million, which consisted of $56.5 million of purchases of available-for-sale marketable securities and $0.8 million of purchases of property and equipment, offset by $43.2 million in proceeds from maturities and sales of available-for-sale marketable securities.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2023, was $58.1 million, which consisted of $59.9 million net cash proceeds from our issuance of shares of Series B Preferred Stock and $0.6 million of proceeds from exercises of stock options, partially offset by a payment of $0.8 million related to finance lease obligations and a payment of $1.6 million related to deferred initial public offering costs.

Net cash provided by financing activities for the year ended December 31, 2022, was $11.9 million, which consisted of $12.0 million net cash proceeds from our issuance of shares of Series B Preferred Stock and $0.2 million of proceeds from exercises of stock options, partially offset by a payment of $0.3 million related to finance lease obligations.

Contractual Obligations and Commitments

We enter into contracts in the normal course of business with CROs for clinical trials, with CMOs for clinical supplies manufacturing and with other vendors for preclinical studies, supplies and other products and services for operating purposes. These agreements generally provide for termination at the request of either party generally with less than one-year notice and, therefore, we believe that our non-cancellable obligations under these agreements are not material. We do not currently expect any of these agreements to be terminated and did not have any non-cancellable obligations under these agreements as of December 31, 2023 and 2022.

We have milestone, royalty and other payments due to third parties under our existing license and collaboration agreements. Refer to Note 6 to our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional details. We cannot estimate when such payments will be due and none of these events were probable to occur as of December 31, 2023 and 2022.

In July 2020, we entered into a lab and office lease agreement, which was amended in November 2021 and expires in January 2027. In January and September 2022, we rented additional space under the amended agreement. We also have multiple leases for laboratory equipment with 36-month terms that are accounted for as finance leases. We have also leased some of our office and lab space under short-term lease agreements. As of December 31, 2023, our non-cancellable lease obligations were $8.2 million and $2.1 million under operating and finance leases, respectively, of which $2.5 million and $1.1 million related to operating and finance leases, respectively, are due within the next 12 months. Refer to Note 7 in our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for more information on our lease obligations.

In February 2024, we entered into an agreement to lease approximately 35,000 square feet of office space in Emeryville, California through February 2027. The lease commenced on February 28, 2024. Monthly rent payments are approximately $0.1 million. There is no renewal option for this lease. As of the lease inception, our non-cancellable lease obligations were approximately $3.0 million, of which $0.7 million are due within the next 12 months.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including, but not limited to, those related to accrued research and development costs and stock-based compensation expense. These estimates and assumptions

are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Although our significant accounting policies are described in more detail in Note 2 to our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, we believe that the following accounting estimates are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, license fees, laboratory supplies, consulting costs, external contract research and development expenses, and allocated overhead, including rent, equipment depreciation and utilities. Advance payments for goods or services for future research and development activities are deferred as prepaid expenses and expensed as the goods are delivered or the related services are performed.

We have entered into various agreements with outsourced vendors, CMOs and CROs. We make estimates of accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly.

Stock-Based Compensation Expense

We measure stock-based awards made to employees and non-employees based on the estimated fair value of the awards as of the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield.

Fair Value of Common Stock. See the subsection titled “Determination of Fair Value of Common Stock” below.

Expected Volatility — Expected volatility is estimated by studying the volatility of the prices of shares of common stock of comparable public companies for similar terms. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.

Expected Term — Expected term represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

Risk-Free Interest Rate — The risk-free interest rate is based on the U.S. Treasury zero-coupon bonds issued in effect at the time of grant for periods corresponding with the expected term of the option.

Expected Dividend — The Black-Scholes valuation model calls for a single expected dividend yield as an input. To date, we have not declared or paid any dividends and we do not expect to declare or pay any dividends in the future.

Determination of Fair Value of Common Stock

As there had been no public market for our common stock prior to the IPO, the estimated fair value of our common stock underlying our stock-based awards has been determined by our board of directors as of each option grant date with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aid.

We determined the hybrid method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more scenarios is calculated using an option pricing model, or OPM. We determined this was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future equity values for our common stock under various possible future liquidity event scenarios, considering the rights and preferences of each class of shares, and discounted for a lack of marketability. Under the hybrid method, an OPM was used to determine the fair value of our common stock in certain of the PWERM scenarios (capturing situations where our development path and future liquidity events were difficult to forecast), and potential exit events were explicitly modeled in the other PWERM scenarios. A discount for lack of marketability was applied to the value derived under each scenario to account for a lack of access to an active public market to estimate our common stock fair value.

In addition to considering the results of independent third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of common stock as of each grant date, including:

- the prices at which we sold shares of our preferred stock and the superior rights, preferences and privileges of our preferred stock relative to those of our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and clinical trials for our product candidates;
- the stage of our development and our business strategy, and material risks related to our business;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the competitive landscape for our product candidates;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company, given prevailing market conditions; and
- general economic conditions.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Following the completion of the IPO, it is no longer necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other equity awards we may grant, as the fair value of our common stock will be based on the quoted market price of our common stock.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks related to changes in interest rates of our cash equivalents and available-for-sale marketable securities. However, due to the nature of these cash equivalents and investments, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Foreign Currency Exchange Risk

Our employees and our operations are currently predominately located in the United States and our expenses are generally denominated in U.S. dollars. However, we do use research and development vendors outside of the United States. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material effect on our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations or financial condition, or on our financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibits and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer, or the CEO, and Chief Financial Officer, or the CFO (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based upon our evaluation our disclosure controls and procedures, as of December 31, 2023, our CEO and our CFO concluded that the disclosure controls were not effective, due to the material weaknesses in internal control over financial reporting described below, to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure and were not effective to provide reasonable assurance that such information is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms.

Notwithstanding these material weaknesses, management has concluded that our financial statements included in this Annual Report on Form 10-K are fairly stated in all material respects in accordance with GAAP for each of the periods presented herein.

Internal Control Over Financial Reporting

Management's Report on Internal Controls Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation of Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation by our independent registered public accounting firm regarding our internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Ongoing Remediation of Material Weaknesses

As previously disclosed in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on February 8, 2024, and in connection with the preparation and audits of our financial statements as of and for the years ended December 31, 2023 and 2022, material weaknesses were identified in the design and operating effectiveness of our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

Specifically, we did not appropriately design and maintain entity-level controls impacting the control environment, risk assessment, control activities, information and communication and monitoring activities to prevent or detect material misstatements to the financial statements. These material weaknesses related to (i) an insufficient number of qualified resources to ensure adequate oversight and accountability over the performance of controls, including retention of control evidence, (ii) ineffective identification and assessment of risks impacting internal control over financial reporting, and (iii) insufficient evaluation and determination as to whether the components of internal controls were present and functioning based upon evidence maintained for management review controls and activity level controls across substantially all financial statement areas.

These material weaknesses contributed to the following additional material weakness: we did not design and maintain effective (i) general controls over information systems that support the financial reporting process, (ii) controls over the completeness and accuracy of information used in the operation of control activities across substantially all financial statement areas, and (iii) management review controls at a sufficient level of precision to detect a material misstatement across substantially all financial statement areas that involve complex and judgmental areas of accounting and disclosure.

We have begun taking measures, and plan to continue to take measures, to remediate these material weaknesses. These measures include hiring a Vice President of Finance/Corporate Controller and a Head of Information Technology and engaging a third party to assist in documenting the design and implementation of internal controls over the financial reporting process, including general controls over information systems. The material weaknesses will not be considered remediated until management completes the design and implementation of the measures described above and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. We expect to implement new procedures and controls and take efforts to address each of the identified weaknesses during fiscal years 2024 and 2025. These remediation measures will be time consuming and require financial and operational resources. See Part I, Item 1A. “Risk Factors”.

Item 9B. Other Information.

During the fiscal quarter ended December 31, 2023, none of our directors or officers (as defined in Section 16 of the Exchange Act) adopted or terminated any contract, instruction or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act or any “non-Rule 10b5-1 trading arrangement,” as defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Board of Directors

As of March 25, 2024, our board of directors consists of seven members. In accordance with our amended and restated certificate of incorporation, which became effective in connection with the closing of our initial public offering, or the IPO, on February 12, 2024, our board of directors is divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms will then expire will be elected to serve from the time of election and qualification until the third annual meeting following their election. Our directors are divided among the three classes as follows:

- Class I, which consists of Beth Seidenberg, M.D. and Fred E. Cohen, M.D., D.Phil., and their terms will expire at the annual meeting of stockholders to be held in 2025;
- Class II, which consists of Ian Clark, Brian Kotzin, M.D. and Steve Liapis, Ph.D., and their terms will expire at the annual meeting of stockholders to be held in 2026; and
- Class III, which consists of Peter Maag, Ph.D. and Daniel K. Spiegelman, and their terms will expire at the annual meeting of stockholders to be held in 2027.

The following table sets forth information regarding our directors as of March 25, 2024:

Name	Age	Position(s)
Peter Maag, Ph.D.	57	Chief Executive Officer and Director
Ian Clark(1)	63	Chairperson and Director
Fred E. Cohen, M.D., D.Phil.(1)(2)	67	Director
Brian Kotzin, M.D.(3)	75	Director
Steve Liapis, Ph.D.(2)(3)	36	Director
Beth Seidenberg, M.D.(1)(2)	67	Director
Daniel K. Spiegelman(3)	65	Director

(1) Member of the Nominating and Corporate Governance Committee.
(2) Member of the Compensation Committee.
(3) Member of the Audit Committee.

Peter Maag, Ph.D. has served as our Chief Executive Officer since October 2022. Dr. Maag is a seasoned global industry executive with a track record of transforming organizations and more than 20 years of executive management experience in the pharmaceutical and diagnostic industry. Prior to joining Kyverna, Dr. Maag was Executive Chairman of CareDx, Inc. (Nasdaq: CDNA) from November 2020 to November 2021 and Chief Executive Officer and President of CareDx from October 2012 to November 2020, where he built the company from a small start-up into a public company and industry-leading transplantation company through a series of BD&L and financing transactions. Prior to joining CareDx, Dr. Maag held multiple positions at Novartis with increasing responsibilities. As President, Novartis Diagnostics, he drove growth and innovation in its blood-screening business. Prior to that, he led one of Novartis' key affiliates as country president, Germany, and lived in a dynamically growing market as Country President, Korea. At headquarters in Switzerland, he served as the head of strategy for Novartis Pharmaceuticals and helped launch the Infectious Diseases franchise. Prior to joining Novartis, Dr. Maag worked at McKinsey& Company in New Jersey and Germany, focusing on pharmaceuticals and globalization strategies. In addition to supporting various healthcare and tech companies in their growth efforts, he holds board and advisory positions at Phoenix Pharma SE, CareDx, Inc. (Nasdaq: CDNA), and the Personalized Medicine Coalition. He previously served on the board of directors of MiroMatrix Medical Inc. (Nasdaq: MIRO) from June 2021 until it was acquired by United Therapeutics Corporation in December 2023. Dr. Maag received his PhD from the University of Berlin, Germany, and studied pharmaceutical sciences in Heidelberg and London.

We believe Dr. Maag's position as our Chief Executive Officer as well as his extensive experience in the pharmaceuticals and life sciences industries provides him with the qualifications and skills to serve on our board of directors.

Ian Clark has served as Chairperson of our board of directors and as a member of our board of directors since September 2021. Mr. Clark has more than 35 years of experience in the biotechnology and pharmaceutical industry, most recently serving as Chief Executive Officer and member of the board of directors for Genentech, Inc., until his retirement in December 2016. During his seven-year tenure as Chief Executive Officer of Genentech, Mr. Clark and his team brought eleven new medicines to market for patients with rheumatoid arthritis, idiopathic pulmonary fibrosis and various types of cancer. Prior to that, Mr. Clark served as the Executive Vice President and Chief Marketing Officer of the Roche Group from April 2009 to December 2009. Prior to his time at the Roche Group, Mr. Clark held several senior management positions at Genentech Inc. from January 2003 to March 2009, including Head of Global Product Strategy, Chief Marketing Officer, Senior Vice President, General Manager of BioOncology and Executive Vice President, Commercial Operations. Prior to joining Genentech, Mr. Clark spent 23 years in the biopharmaceutical industry holding several positions of increasing responsibility at Novartis AG (NYSE: NVS, SIX: NOVN), Sanofi (Nasdaq: SNY), Ivax and Searle, working in the USA, United Kingdom, Canada, Eastern Europe and France. Currently, Mr. Clark is on the board of directors of several public biopharmaceutical and biotechnology companies: Takeda Pharmaceutical Company Limited (NYSE: TAK), Corvus Pharmaceuticals, Inc. (Nasdaq: CRVS), Guardant Health, Inc. (Nasdaq: GH), Olema Pharmaceuticals, Inc. (Nasdaq: OLMA) and Avrobio, Inc. (Nasdaq: AVRO). Mr. Clark previously served on the boards of Agios Pharmaceuticals, Inc. (Nasdaq: AGIO), Forty Seven Inc., Shire Pharmaceuticals, Inc., Kite Pharma, Inc., TerraVia Holdings, Inc., Gyroscope Therapeutics Limited, Dendreon Pharmaceuticals LLC and Vernalis (R&D) Limited. He was also on the Board of Biotechnology Industry Association, on the BioFulcrum Board of the Gladstone Institute and on the Economic Advisory Council of the 12th District of the Federal Reserve. In addition, he served as an advisor to Blackstone Life Sciences, formerly Clarus Ventures, LLC, a venture capital firm, from September 2017 to September 2020, as well as to Perella Weinberg Partners LP and Lazard Ltd. Mr. Clark received his Bachelor of Science in Biological Sciences and an Honorary Doctorate of Science from Southampton University in the United Kingdom.

We believe Mr. Clark is qualified to serve on our board of directors because of his vast experience in the biopharmaceutical industry, combined with his experience serving on the boards of directors of successful, high-growth public and private companies.

Fred E. Cohen, M.D., D.Phil. has served as a member of our board of directors since September 2018. Since November 2017, Dr. Cohen has served as a Senior Managing Director of Vida Ventures, a venture capital firm that he co-founded in 2017. Dr. Cohen has also served as a co-founder and Chairman of Monograph Capital Partners, a biotechnology venture capital fund, since July 2021. Dr. Cohen currently serves as a Senior Advisor to TPG, where he previously served as a Partner and founder of TPG Biotechnology, a life science venture capital fund, from 2001 to 2016. Dr. Cohen was also a co-founder and executive chairperson of privately held Cell Design Labs, which was acquired by Gilead Sciences, Inc. (Nasdaq: GILD) in December 2017. From 1980 through 2014, Dr. Cohen was at the University of California, San Francisco (UCSF), where he held various responsibilities as a research scientist, an Internist for hospitalized patients, a consulting Endocrinologist, and as the Chief of the Division of Endocrinology and Metabolism. Dr. Cohen's research interests included structure based drug design, prion diseases, computational biology and heteropolymer chemistry. Dr. Cohen has published over 200 peer reviewed articles, participated as a co-inventor on over 10 patents and has served as an editor or editorial board member of several international scientific journals. Dr. Cohen received his Bachelor of Science degree in Molecular Biophysics and Biochemistry from Yale University, his D.Phil. in Molecular Biophysics from the University of Oxford on a Rhodes Scholarship, his MD from Stanford University and his postdoctoral training and postgraduate medical training in Internal Medicine and Endocrinology at UCSF. He is a Fellow of the American College of Physicians and the American College of Medical Informatics and a member of the American Society for Clinical Investigation and Association of American Physicians. Dr. Cohen has received several awards for his work including a Searle Scholarship, Young Investigator Awards from the Endocrine Society and the Western Society for Clinical Investigation, and the LVMH Science pour l'art prize (shared with Stanley Prusiner). Dr. Cohen was elected to the National Academy of Medicine in 2004 and the American Academy of Arts and Sciences in 2008. Dr. Cohen currently serves on the Board of Directors of several biotechnology and pharmaceutical organizations, including CareDx, Inc. (Nasdaq: CDNA), Progyny, Inc. (Nasdaq: PGNY), Intellia Therapeutics, Inc. (Nasdaq: NTLA) and UroGen Pharma Ltd. (Nasdaq: URGN). He is a past member of the boards of Quintiles Transnational (merged with IQVIA Holdings (NYSE: IQV)), Biocryst (Nasdaq: BCRX), Genomic Health (acquired by Exact Sciences Corp.) (Nasdaq: GHDX), Tandem Diabetes Care, Inc. (Nasdaq: TNDM), Five Prime Therapeutics, Inc. (Nasdaq: FPRX, acquired by Amgen Inc.), Roka Biosciences (Nasdaq: ROKA), and Veracyte, Inc. (Nasdaq: VCYT).

We believe Dr. Cohen is qualified to serve on our board of directors because of his extensive experience in the biotechnology industry, including providing strategic advice and oversight to biopharmaceutical companies, as well as his financial and medical knowledge and experience.

Brian Kotzin, M.D. has served as a member of our board of directors since August 2019. Dr. Kotzin brings experience including more than 25 years of academic research and 19 years of executive leadership at life science companies. Dr. Kotzin is a Board of Directors member at Rigel Pharmaceuticals Inc. (Nasdaq: RIGL), Biora Therapeutics, Inc. (Nasdaq: BIOR) and Genascence, Inc. Dr. Kotzin previously served as a member of the board of directors of Vera Therapeutics, Inc. (Nasdaq: VERA). Dr. Kotzin served as Senior Vice President for Nektar Therapeutics (Nasdaq: NKTR) from April 2017 to June 2023, and has held various leadership positions at Nektar, including serving as Chief Medical Officer and Head of Clinical Development from January 2021 to September 2021 and again from May 2022 to June 2023. From 2004 to 2015, Dr. Kotzin was Vice President, Global and Clinical Development and Head, Inflammation Therapeutic Area at Amgen Inc. (Nasdaq: AMGN), directing the global development efforts for product candidates in the inflammation area. During his employment at Amgen, Dr. Kotzin also served as Vice President of Translational Sciences and Head of Medical Sciences from 2006 to 2011. Prior to entering the life sciences industry, he held several positions from 1981 to 2004 as a professor and faculty member at the University of Colorado Health Sciences Center, where his research focused on the immunopathogenesis of autoimmune and inflammatory diseases. He received a doctorate in medicine from Stanford University and a bachelor's degree in mathematics from the University of Southern California. Dr. Kotzin has held leadership roles at several national organizations, including as a member of the American College of Rheumatology (ACR) Board of Directors, Member and Chairperson of the NIH Immunological Sciences Study Section, Chairperson of the NIH Autoimmunity Centers of Excellence, and Member of the Board of Directors for the Federation of Clinical Immunology Societies. He is currently an elected Master of the ACR.

We believe Dr. Kotzin is qualified to serve on our board of directors because of his extensive academic research experience in immunology and experience as a senior executive and board member for life sciences companies.

Steve Liapis, Ph.D. has served as a member of our board of directors since November 2022. Dr. Liapis is a Principal at Northpond Ventures where he focuses on biotechnology platforms and therapeutics and leads Northpond's newco incubation efforts with the Wyss Institute at Harvard and the School of Engineering at MIT. Dr. Liapis is a board director at Garuda Therapeutics, Incendia Therapeutics, Walking Fish Therapeutics, Totus Medicines, Opna Bio, and Aro Biotherapeutics, and is a board observer at Ori Biotech. Previously, Dr. Liapis was Director of Portfolio Decision Resources at Sanofi (Nasdaq: SNY), where he led global strategy and resource prioritization for Sanofi Oncology. Prior to Sanofi, Dr. Liapis was Head of Strategy at Arbor Biotechnologies and served in leadership positions at L.E.K.Consulting where he focused on research and development and commercial strategy for immuno-oncology as well as advanced therapeutic modalities including gene therapy, gene editing, and cell therapy. Dr. Liapis holds a Ph.D. in molecular biology from Harvard University where he trained in the laboratory of Dr. John Rinn, focusing on the discovery and molecular characterization of novel long noncoding RNAs (lncRNAs), as well as identifying the role of lncRNAs in disease pathogenesis. He also holds a Master's Degree in genetics and plant biology from Yale University and an undergraduate degree in environmental science from Stockton College.

We believe Dr. Liapis is qualified to serve on our board of directors because of his vast experience in biotechnology platforms and therapeutics and focus on the areas of global research and development and commercial strategy.

Beth Seidenberg, M.D. has served as a member of our board of directors since September 2018. Dr. Seidenberg is a managing director of Westlake Village BioPartners, a venture capital firm she founded in September 2018. Since May 2005, Dr. Seidenberg has been a general partner at Kleiner Perkins Caufield & Byers, LLC, a venture capital firm, where she has primarily focused on life sciences investing. Dr. Seidenberg was previously the Senior Vice President, Head of Global Development and Chief Medical Officer at Amgen, Inc. (Nasdaq: AMGN). In addition, Dr. Seidenberg was a senior executive in research and development at Bristol Myers Squibb Company (NYSE: BMY) and Merck & Co., Inc. (NYSE: MRK). From February 2008 to September 2019, Dr. Seidenberg served as a director of Epizyme, Inc. Dr. Seidenberg served on the boards of directors of TESARO, Inc., ARMO BioSciences, Inc. and Atara Biotherapeutics, Inc. (Nasdaq; ATRA), from June 2011 to January 2019, December 2012 to June 2018 and August 2012 to June 2023, respectively. Dr. Seidenberg serves on the boards of directors of Vera Therapeutics, Inc. (Nasdaq: VERA), Progyny, Inc. (Nasdaq: PGNY) and several privately held life sciences

companies. Dr. Seidenberg holds a Bachelor of Arts degree in biology and anthropology from Barnard College and attended medical school at the University of Miami School of Medicine. She completed her medical residency at Johns Hopkins University and George Washington University, and Fellowship at the National Institutes of Health.
We believe Dr. Seidenberg is qualified to serve on our board of directors because of her training as a physician and her experience in the life sciences industry as a senior executive and venture capitalist who has incubated and invested in over twenty-five biotechnology ventures.

Daniel K. Spiegelman has served as a member of our board of directors since April 2021. Mr. Spiegelman has over 25 years of Biotech finance experience. Mr. Spiegelman was most recently Chief Financial Officer and Executive Vice President of BioMarin Pharmaceutical Inc. (Nasdaq: BMRN), a biotechnology company focused on developing, manufacturing and commercializing treatments for rare genetic disorders, from 2012 to 2020. Mr. Spiegelman oversaw growth from $500M in revenues to $2.0B in revenues with sales in 70 countries and from $4B market cap to $15B. Prior to BioMarin, Mr. Spiegelman served as Chief Financial Officer and Senior Vice President of CV Therapeutics, Inc. for 11 years from 1998 through its sale in 2009 to Gilead Sciences, Inc. From July 1991 to January 1998, Mr. Spiegelman served in various roles at Genentech, Inc. (now a member of the Roche Group) most recently as Treasurer. Mr. Spiegelman currently provides consulting and board services to various life sciences companies. He currently serves as a member of the board of directors and audit committee chair of Myriad Genetics (Nasdaq: MYGN), Spruce Biosciences (Nasdaq: SPRB) and Opthea Limited (Nasdaq: OPT), and serves on the board of directors of several private biotechnology companies, including Tizona Therapeutics, Inc. and Maze Therapeutics Inc. Mr. Spiegelman also serves as venture partner at Samsara BioCapital. Mr. Spiegelman received his Master's in Business Administration from the Stanford Graduate School of Business and a Bachelor's in Economics from Stanford University.

We believe Mr. Spiegelman is qualified to serve on our board of directors because of his important expertise in finance in the healthcare industry based on his extensive experience in several senior finance positions at
major pharmaceutical companies.

Executive Officers

The following table sets forth information regarding our executive officers as of March 25, 2024:

Name	Age	Position(s)
Peter Maag, Ph.D.	57	Chief Executive Officer and Director
Ryan Jones	37	Chief Financial Officer
Dominic Borie, M.D., Ph.D.	61	President, Research and Development
James Chung, M.D., Ph.D.	56	Chief Medical Officer
Karen Walker	62	Chief Technology Officer

Peter Maag, Ph.D. Biographical information regarding Dr. Maag is set forth above under "Board of Directors".

Ryan Jones has served as our Chief Financial Officer since January 2023. Mr. Jones joined Kyverna's founding team in 2018 and brings extensive industry experience in healthcare and life sciences. Prior to joining Kyverna, Mr. Jones was on the New Business Creation team at GE Ventures, where he focused on launching and financing new companies in cell engineering and healthcare technologies. Before joining GE Ventures, Mr. Jones led the technical development and launch of multiple next-generation DNA sequencing products as a Staff Engineer at Thermo Fisher Scientific Inc. (Life Technologies, Ion Torrent division)(NYSE: TMO). Prior to that, he was a Staff Scientist on the founding team at Nanosense, a DARPA-funded biosensor company. Mr. Jones is a co-inventor on five issued patents in biosensors and DNA sequencing. He has also served as a Board Observer for multiple companies founded by GE Ventures, including Menlo Microsystems, Inc., Drawbridge Health (acquired by Thorne Health), and Evidation Health, Inc. Mr. Jones holds a Bachelor's degree in Biophysics and History from the University of Pennsylvania and an MBA from Harvard Business School.

Dominic Borie, M.D., Ph.D. has served as our President, Research and Development since October 2022. Prior to that, he served as our Chief Executive Officer and President and a member of our board of directors from January 2020 to October 2022. Dr. Borie is an accomplished immunologist and digestive tract and liver transplant surgeon with extensive experience in drug development. He joined Kyverna from Horizon Therapeutics Public Ltd Co. (Nasdaq: HZNP), where he served as Vice-President and Head, External Research and Development. From 2005 through 2018, Dr. Borie held leadership positions at Genentech, Inc., Amgen Inc. (Nasdaq: AMGN), and

Roche Holding AG. While at Genentech, Dr. Borie was Senior Medical Director in the Product Development Immunology group where he contributed to the design, implementation and monitoring of global clinical trials for inflammation-related diseases such as inflammatory bowel diseases. During the latter part of his tenure at Genentech, Dr. Borie was Associate Group Medical Director, Global Head of Anti-CD20 Immunology and filed two sBLAs leading to new indications for Rituxan® in orphan diseases (pemphigus vulgaris and granulomatosis with polyangiitis). Dr. Borie joined Genentech from Amgen where he served as Medical Director and Global Development Leader for Inflammation. He started his career in industry at Roche as Director of Transplantation Research before transitioning to Translational Medicine roles for immune diseases. Prior to the transition to industry, Dr. Borie was in academia at Stanford University as the Director, Transplantation Immunology Laboratory. During this time, Dr. Borie was a key contributor to the validation of JAK inhibition as a new immunomodulatory approach, culminating in the approval of a new molecule for rheumatoid arthritis patients. Dr. Borie was previously a digestive surgery and liver transplantation attending surgeon at Pitie-Salpetriere Hospital, Assistance Publique in Paris, France. Dr. Borie has an extensive publication history with over 50 publications in peer-reviewed journals, 10 book chapters, and four issued patents. Dr. Borie received his Ph.D. in transplantation immunology from the University of Paris V – Descartes and his M.D., Master's degree in Immunology, and Certificate of Immunology and Immunopathology from the University of Paris XII.

James Chung, M.D., Ph.D. has served as our Chief Medical Officer since April 2021. Dr. Chung brings extensive biopharmaceutical industry experience working across the entire drug development process focused on autoimmune diseases. He has dedicated a significant part of his career working in translational medicine and early development. Dr. Chung joined Kyverna from Amgen Inc. (Nasdaq: AMGN), where he most recently was Executive Medical Director, head of Inflammation and Neuroscience, Global Medical Organization, and Global Development Leader for Enbrel®. He joined Amgen in 2004 in Medical Sciences/Early Development advancing inflammation programs from first-in-human to proof-of-concept, eventually serving as the Early Development Inflammation Therapeutic Area Head leading a team of physician-scientists, biomarker scientists, and clinical study managers. In 2013, he transitioned to late-stage Global Development and then in 2015 to Amgen's Global Medical Organization where he held numerous positions of increasing responsibility, including therapeutic area head for Inflammation, Nephrology, and Neuroscience, where he was responsible for the development and execution of medical strategies for a portfolio of marketed drugs and near-launch molecules. Prior to Amgen, Dr. Chung began his industry career as an Associate Director in Clinical Sciences at Pfizer Inc. (NYSE: PFE), where he served as the Early Clinical Leader for several early development programs in inflammation. Prior to joining industry, Dr. Chung was Instructor of Medicine in the Division of Rheumatology at the University of Pennsylvania where he also completed his residency in Internal Medicine and fellowship in Rheumatology. He obtained his M.D. and Ph.D. in Immunology at the University of Pennsylvania and BA in Biology at Harvard College.

Karen Walker has served as our Chief Technology Officer since September 2021. Ms. Walker has broad and deep industry experience developing biopharmaceuticals and cell and gene therapy, or CGT, products. She brings extensive and pioneering expertise in the product development, manufacturing, and supply of cell-based therapies and associated analytics. Ms. Walker has several decades of biotech industry experience, holding positions in Technical Development, Regulatory Affairs, and Quality at a number of companies including Roche Holding AG (SIX: ROG), Genentech, Inc., Seagen Inc., formerly Seattle Genetics (Nasdaq: SGEN), Novartis AG (NYSE: NVS, SIX: NOVN), Amgen Inc. (Nasdaq: AMGN), Bayer AG (FWB: BAYN), Bristol-Myers Squibb Co (NYSE: BMY), and several other small to mid-sized biotech companies. Prior to joining Kyverna, Ms. Walker was a Senior Advisor, Cell and Gene Therapy Manufacturing at Roche/Genentech from 2019 to 2021. In this position, she was instrumental in developing and implementing the strategy for CGT manufacturing and controls into the Roche/Genentech organization. Prior to Roche/Genentech, Ms. Walker was Vice President of Global Quality at Seagen Inc., where she oversaw and directed the Global Quality Organization in the United States and Europe from 2017 to 2019. Previously, she was Vice President and Global Head of Cell and Gene Therapy Technical Development and Manufacturing for Novartis' CGT Unit from 2016 to 2017. There, she led the Chemistry, Manufacturing, and Controls teams through the formation of the strategies and execution of those strategies to develop KYMRIAH® (tisagenlecleucel) through the pivotal trial stage and to filing of the first CAR-T Biologics License Application in pediatric acute lymphoblastic leukemia. During her time at Novartis and continuing to the present, Ms. Walker has been a strong and leading voice in the establishment of industry standardization and contributed to influence emerging regulatory guidance in the area of CGT products globally. Ms. Walker holds a Bachelor's degree from St. Olaf College. She is a member of numerous pharmaceutical industry trade organizations, including the Alliance for Regenerative Medicines Cell Therapy Manufacturing Committee, DeLoitte Industry

Working Group for Advanced Therapy Medicinal Products, or ATMPs, Parenteral Drug Association, or PDA, PDA Biologics Advisory Board, where she was vice chair from 2018 to 2020, and the PDA ATMP Working Group.

Family Relationships

There are no family relationships between or among any of our executive officers or directors.

Legal Proceedings with Directors or Executive Officers

There are no legal proceedings related to any of our directors or executive officers that require disclosure pursuant to Items 103 or 401(f) of Regulation S-K.

Code of Business Conduct and Ethics

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. The code of business conduct and ethics is available on our website at https://kyvernatx.com/. We intend to disclose any amendments to the code, or any waivers of its requirements, on our website to the extent required by the applicable rules and exchange requirements. The inclusion of our website address in this Annual Report on Form 10-K does not incorporate by reference the information on or accessible through our website into this Annual Report on Form 10-K .

Director Nominations

No material changes have been made to the procedures by which security holders may recommend nominees to our board of directors from those that were described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on February 8, 2024.

Audit Committee

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. Our Audit Committee is currently comprised of Daniel K. Spiegelman, Brian Kotzin, M.D. and Steve Liapis, Ph.D., with Mr. Spiegelman serving as Chairperson of the Audit Committee.

Our board of directors has determined that each member of the Audit Committee is "independent" and "financially literate" under the rules of The Nasdaq Stock Market LLC, or Nasdaq, and the SEC and that Mr. Spiegelman is an "audit committee financial expert" under the rules of the SEC. Both our independent registered public accounting firm and internal financial personnel regularly meet privately with our Audit Committee and have unrestricted access to the Audit Committee. The information under the heading "Board Independence" in Item 13 below is incorporated herein by reference.

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires the Company's directors and certain officers, as well as persons who beneficially own more than 10% of the outstanding shares of our common stock, to file reports regarding their initial stock ownership and subsequent changes to their ownership with the SEC. As of the fiscal year ended December 31, 2023, we did not have a class of equity securities registered pursuant to Section 12 of the Exchange Act. Our directors, officers who are now subject to Section 16(a) of the Exchange Act, and persons who beneficially own more than 10% of the outstanding shares of our common stock became subject to Section 16(a) of the Exchange Act on February 7, 2024 and had an obligation to file initial statements of ownership on Form 3 on that date. Due to an unexpected delay by the financial printer, the initial statement of ownership on Form 3 for Dr. Liapis, one of our directors, was filed on February 8, 2024.

Item 11. Executive Compensation.

Executive Compensation

Our named executive officers for the year ended December 31, 2023, are:

- Peter Maag, Ph.D., our Chief Executive Officer;
- James Chung, M.D., Ph.D. our Chief Medical Officer; and
- Karen Walker, our Chief Technology Officer.

Summary Compensation Table

The following table sets forth certain information with respect to the compensation paid to our named executive officers for the fiscal year ended December 31, 2023:

Name and principal position	Year	Salary ($)	Bonus ($)	Option awards ($)[1]	All Other Compensation ($)	Total ($)
Peter Maag, Ph.D.	2023	438,875	247,500	1,554,197	23,617 [2]	2,264,189
Chief Executive Officer						
James Chung, M.D., Ph.D.	2023	401,995	152,982	520,502	90,643 [3]	1,166,122
Chief Medical Officer						
Karen Walker	2023	387,899	150,150	520,502	23,593 [2]	1,082,144
Chief Technology Officer						

(1) The amounts in this column represent the aggregate grant date fair value of the option awards computed in accordance with Accounting Standards Codification Topic 718. Assumptions used in the calculation of these amounts are included in Note 10 to our audited condensed financial statements and related notes included in Part II, Item 8 of this Annual Report on Form 10-K. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.

(2) Comprised solely of insurance benefits paid by us on behalf of the named executive officer.

(3) Comprised of $29,101 of insurance benefits paid by us on behalf of Dr. Chung and $61,542 of temporary housing and relocation expenses reimbursed by us to Dr. Chung.

Employment Arrangements

Below are descriptions of employment offer letters with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control of the Company under the arrangements with our executive officers, see the subsection titled "—Potential Payments upon Termination or Change in Control" below.

Peter Maag, Ph.D.

In October 2022, we entered into an offer letter with Dr. Maag, or the Maag Offer Letter, which provides for at-will employment as our Chief Executive Officer with an initial base salary of $450,000 per year, a discretionary annual target bonus equal to 50% of his annual base salary and the grant of a non-statutory option to purchase shares of our common stock at the fair market value as determined by our board of directors as of the date of grant, with the number of shares to be equal to approximately 6.5% of our fully-diluted capitalization as of the date of grant. In accordance with the Maag Offer Letter, on November 22, 2022, we granted to Dr. Maag an option to purchase an aggregate of 1,397,285 shares of our common stock pursuant to the 2019 Plan, with an exercise price of $3.15 per share, or the Initial Option, with the following vesting schedule: 25% of the shares subject to the Initial Option vest on October 13, 2023, the 12-month anniversary of Dr. Maag's start date, and the balance vest in equal monthly installments over the following 36 months, subject to Dr. Maag's Continuous Service (as defined in the 2019 Plan) as of each vesting date. The Initial Option has an early exercise feature whereby it was immediately exercisable in full, as to the both the vested and unvested shares subject to the Initial Option, with any shares of common stock issued upon an early exercise that have not yet vested subject to repurchase by us in the event of termination of Dr. Maag's Continuous Service. We also agreed to pay or reimburse Dr. Maag for up to $5,000 for legal and tax-related fees incurred in negotiating and drafting the Maag Offer Letter and promissory note (described below).

The Maag Offer Letter also provides that Dr. Maag may pay up to 50% of the aggregate exercise price of the Initial Option with a promissory note on terms approved by our board of directors. In accordance with this provision in the Maag Offer Letter, on December 28, 2022, Dr. Maag early exercised 349,321 shares of our common stock subject to the Initial Option in exchange for a partial recourse promissory note receivable in an aggregate principal amount of $1.1 million. On January 12, 2024, we forgave the promissory note in full, which includes the outstanding principal amount and interest through that date. The promissory note bore interest of 4.27% per annum and was due

in December 2027 but would have become immediately due and payable upon the occurrence of certain events, including upon a change of control of our company or on the date prior to the filing of a registration statement by us in connection with an initial public offering.

Effective January 1, 2024, Dr. Maag's base salary was increased to $550,000 per year and his discretionary annual target bonus was increased to equal to 55% of his annual base salary.

James Chung, M.D., Ph.D.

In March 2021, we entered into an offer letter with Dr. Chung, or the Chung Offer Letter, which provides for at-will employment as our Senior Vice President, Chief Medical Officer, with an initial base salary of $375,000 per year, an annual target bonus equal to 35% of his annual base salary, a one-time sign-on/retention bonus of $30,000 granted on the condition that Dr. Chung remain employed by us through the two-year anniversary of his start date, as well as grant of an option to purchase 98,877 shares of our common stock. In accordance with the Chung Offer Letter, on April 27, 2021, we granted to Dr. Chung an option to purchase an aggregate of 98,877 shares of our common stock with an exercise price of $3.37 per share, which is subject to the following vesting schedule: 25% of the shares subject to the option vested on April 12, 2022 and the balance vest in equal monthly installments over the following 36 months of his Continuous Service (as defined in the 2019 Plan).

The Chung Offer Letter also provides for reimbursement of moving expenses related to Dr. Chung's relocation to the San Francisco Bay Area in the amount up to $40,000 payable in 2023, 30 days of housing allowance for temporary living up to approximately $3,500 per month on the condition that he remain employed by us through the two-year anniversary of his start date, as well as payment for the travel and lodging expenses related to his presence at our headquarter offices from his start date through his relocation date, capped at $3,500 per month.

Effective January 1, 2024, Dr. Chung's base salary was increased to $440,000 per year and his discretionary annual target bonus was increased to equal to 40% of his annual base salary.

Karen Walker

In July 2021, we entered into an offer letter with Ms. Walker, or the Walker Offer Letter, which provides for at-will employment as our Senior Vice President, Chief Technology Officer, with an initial base salary of $370,000 per year, an annual target bonus equal to 35% of her annual base salary and grant of an option to purchase 92,285 shares of our common stock. In accordance with the Walker Offer Letter, on November 18, 2021, we granted to Ms. Walker an option to purchase an aggregate of 92,285 shares of our common stock with an exercise price of $4.42 per share, which is subject to the following vesting schedule: 25% of the shares subject to the option vested on September 13, 2022 and the balance vest in equal monthly installments over the following 36 months of her Continuous Service (as defined in the 2019 Plan).

The Walker Offer Letter also provides for reimbursement of expenses related to her travel to our headquarter offices on a regular basis to perform her duties in person.

Effective January 1, 2024, Ms. Walker's base salary was increased to $440,000 per year and her discretionary annual target bonus was increased to equal to 40% of her annual base salary.

Potential Payments Upon Termination or Change in Control

Peter Maag, Ph.D.

The Maag Offer Letter provides that if we terminate Dr. Maag's employment for Cause (as defined in the Maag Offer Letter) at any time, if he resigns without Good Reason (as defined in the Maag Offer Letter) or if his employment terminates as a result of his death or disability, he will receive his base salary accrued through his last day of employment but will not be entitled to any other form of compensation from the Company, including severance benefits. If the Company terminates Dr. Maag's employment without Cause or he resigns for Good Reason and other than as a result of his death or disability, and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h)), then, subject to his obligations set forth in the Maag Offer Letter, he will be entitled to receive (i) 12 months of his then-current base salary and (ii) COBRA premiums until the earliest of (A) the end of the 12-month period following the termination of his employment, (B) the expiration of his eligibility for the continuation coverage under COBRA and(C) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment. In addition, if a Change in

Control(as defined in the Maag Offer Letter)occurs, the Initial Option (including for this purpose any unvested shares of our common stock issued upon exercise of the Initial Option) shall vest in full, subject to Dr. Maag's Continuous Service through and including the date on which the Change in Control is consummated.

James Chung, M.D., Ph.D.

The Chung Offer Letter provides that if the Company terminates Dr. Chung's employment for Cause (as defined in the Chung Offer Letter), if he resigns without Good Reason (as defined in the Chung Offer Letter) or if his employment terminates as a result of his death or disability, he will receive his base salary accrued through his last day of employment but will not be entitled to any other form of compensation from the Company, including severance benefits. If, outside of a CIC Period (as defined in the Chung Offer Letter), the Company terminates Dr. Chung's employment without Cause or he resigns for Good Reason and other than as a result of his death or disability, and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h)), then, subject to his obligations set forth in the Chung Offer Letter, he will be entitled to receive (i) three months of his then-current base salary and (ii) COBRA premiums until the earliest of (A) the end of the three-month period following the termination of his employment, (B) the expiration of his eligibility for the continuation coverage under COBRA and (C) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment. If, within a CIC Period, the Company terminates Dr. Chung's employment without Cause or he resigns for Good Reason and other than as a result of his death or disability, and provided such termination constitutes a "separation from service," then, subject to his obligations set forth in the Chung Offer Letter, he will be entitled to receive (1) six months of his then-current base salary, (ii) COBRA premiums until the earliest of (A) the end of the six-month period following the termination of his employment, (B) the expiration of his eligibility for the continuation coverage under COBRA and (C) the date he becomes eligible for substantially equivalent health insurance coverage in connection with new employment and (iii) accelerated vesting of any of his then-outstanding options such that, as of the date of his employment termination, he will be deemed to have vested in those shares that would have vested on the 12-month anniversary of his employment termination.

Karen Walker

The Walker Offer Letter provides that if, at any time, the Company terminates Ms. Walker's employment for Cause (as defined in the Walker Offer Letter), if she resigns without Good Reason (as defined in the Walker Offer Letter) or if her employment terminates as a result of her death or disability, she will receive her base salary accrued through her last day of employment but will not be entitled to any other form of compensation from the Company, including severance benefits. If, outside of a CIC Period (as defined in the Walker Offer Letter), the Company terminates Ms. Walker's employment without Cause or she resigns for Good Reason and other than as a result of her death or disability, and provided such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h)), then, subject to her obligations set forth in the Walker Offer Letter, she will be entitled to receive (i) three months of her then-current base salary and (ii) COBRA premiums until the earliest of (A) the end of the three-month period following the termination of her employment, (B) the expiration of her eligibility for the continuation coverage under COBRA and (C) the date she becomes eligible for substantially equivalent health insurance coverage in connection with new employment. If, within a CIC Period, the Company terminates Ms. Walker's employment without Cause or she resigns for Good Reason and other than as a result of her death or disability, and provided such termination constitutes a "separation from service," then, subject to her obligations set forth in the Walker Offer Letter, she will be entitled to receive (1) six months of her then-current base salary, (ii) COBRA premiums until the earliest of (A) the end of the six-month period following the termination of her employment, (B) the expiration of her eligibility for the continuation coverage under COBRA and (C) the date she becomes eligible for substantially equivalent health insurance coverage in connection with new employment and (iii)accelerated vesting of any of her then-outstanding options such that, as of the date of her employment termination, she will be deemed to have vested in those shares that would have vested on the 12-month anniversary of her employment termination.

Perquisites, Health, Welfare and Retirement Plans and Benefits

All of our named executive officers are eligible to participate in our employee benefit plans offered to similarly situated employees of the Company, including medical, dental, vision, disability, life insurance and 401(k) plans. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited

circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

Outstanding Equity Awards at Fiscal Year-End 2023

The following table presents certain information concerning outstanding equity awards held by each of our named executive officers at December 31, 2023:

			Option Awards[1]			
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable[2]	Number of Securities Underlying Unexercised Options (#) Unexercisable[2]	Option Exercise Price ($)	Option Expiration Date
Peter Maag, Ph.D.	11/22/2022 [2][3]	10/13/2022	—	989,743	$ 3.15	11/21/2032
	7/13/2023 [4]	7/1/2023	—	1,098	$ 4.33	7/12/2033
	11/6/2023 [4]	1/1/2024	—	329,590	$ 4.83	11/5/2033
James Chung, M.D., Ph.D.	4/27/2021 [4]	4/12/2021	—	32,959	$ 3.37	4/26/2031
	7/13/2023 [4]	7/1/2023	—	1,098	$ 4.33	7/12/2033
	11/6/2023 [4]	1/1/2024	—	109,863	$ 4.83	11/5/2033
Karen Walker	11/18/2021 [4]	9/13/2021	51,910	40,374	$ 4.42	11/17/2031
	7/13/2023 [4]	7/1/2023	—	1,098	$ 4.33	7/12/2033
	11/6/2023 [4]	1/1/2024	—	109,863	$ 4.83	11/5/2033

(1) All of the option awards were granted under the 2019 Plan.
(2) This option is exercisable immediately subject to a repurchase right in favor of the Company which lapses as the option vests. Accordingly, the "Number of Securities Underlying Unexercised Options Unexercisable" column reflects the number of options held by the named executive officer that were outstanding, exercisable and unvested as of December 31, 2023.
(3) 25% of the shares originally subject to the option will vest one year after the vesting commencement date, and 1/48th of the shares originally subject to the option vested or vest monthly thereafter subject to Dr. Maag's continued service to the company through each vesting date. Upon a Change in Control (as defined in the Maag Offer Letter), the vesting of any then-unvested, unexercised and outstanding portion of the option (or then-unvested and outstanding shares issued upon exercise of the option) will become fully vested.
(4) 25% of the shares originally subject to the option vested one year after the vesting commencement date, and 1/48th of the shares originally subject to the option vested or vest monthly thereafter subject to the named executive officer's continued service to the Company through each vesting date.

Equity Benefit Plans

2024 Equity Incentive Plan

In connection with the IPO, effective February 6, 2024, our board of directors adopted, and our stockholders approved, the Kyverna Therapeutics, Inc. 2024 Equity Incentive Plan, which we refer to as the 2024 Plan. The purpose of the 2024 Plan is to provide incentives for our employees, directors and consultants to exert maximum efforts for the success of the Company and our affiliates and to provide a means by which such persons may be given an opportunity to benefit from increases in value of our common stock through the granting of awards.

2024 Employee Stock Purchase Plan

In connection with the IPO, effective February 6, 2024, our board of director adopted and our stockholders approved, the Kyverna Therapeutics, Inc. 2024 Employee Stock Purchase Plan, which we refer to as the ESPP. The ESPP is intended to provide incentives for our employees to exert maximum efforts toward our success and that of our related corporations.

The ESPP is intended to qualify as an "employee stock purchase plan" under Section 423 of the Internal Revenue Code of 1986, as amended, or the Code. We may also authorize offerings under the ESPP that are not intended to comply with the requirements of Section 423 of the Code, which may, but are not required to, be made pursuant to any rules, procedures or sub-plans adopted by the compensation committee of our board of directors for such purpose.

Limitations on Liability and Indemnification

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our officer or director, or served any other enterprise at our request as an officer or director. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment. Delaware law provides that directors and officers of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors or officers, except liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by our board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Rule 10b5-1 Plans

Our directors, officers and key employees may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from the director or officer. The director or officer may amend or terminate a Rule 10b5-1 plan, subject to certain requirements. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information, subject to compliance with the terms of our insider trading policy and any applicable Rule 10b5-1 guidelines. Prior to August 10, 2024, subject to early termination, the sale of any shares under such Rule 10b5-1 plan would be subject to the lock-up agreement that the director or executive officer entered into with the underwriters in connection with the IPO.

Non-Employee Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the year ended December 31, 2023. Other than as set forth in the table and described more fully below, in 2023 we did not pay any compensation to, reimburse any expense of, or grant any equity awards or non-equity awards to any of the non-employee members of our board of directors.

In 2023, we did not have a formal or standard compensation policy for our non-employee directors. However, pursuant to an offer letter, dated September 14, 2021, with Mr. Clark to serve as the chairperson of our board of directors, we have agreed to pay Mr. Clark an annual cash retainer of $100,000. In addition, on February 28, 2022, Mr. Clark was granted an option to purchase 38,736 shares of our common stock with an exercise price of $4.42 per share. Similarly, pursuant to our offer letter with Brian Kotzin, M.D., dated January 8, 2020, we agreed to pay him $100,000 per calendar year for his service on our board of directors. Pursuant to our offer letter, dated March 31, 2021, with Daniel Spiegelman, we agreed to pay Mr. Spiegelman an annual cash retainer for service on our board of directors of $50,000. On September 1, 2023, we entered into an advisor agreement with Mr. Spiegelman, pursuant to which he agreed to provide us advice in our evaluation of strategic options in the context of corporate finance activities, including, but not limited to, an initial public offering by us, in exchange for a payment of $10,000 per month. In addition, we have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

The following table sets forth information for the year ended December 31, 2023 regarding the compensation awarded to, earned by or paid to persons who served as our directors during 2023 who are not named executive officers.

Name[(1)]	Fees Earned or Paid in Cash ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Ian Clark	100,000	206,739	—	306,739
Fred E. Cohen, M.D., D.Phil.	—	155,054	—	155,054
Brian Kotzin, M.D.	100,000	155,054	—	255,054
Steve Liapis, Ph.D.	—	—	—	—
Beth Seidenberg, M.D.	—	155,054	—	155,054
Daniel K. Spiegelman	50,000	155,054	40,000[(2)]	245,054

(1) As of December 31, 2023, our then-serving non-employee directors held unexercised stock options with respect to the following number of shares of our common stock: Mr. Clark: 364,398 shares, Dr. Cohen: 32,959 shares, Dr. Kotzin: 76,265 shares, Dr. Liapis: no shares, Dr. Seidenberg: 32,959 shares; and Mr. Spiegelman: 50,537 shares.

(2) Represents compensation payable to Mr. Spiegelman under the advisor agreement, dated September 1, 2023.

Non-Employee Director Compensation Policy

Effective upon the closing of the IPO, our non-employee directors are compensated in accordance with our non-employee director compensation program, or the Director Compensation Program. Pursuant to the Director Compensation Program, our non-employee directors will receive cash compensation, paid quarterly in arrears, as follows:

- Each non-employee director will receive a cash retainer in the amount of $40,000 per year.
- The independent Chairperson of our board of directors will receive an additional cash retainer of $35,000 per year.
- The Chairperson of the Audit Committee will receive a cash retainer in the amount of $20,000 per year for such Chairperson's service on the Audit Committee. Each non-Chairperson member of the Audit Committee will receive a cash retainer in the amount of $10,000 per year for such member's service on the Audit Committee.

- The Chairperson of the Compensation Committee will receive a cash retainer in the amount of $15,000 per year for such Chairperson's service on the Compensation Committee. Each non-Chairperson member of the Compensation Committee will receive a cash retainer in the amount of $7,500 per year for such member's service on the Compensation Committee.
- The Chairperson of the Nominating and Corporate Governance Committee will receive a cash retainer in the amount of $10,000 per year for such Chairperson's service on the Nominating and Corporate Governance Committee. Each non-Chairperson member of the Nominating and Corporate Governance Committee will receive a cash retainer in the amount of $5,000 per year for such member's service on the Nominating and Corporate Governance Committee.
- The Chairperson of the Science and Technology Committee will receive a cash retainer in the amount of $15,000 per year for such Chairperson's service on the Science and Technology Committee. Each non-Chairperson member of the Science and Technology Committee will receive a cash retainer in the amount of $7,500 per year for such member's service on the Science and Technology Committee.

Each non-employee director may elect, on an annual basis, to convert all or a portion of such non-employee director's annual retainer into a number of restricted stock units granted under the 2024 Plan, which will be fully vested on the date of grant, and settlement of the restricted stock units may be deferred at the election of the non-employee director.

Under the Director Compensation Program, each non-employee director who is initially elected or appointed to our board of directors following the IPO will automatically be granted an option, or the Initial Grant, under the 2024 Plan to purchase that number of shares of our common stock equal to (i) $350,000, divided by (ii) the per share grant date fair value of the option award. The Initial Grant will vest as to 1/36th of the underlying shares on a monthly basis over three years, subject to continued service through the applicable vesting date. In addition, on the date of each annual meeting of our stockholders following the completion of the IPO, each non-employee director who (i) has been serving on our board of directors for at least four months and (ii) will continue to serve as a non-employee director immediately following such annual meeting will automatically be granted an option, or the Annual Grant, under the 2024 Plan to purchase that number of shares of our common stock equal to (i) $175,000, divided by (ii) the per share grant date fair value of the option award. The Annual Grant will vest in full on the earlier of the (i) first anniversary of the grant date and (ii) immediately prior to the annual meeting of our stockholders following the date of grant, subject to continued service through the applicable vesting date.

Pursuant to the Director Compensation Program, upon a change in control transaction, all outstanding equity awards held by our non-employee directors will vest in full.

Compensation Committee Interlocks and Insider Participation

None of the expected members of the Compensation Committee has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of our board of directors or the compensation committee of any entity that has one or more executive officers on our board of directors or the Compensation Committee.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 1, 2024, by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our outstanding shares common stock.

We have determined beneficial ownership in accordance with the rules of the SEC, which generally means that a person has beneficial ownership of a security if he or she possesses sole or shared voting or investment power of that security, including options that are currently exercisable or exercisable within 60 days of March 1, 2024. Unless otherwise indicated, to our knowledge, the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to community property laws where applicable. The information in the table below does not necessarily indicate beneficial ownership for any other purpose, including for purposes of Sections 13(d) and 13(g) of the Securities Act.

We have based our calculation of the percentage of shares beneficially owned on 43,115,244 shares of our common stock outstanding as of March 1, 2024.

In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of our common stock subject to options, convertible securities or other rights, held by such person that are currently exercisable or will become exercisable within 60 days of March 1, 2024, are considered outstanding. We did not, however, deem such shares outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Kyverna Therapeutics, Inc., 5980 Horton St., STE 550 Emeryville, CA 94608.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percent of Shares Beneficially Owned
5% and Greater Stockholders:		
Bain Capital Life Sciences Opportunities III, LP(1)	3,163,868	7.3%
Gilead Sciences, Inc.(2)	4,126,119	9.6%
Entities affiliated with Northpond Ventures III, LP(3)	3,255,426	7.6%
Entities affiliated with Vida Ventures, LLC(4)	4,777,060	11.1%
Entities affiliated with Westlake BioPartners Fund I, L.P.(5)	4,523,924	10.5%
Named Executive Officers and Directors:		
Peter Maag, Ph.D.(6)	523,985	1.2%
James Chung, M.D., Ph.D.(7)	74,160	*
Karen Walker(8)	59,607	*
Ian Clark(9)	191,188	*
Fred Cohen, M.D.(10)	4,523,924	10.5%
Brian Kotzin, M.D.(11)	43,306	*
Steve Liapis, Ph.D.	—	—
Beth Seidenberg, M.D.(12)	4,523,924	10.5%
Daniel K. Spiegelman(13)	13,186	*
All executive officers and directors as a group (11 persons)(14)	10,465,044	24.0%

* Represents beneficial ownership of less than 1%.

(1) Number of shares beneficially owned as of February 7, 2024 as reported in a Schedule 13G filed by Bain Capital Life Sciences Opportunities III, LP on February 14, 2024. Bain Capital Life Sciences Investors, LLC ("BCLSI") is the manager of Bain Capital Life Sciences III General Partner, LLC, which is the general partner of Bain Capital Life Sciences Fund III, L.P., which is the sole member of Bain Capital Life Sciences Opportunities III GP, LLC, which is the general partner of Bain Capital Life Sciences Opportunities III, LP. As a result, BCLSI may be deemed to share voting and dispositive power with respect to the shares held by Bain Capital Life Sciences Opportunities III, LP. Voting and investment decisions with respect to shares held by Bain Capital Life Sciences Opportunities III, L.P. are made by the partners of BCLSI, of whom there are three or more and none of whom individually has the power to direct such decisions. The address of Bain Capital Life Sciences Opportunities III, LP is c/o Bain Capital Life Sciences, LP, 200 Clarendon Street, Boston, MA 02116.

(2) Number of shares beneficially owned as of February 12, 2024 as reported in a Schedule 13G filed by Gilead Sciences, Inc. on February 20, 2024. The principal business address of Gilead Sciences, Inc. is 333 Lakeside Drive, Foster City, CA 94404.

(3) Number of shares beneficially owned as of February 12, 2024 as reported in a Schedule 13G filed by Northpond Ventures, LP ("Northpond"), Northpond Ventures GP, LLC ("Northpond GP"), Northpond Ventures III, LP ("Northpond III"), Northpond Ventures III GP, LLC ("Northpond III GP") and Michael P. Rubin on February

22, 2024. Consists of: (i) 450,000 shares held by Northpond, and (ii) 2,805,426 shares of common stock held by Northpond III. Northpond GP is the general partner of Northpond and Mr. Rubin is the managing member of Northpond GP. As such, Northpond GP and Mr. Rubin have shared dispositive and voting power over the shares held by Northpond and may be deemed to have indirect beneficial ownership of the shares held by Northpond. Northpond III GP is the general partner of Northpond III and Mr. Rubin is the managing member of Northpond III GP. As such, Northpond III GP and Mr. Rubin have shared dispositive and voting power over the shares held by Northpond III and may be deemed to have indirect beneficial ownership of the shares held by Northpond III. The address for each of these entities is 7500 Old Georgetown Rd, Suite 850, Bethesda, MD 20814.

(4) Number of shares beneficially owned as of February 12, 2024 as reported in a Form 4 filed by Vida Ventures, LLC ("Vida"), Vida Ventures GP III, L.L.C. ("Vida III GP"), Vida Ventures III, L.P. ("Vida III") and Vida Ventures III-A, L.P. ("Vida III-A") on February 14, 2024. Consists of: (i) 4,523,924 shares of common stock held by Vida, (ii) 252,553 shares held by Vida III and (iii) 583 shares held by Vida III-A. Vida Ventures Advisors, LLC is the investment advisor to Vida. Arie Belldegrun, Leonard Potter and Dr. Fred E. Cohen, a member of our board of directors, are the managing members of Vida Ventures Advisors, LLC, and may be deemed to share voting and dispositive power over the shares held by Vida. Vida III GP is the general partner of Vida III and Vida III-A. The address of Vida, Vida III, Vida III-A and Vida III GP is 40 Broad Street, Suite 201, Boston, Massachusetts 02109.

(5) Number of shares beneficially owned as of February 12, 2024 as reported in a Form 4 filed by Westlake BioPartners Fund I, L.P. ("Westlake I"), Westlake BioPartners GP I, LLC ("Westlake GP I"), Westlake BioPartners Opportunity Fund I, L.P. ("Westlake Opportunity"), Westlake BioPartners Opportunity GP I, LLC ("Westlake Opportunity GP I") and Sean Harper on February 14, 2024. Consists of: (i) 3,787,940 shares of common stock held by Westlake I and (ii) 735,984 shares of common stock held by Westlake Opportunity. The general partners of Westlake I and Westlake Opportunity are Westlake GP I and Westlake Opportunity GP I. The voting and dispositive control over Westlake GP I and Westlake Opportunity GP I is shared by managing directors of Westlake GP I and Westlake Opportunity GP I, Beth Seidenberg and Sean Harper, none of whom has veto power. The address for Westlake I and Westlake Opportunity is 3075 Townsgate Rd., Suite 140, Westlake Village, CA 91361.

(6) Represents (i) 58,220 shares of common stock held directly, (ii) 349,321 shares of common stock held by The Maag Family Irrevocable Trust, and (iii) 116,444 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024.

(7) Represents (i) 65,918 shares of common stock, and (ii) 8,242 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024.

(8) Represents 59,607 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024.

(9) Represents 191,188 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024.

(10) Represents the 4,523,924 shares of common stock held by Vida listed in footnote (4) above. Dr. Cohen, a member of our board of directors, is a Senior Managing Director of Vida, and may be deemed to share voting and dispositive power over the shares held by Vida.

(11) Represents 43,306 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024.

(12) Represents the shares listed in footnote (5) above. Dr. Seidenberg, a member of our board of directors, is a managing director of Westlake GP I and, therefore, may be deemed to exercise voting and investment discretion with respect to such shares.

(13) Represents 13,186 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024.

(14) Consists of (i) 9,996,450 shares of common stock beneficially owned by our current executive officers and directors (which includes an aggregate of 475,143 beneficially owned by two additional executive officers), and (ii) 468,594 shares of common stock subject to options that are exercisable within 60 days of March 1, 2024 (which includes an aggregate of 36,621 shares of common stock subject to options held by two additional executive officers).

Equity Compensation Plan Information

The following table sets forth additional information as of December 31, 2023 with respect to the shares of common stock that may be issued upon the exercise of options and other rights under our existing equity compensation plans and arrangements in effect as of December 31, 2023. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options and the number of shares remaining available for future grant, excluding the shares to be issued upon exercise of outstanding options.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders[(1)]	3,960,713	$ 4.18	487,673
Equity compensation plans not approved by security holders	—	—	—
Total	3,960,713	$ 4.18	487,673

(1) Our Amended and Restated 2019 Stock Plan, or the 2019 Plan, which was approved by our board of directors and stockholders, was the only equity compensation plan we had in place as of December 31, 2023. In connection with the IPO, our board of directors and our stockholders approved two new equity compensation plans, the Kyverna Therapeutics, Inc. 2024 Equity Incentive Plan and the Kyverna Therapeutics, Inc. 2024 Employee Stock Purchase Plan. Each plan became effective on February 6, 2024. The table above does not include any amounts issuable under either the 2024 Equity Incentive Plan or the Kyverna Therapeutics, Inc. 2024 Employee Stock Purchase Plan because they were not in effect as of December 31, 2023.

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

The following is a summary of transactions since January 1, 2023 and any currently proposed transactions to which we have been a participant in which the amount involved exceeded or will exceed the lesser of $120,000 or 1% of the average of our total assets as of each of December 31, 2022 and 2023, and in which any of our then directors, executive officers or holders of more than 5% of any class of our capital stock at the time of such transaction, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described in Part III, Item 11 of this Annual Report on Form 10-K.

Series B Preferred Stock Financing

In multiple closings held between November 9, 2021 and July 31, 2023, we issued and sold an aggregate of 77,461,394 shares of our Series B convertible preferred stock at a purchase price of $1.8719 per share for an aggregate purchase price of $144,999,983.61. In addition, on December 29, 2021, we issued 3,739,515 shares of Series B convertible preferred stock in consideration for a certain license agreement entered into by us for a non-cash purchase price of $6,999,998.13.

The following table summarizes the Series B convertible preferred stock purchased by holders of more than 5% of our capital stock as of the date of the applicable closing of the Series B convertible preferred stock, and entities affiliated with certain of our executive officers and directors. Each outstanding share of Series B convertible preferred stock identified in the table below will automatically converted into shares of our common stock at a ratio of one-for-4.5511 immediately prior to the closing of the IPO.

Name[1]	Series B Preferred Stock Purchased (Shares)	Aggregate Purchase Price ($)
Northpond Ventures III, LP[2]	12,767,776	$23,899,999.90
Entities affiliated with Westlake BioPartners Fund I, L.P.[3]	7,356,162	$13,769,999.66
Vida Ventures, LLC[4]	7,356,162	$13,769,999.66
Gilead Sciences, Inc.	7,746,139	$14,499,997.60
Entities affiliated with RTW Investments LP[5]	6,383,887	$11,949,998.12
jVen Capital, LLC[6]	630,375	$1,179,998.98
Bain Capital Life Sciences Opportunities III, LP	12,351,087	$23,119,999.76

(1) Additional details regarding these stockholders that are currently beneficial owners of 5% of our outstanding shares of common stock and their equity holdings are included in Part III, Item 12 of this Annual Report on Form 10-K.
(2) Northpond Ventures III, LP beneficially owns more than 5% of our outstanding capital stock. Dr. Liapis is a member of our board of directors and is a principal at Northpond Ventures, LLC, an affiliate of Northpond Ventures III, LP.
(3) Consists of (i) 4,006,624 shares of Series B preferred stock issued to Westlake BioPartners Fund I, L.P. and (ii) 3,349,538 shares of Series B Preferred Stock issued to Westlake BioPartners Opportunity Fund I, L.P. Dr. Seidenberg is a member of our board of directors and is a managing director of Westlake BioPartners GP I, LLC and Westlake BioPartners Opportunity GP I, L.P., the general partner of Westlake BioPartners Fund I, L.P. and Westlake BioPartners Opportunity Fund I, L.P., respectively.
(4) Vida Ventures, LLC beneficially owns more than 5% of our outstanding capital stock. Dr. Cohen is a member of our board of directors and is a Senior Managing Director of Vida Ventures, LLC.
(5) Consists of (i) 3,553,387 shares of Series B preferred stock issued to RTW Master Fund, Ltd., (ii) 1,834,938 shares of Series B preferred stock issued to RTW Innovation Master Fund, Ltd., and (iii) 995,562 shares of Series B preferred stock issued to RTW Biotech Opportunities Ltd (formerly RTW Venture Fund Limited).
(6) jVen Capital, LLC is an entity controlled by an immediate family member of Mr. Ryan Jones, our Chief Financial Officer.

Investors' Rights Agreement

In November 2021, in connection with the initial issuance and sale of our Series B preferred stock, we entered into an Amended and Restated Investors' Rights Agreement, as subsequently amended, or the Rights Agreement, with, among others, the following holders of more than 5% of our outstanding capital stock: Northpond Ventures III, LP, Westlake Biopartners Fund I, L.P., Vida Ventures, LLC, Gilead Sciences, Inc., entities affiliated with RTW Master Fund, Ltd. and Bain Capital Life Sciences Opportunities III, LP.

The Rights Agreement grants certain rights to the holders of our outstanding convertible preferred stock, including certain registration rights with respect to the registrable securities held by them. In addition, the Rights Agreement imposed certain affirmative obligations on us, including, among other things, our obligation to grant each investor who holds shares of our convertible preferred stock a right of first offer with respect to future sales of our equity, excluding the shares offered and sold in the IPO, and grant certain information and inspection rights to such investors. Each of these other obligations terminated in connection with the closing of the IPO.

Voting Agreement

In November 2021, in connection with the initial issuance and sale of our Series B preferred stock, we entered into an Amended and Restated Voting Agreement, as subsequently amended, or the Voting Agreement, with, among others, the following holders of more than 5% of our outstanding capital stock: Gilead Sciences, Inc., entities

affiliated with RTW Master Fund, Ltd. and Bain Capital Life Sciences Opportunities III, LP. Northpond Ventures III, LP, Westlake Biopartners Fund I, L.P. and Vida Ventures, LLC, each of which currently has a director designee on our board of directors and is a holder of more than 5% of our outstanding capital stock, were also parties to the Voting Agreement.

Pursuant to the Voting Agreement, (i) Westlake BioPartners Fund I, L.P. had the right to designate one member to be elected to our board of directors, (ii) Vida Ventures, LLC had the right to designate one member to be elected to our board of directors, (iii) Gilead Sciences, Inc. had the right to designate one member to be elected to our board of directors, and (iv) Northpond Ventures III, LP had the right to designate one member to be elected to our board of directors. The Voting Agreement terminated by its terms in connection with the closing of the IPO and none of our stockholders have any continuing rights regarding the election or designation of members of our board of directors following the IPO.

Right of First Refusal and Co-Sale Agreement

In November 2021, in connection with the initial issuance and sale of our Series B preferred stock, we entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement, as subsequently amended, or the Co-Sale Agreement, with, among others, the following holders of more than 5% of our outstanding capital stock: entities affiliated with Gilead Sciences, Inc., entities affiliated with RTW Master Fund, Ltd. and Bain Capital Life Sciences Opportunities III, LP. Northpond Ventures III, LP, Westlake Biopartners Fund I, L.P. and Vida Ventures, LLC, each of which currently has a director designee on our board of directors and is a holder of more than 5% of our outstanding capital stock, were also parties to the Co-Sale Agreement.

Pursuant to the Co-Sale Agreement, we had a right of first refusal in respect of certain sales of securities by certain holders of our common stock and convertible preferred stock, including holders of more than 5% of our outstanding capital stock. To the extent we did not exercise such right in full, certain holders of our capital stock were entitled to certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement terminated in connection with the closing of the IPO.

Management Rights Letters

In connection with the initial issuance and sale of our Series A-2 and Series B preferred stock, we entered into management rights letters with certain purchasers of our convertible preferred stock, including holders of more than 5% of our capital stock and entities with which certain of our directors or officers are affiliated, pursuant to which such entities were granted certain management rights, including the right to consult with and advise our management on significant business issues, review our operating plans, examine our books and records and inspect our facilities. These management rights letters terminated upon completion of the IPO.

Employment Arrangements

We have entered into employment offer letters with certain of our executive officers. For more information regarding these agreements with our executive officers, see Part III, Item 11 of this Annual Report on Form 10-K.

Equity Grants

We have granted options to purchase shares of our common stock to certain of our executive officers and directors. For more information regarding the options granted to our executive officers and directors, see Part III, Item 11 of this Annual Report on Form 10-K.

Indemnification Agreements

We have entered into indemnification agreements with certain of our current directors and executive officers and entered into indemnification agreements with each of our directors and executive officers in connection with the IPO. The indemnification agreements and our amended and restated bylaws, require us to indemnify our directors and executive officers to the fullest extent permitted by Delaware law. For more information regarding these agreements, see Part III, Item 11 of this Annual Report on Form 10-K.

Promissory Note with Dr. Maag

See Part III, Item 11 of this Annual Report on Form 10-K for a discussion of the partial recourse promissory note previously issued to us by Dr. Maag as consideration for an early exercise of an option to purchase shares of our common stock. On January 12, 2024, we forgave the promissory note in full, which includes the outstanding principal amount and interest through that date.

Advisor Agreement with Daniel Spiegelman

On September 1, 2023, we entered into an advisor agreement with Daniel Spiegelman, a member of our board of directors, pursuant to which Mr. Spiegelman agreed to provide us advice in our evaluation of strategic options in the context of corporate finance activities, including, but not limited to, an initial public offering by us, in exchange for a payment of $10,000 per month. The advisor agreement provided that it would terminate on the earliest to occur of April 1, 2024, immediately prior to the effectiveness of a registration statement on Form S-1 filed by us with the SEC related to the initial public offering of our common stock and the date terminated by either party upon written notice to the other party. In accordance with the foregoing, the advisor agreement terminated on February 7, 2024.

Participation in our Initial Public Offering

On February 12, 2024, we closed the IPO, pursuant to which we issued and sold 16,675,000 shares of common stock, which included the exercise in full by the underwriters of their option to purchase 2,175,000 additional shares, at an initial public offering price of $22.00 per share. The following table sets forth the number of shares of our common stock purchased by our directors, executive officers and 5% stockholders and their affiliates and the aggregate purchase price paid for such shares:

Purchaser	Shares of Common Stock Purchased	Aggregate Purchase Price
Bain Capital Life Sciences Opportunities III, LP	450,000	$9,900,000
Gilead Sciences, Inc.	910,000	$20,020,000
Northpond Ventures, LLC, affiliated with Northpond Ventures III, LP, a holder of more than 5% of our common stock	450,000	$9,900,000
Vida Ventures III, L.P., affiliated with Vida Ventures, LLC, a holder of more than 5% of our common stock	252,553	$5,556,166
Vida Ventures III-A, L.P., affiliated with Vida Ventures, LLC, a holder of more than 5% of our common stock	583	$12,826

Related Person Transaction Policy

Prior to the IPO, we did not have a formal policy regarding approval of transactions with related parties. In connection with the IPO, we have adopted a written related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. The policy became effective on February 7, 2024. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants and in which the amount involved exceeds $120,000. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any officer, director (or nominee to become a director) or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members.

All of the transactions described above were entered into prior to the adoption of the written related person transaction policy, but all were approved by our board of directors considering similar factors to those described above.

Director Independence

Under the rules and listing standards of The Nasdaq Stock Market LLC, or the Nasdaq Rules, a majority of the members of our board of directors must satisfy the Nasdaq criteria for “independence.” No director qualifies as independent under the Nasdaq Rules unless our board of directors affirmatively determines that the director does not

have a relationship with us that would impair independence (directly or as a partner, stockholder or officer of an organization that has a relationship with us). Our board of directors has determined that Ian Clark, Fred E. Cohen, M.D., D.Phil., Brian Kotzin, M.D., Steve Liapis, Ph.D., Beth Seidenberg, M.D. and Daniel K. Spiegelman are independent directors as defined under the Nasdaq Rules. Dr. Maag is not independent under the Nasdaq Rules as a result of his position as our Chief Executive Officer. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in this Part III, Item 13 above.

Item 14. Principal Accounting Fees and Services.

Fees Paid to Independent Registered Public Accounting Firm

The following table summarizes the aggregate fees paid or accrued by us for professional services provided by BDO USA, P.C., our independent registered public accounting firm, in the fiscal years ended December 31, 2023 and 2022:

	Fiscal Year Ended December 31,	
	2023	**2022**
Audit Fees[1]	$ 883,385	$ 269,283
Audit-Related Fees	—	—
Tax Fees[2]	70,232	—
All Other Fees	—	—
Total Fees	$ 953,617	$ 269,283

(1) Audit fees for the year ended December 31, 2023 were for professional services rendered for the audits of our financial statements, review of interim financial statements, assistance with registration statements filed with the SEC and services that are normally provided by the independent registered public accounting firm in connection with statutory and regulatory filings or engagements. Audit Fees for the year ended December 31, 2023 included $582,000 incurred in connection with the filing of our Registration Statement on Form S-1 in connection with our IPO in February 2024. Audit fees for the year ended December 31, 2022, were for professional services rendered for the audit of our 2022 financial statements.
(2) Tax fees include fees for professional services related to tax compliance and reporting.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, BDO USA, P.C. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee's approval of the scope of the engagement of the independent registered public accounting firm or on an individual case-by-case basis before the independent registered public accounting firm is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee's members, but the decision must be reported to the full Audit Committee at its next scheduled meeting. By the adoption of this policy, the Audit Committee has delegated the authority to pre-approve services to the Chairperson of the Audit Committee, subject to certain limitations.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) *Financial Statements.* The financial statements of Kyverna Therapeutics, Inc. and the report of BDO USA, P.C., Independent Registered Public Accounting Firm, are included in a separate section of this Annual Report on Form 10-K beginning on page F-1.

(b) *Exhibits*. The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit Number	Description	Registrant's Form	Date Filed with the SEC	Exhibit Number
3.1	Amended and Restated Certificate of Incorporation of Kyverna Therapeutics, Inc.	8-K	2/12/2024	3.1
3.2	Amended and Restated Bylaws of Kyverna Therapeutics, Inc.	8-K	2/12/2024	3.2
4.1	Form of Common Stock Certificate.	S-1	1/16/2024	4.1
4.2*	Description of Registrant's Securities.			
10.1#	Kyverna Therapeutics, Inc. Amended and Restated 2019 Stock Plan, as amended, and forms of agreement thereunder.	S-1	1/16/2024	10.1
10.2#	Kyverna Therapeutics, Inc. 2024 Equity Incentive Plan.	S-8	2/8/2024	10.2
10.3#	Kyverna Therapeutics, Inc. 2024 Equity Incentive Plan Form of Stock Option Agreement.	S-1/A	2/1/2024	10.3
10.4#	Kyverna Therapeutics, Inc. 2024 Equity Incentive Plan Form of Restricted Stock Unit Award Agreement.	S-1/A	2/6/2024	10.4
10.5#	Kyverna Therapeutics, Inc. 2024 Employee Stock Purchase Plan.	S-8	2/8/2024	10.5
10.6#	Form of Indemnification Agreement.	S-1/A	2/6/2024	10.6
10.7#	Employment Offer Letter, dated October 4, 2022, between Kyverna Therapeutics, Inc. and Peter Maag, Ph.D.	S-1	1/16/2024	10.7
10.8#	Employment Offer Letter, dated March 23, 2021, between Kyverna Therapeutics, Inc. and James Chung, M.D., Ph.D.	S-1	1/16/2024	10.8
10.9#	Employment Offer Letter, dated July 9, 2021, between Kyverna Therapeutics, Inc. and Karen Walker.	S-1	1/16/2024	10.9
10.10	Amended and Restated Investors' Rights Agreement, dated November 9, 2021.	S-1	1/16/2024	10.10
10.11	Office/Laboratory Lease, dated July 21, 2020, between Kyverna Therapeutics, Inc. and Emery Station Office II, LLC.	S-1	1/16/2024	10.11
10.12	First Amendment to Office/Laboratory Lease, dated November 29, 2021, between Kyverna Therapeutics, Inc. and Emery Station Office II, LLC.	S-1	1/16/2024	10.12

Exhibit Number	Description	Registrant's Form	Date Filed with the SEC	Exhibit Number
10.13†	License and Collaboration Agreement, dated December 29, 2021, between Kyverna Therapeutics, Inc. and Intellia Therapeutics, Inc.	S-1	1/16/2024	10.13
10.14†	Patent License Agreement (License Number L-158-2021-0), dated May 20, 2021, between Kyverna Therapeutics, Inc. and the National Institutes of Health.	S-1	1/16/2024	10.14
10.15†	Patent License Agreement (License Number L-159-2021-0), dated May 27, 2021, between Kyverna Therapeutics, Inc. and the National Institutes of Health.	S-1	1/16/2024	10.15
10.16#	Kyverna Therapeutics, Inc. Non-Employee Director Compensation Program.	S-1/A	2/6/2024	10.16
23.1*	Consent of BDO USA, P.C., Independent Registered Public Accounting Firm.			
24.1*	Power of Attorney (included on the signature page to this Annual Report on Form 10-K).			
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.			
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.			
32.1‡	Certification of the 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 the 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*	Kyverna Therapeutics, Inc. Clawback Policy.			

* Filed herewith

\# Indicates management contract or compensatory plan or arrangement.

† Portions of this exhibit (indicated by […***…]) have been omitted because the registrant has determined that the information is both (i) not material and (ii) of the type that the Registrant treats as private and confidential.

‡ Furnished herewith.

(c) *Financial Statement Schedules*. All financial statement schedules are omitted because they are not applicable or required, or the information required to be set forth therein is included in the consolidated financial statements or notes thereto included in the Index to Financial Statements on Page F-1 of this Annual Report on Form 10-K.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

KYVERNA THERAPEUTICS, INC.

Date: March 26, 2024

By: /s/ Peter Maag, Ph.D.

Peter Maag, Ph.D.
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter Maag, Ph.D. and Ryan Jones, and each of them, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution and full power to act without the other, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ Peter Maag, Ph.D. **Peter Maag, Ph.D.**	Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2024
/s/ Ryan Jones **Ryan Jones**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2024
/s/ Ian Clark **Ian Clark**	Director	March 26, 2024
/s/ Fred E. Cohen, M.D., D.Phil. **Fred E. Cohen, M.D., D.Phil.**	Director	March 26, 2024
/s/ Brian Kotzin, M.D. **Brian Kotzin, M.D.**	Director	March 26, 2024
/s/ Steve Liapis, Ph.D. **Steve Liapis, Ph.D.**	Director	March 26, 2024
/s/ Beth Seidenberg, M.D. **Beth Seidenberg, M.D.**	Director	March 26, 2024
/s/ Daniel Spiegelman **Daniel Spiegelman**	Director	March 26, 2024

Kyverna Therapeutics, Inc.

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements as of and for the Years Ended December 31, 2023 and 2022

Report of Independent Registered Public Accounting Firm

Stockholders and Board of Directors
Kyverna Therapeutics, Inc.
Emeryville, California

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Kyverna Therapeutics, Inc. (the "Company") as of December 31, 2023 and 2022, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the 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 the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

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.

/s/ BDO USA, P.C.

We have served as the Company's auditor since 2020.

San Diego, California

March 26, 2024

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

	December 31,	
	2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 34,647	$ 37,735
Available-for-sale marketable securities	22,896	13,587
Prepaid expenses and other current assets	3,121	1,929
Total current assets	60,664	53,251
Restricted cash	565	554
Property and equipment, net	2,326	2,575
Operating lease right-of-use assets	6,494	8,214
Finance lease right-of-use assets	1,790	1,652
Other non-current assets	3,356	678
Total assets	$ 75,195	$ 66,924
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities		
Accounts payable	$ 4,358	$ 1,451
Accrued compensation	2,812	1,411
Accrued license expense – related party	6,250	6,250
Other current liabilities	3,519	565
Operating lease liabilities, short-term portion	1,964	1,672
Finance lease liabilities, short-term portion	956	605
Total current liabilities	19,859	11,954
Operating lease liabilities, net of short-term portion	5,238	7,209
Finance lease liabilities, net of short-term portion	921	1,078
Other long-term liabilities	—	6
Total liabilities	26,018	20,247
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, $0.00001 par value, 114,556,997 and 97,462,067 shares authorized as of December 31, 2023 and 2022, respectively; 114,556,997 and 82,504,003 shares issued and outstanding as of December 31, 2023 and 2022, respectively; liquidation preference of $181,273 and $121,273 as of December 31, 2023 and 2022, respectively.	180,574	120,674
Stockholders' deficit		
Common stock, $0.00001 par value; 140,492,016 and 117,000,000 shares authorized as of December 31, 2023 and 2022, respectively; 1,250,103 and 1,007,537 shares issued and outstanding as of December 31, 2023 and 2022, respectively; 8,125 and 454,950 shares subject to repurchase as of December 31, 2023 and 2022, respectively.	—	—
Additional paid-in capital	4,642	1,706
Accumulated other comprehensive income (loss)	4	(26)
Accumulated deficit	(136,043)	(75,677)
Total stockholders' deficit	(131,397)	(73,997)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 75,195	$ 66,924

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

Kyverna Therapeutics, Inc.
Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	**2022**
Revenue		
Collaboration revenue - related party	$ —	$ 7,025
Operating expenses		
Research and development	49,923	28,402
General and administrative	12,483	8,007
Total operating expenses	62,406	36,409
Loss from operations	(62,406)	(29,384)
Interest income	2,282	565
Interest expense	(187)	(65)
Other expense, net	(55)	(9)
Total other income, net	2,040	491
Net loss	(60,366)	(28,893)
Other comprehensive gain (loss)		
Unrealized gain (loss) on available-for-sale marketable securities, net	30	(26)
Total other comprehensive gain (loss)	30	(26)
Net loss and other comprehensive loss	$ (60,336)	$ (28,919)
Net loss per share attributable to common stockholders, basic and diluted	$ (89.61)	$ (63.43)
Weighted-average shares of common stock outstanding, basic and diluted	673,622	455,478

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

Kyverna Therapeutics, Inc.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share data)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance at December 31, 2021	76,093,406	$ 108,720	567,007	$ —	$ 530	$ (46,784)	$ —	$ (46,254)
Issuance of Series B redeemable convertible preferred stock for cash, net of issuance costs of $45	6,410,597	11,954	—	—	—	—	—	—
Vesting of early exercised options and restricted stock	—	—	—	—	72	—	—	72
Common shares issued upon exercise of options	—	—	91,209	—	175	—	—	175
Common shares issued upon early exercise of options	—	—	349,321	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	929	—	—	929
Net loss	—	—	—	—	—	(28,893)	—	(28,893)
Unrealized loss on available-for-sale marketable securities, net	—	—	—	—	—	—	(26)	(26)
Balance at December 31, 2022	82,504,003	$ 120,674	1,007,537	$ —	$ 1,706	$ (75,677)	$ (26)	$ (73,997)
Issuance of Series B redeemable convertible preferred stock for cash, net of issuance costs of $100	32,052,994	59,900	—	—	—	—	—	—
Vesting of early exercised options and restricted stock	—	—	—	—	71	—	—	71
Common shares issued upon exercise of options	—	—	242,566	—	645	—	—	645
Stock-based compensation expense	—	—	—	—	2,220	—	—	2,220
Net loss	—	—	—	—	—	(60,366)	—	(60,366)
Unrealized gain on available-for-sale marketable securities, net	—	—	—	—	—	—	30	30
Balance at December 31, 2023	114,556,997	$ 180,574	1,250,103	$ —	$ 4,642	$ (136,043)	$ 4	$ (131,397)

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

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

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (60,366)	$ (28,893)
Adjustments to reconcile net loss to net cash used by operations:		
Stock-based compensation	2,220	929
Accretion of discounts on available-for-sale marketable securities	(1,115)	(284)
Depreciation and amortization expense	1,707	1,051
Non-cash lease expense	1,720	1,411
Changes in assets and liabilities:		
Prepaid expense and other current assets	(1,192)	(909)
Other non-current assets	(1,849)	(637)
Accounts payable	4,083	677
Accrued compensation	1,401	270
Other current liabilities	2,660	(10)
Operating lease liability	(1,679)	(1,068)
Accrued license expense	—	(1,625)
Deferred revenue – related party	—	(7,025)
Net cash used in operating activities	(52,410)	(36,113)
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(54,847)	(56,495)
Proceeds from maturities of available-for-sale marketable securities	46,683	38,706
Proceeds from sales of available-for-sale marketable securities	-	4,460
Purchases of property and equipment	(621)	(768)
Net cash used in investing activities	(8,785)	(14,097)
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	59,900	11,954
Proceeds from exercise of common stock options	645	175
Principal paid on finance lease liabilities	(781)	(249)
Payments for deferred offering costs	(1,646)	—
Net cash provided by financing activities	58,118	11,880
Net decrease in cash and cash equivalents and restricted cash	(3,077)	(38,330)
Cash, cash equivalents and restricted cash, at beginning of period	38,289	76,619
Cash, cash equivalents and restricted cash, at end of period	$ 35,212	$ 38,289
Reconciliation of cash, cash equivalents and restricted cash to statement of financial position		
Cash and cash equivalents	34,647	37,735
Restricted cash	565	554
Cash, cash equivalents and restricted cash at end of period	$ 35,212	$ 38,289
Supplemental disclosure for non-cash investing and financing activities		
Unpaid deferred offering costs included in accounts payable and other current liabilities	$ 829	$ —
Purchase of property and equipment in accounts payable	$ —	$ 4
Vesting of restricted stock	$ 71	$ 72
Right-of-use asset obtained in exchange for operating and finance lease liability	$ 975	$ 6,326
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 187	$ 65

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

Kyverna Therapeutics, Inc.
Notes to the Financial Statements

1. Description of Business, Organization and Liquidity

Kyverna Therapeutics, Inc. ("Kyverna" or "the Company") is a patient-centered, clinical-stage biopharmaceutical company focused on developing cell therapies for patients suffering from autoimmune diseases. The lead product candidate, KYV-101, is advancing through clinical development across two broad areas of autoimmune disease: rheumatology and neurology. The Company was incorporated on June 14, 2018, was initially named BAIT Therapeutics, Inc., changed its name to Kyverna Therapeutics, Inc. on October 1, 2019, and is headquartered in Emeryville, California.

Initial Public Offering

On February 7, 2024, the Company's Registration Statement on Form S-1 for its initial public offering (the "IPO") was declared effective, and on February 12, 2024, the Company closed the IPO and issued 16,675,000 shares of common stock at a price to the public of $22.00 per share, including 2,175,000 shares issued upon the exercise of underwriters' option to purchase additional shares of common stock. The Company received gross proceeds of $366.9 million. Net proceeds were approximately $336.2 million, after deducting underwriting discounts and commissions and estimated other offering costs totaling approximately $30.7 million. On February 8, 2024, the Company's common stock began trading on the Nasdaq Global Select Market under the symbol "KYTX". Immediately prior to the IPO closing, all of the outstanding shares of the Company's redeemable convertible preferred stock converted into shares of the Company's common stock on a 1-for-4.5511 basis.

Reverse Stock Split

On January 30, 2024, the Company's shareholders approved and the Company effected a reverse stock split of the shares of common stock at a ratio of 1-for-4.5511 (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, restricted stock awards, restricted stock units and options to purchase common stock, share data, per share data, and related information contained in the financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The conversion ratios for each series of the Company's redeemable convertible preferred stock, which was automatically converted into shares of common stock upon the closing of the IPO, were proportionally adjusted.

Liquidity

The Company has incurred losses and negative cash flows from operations since inception. As of December 31, 2023, the Company has an accumulated deficit of approximately $136.0 million. The Company had net losses of $60.4 million and $28.9 million for the years ended December 31, 2023 and 2022, respectively.

The Company has historically financed its operations primarily through issuances of redeemable convertible preferred stock and convertible notes and revenue from its collaboration agreement. As of December 31, 2023, the Company had cash and cash equivalents and available-for-sale marketable securities of $57.5 million. On February 12, 2024, the Company closed the IPO and received gross proceeds of $366.9 million. Net proceeds were approximately $336.2 million, after deducting underwriting discounts and commissions and estimated other offering costs. The Company expects to continue to incur operating losses and negative cash flows from operations to support the development of its product candidates, for the expansion of its product portfolio and to continue its research and development activities, including preclinical studies and clinical trials. The Company's activities are subject to significant risks and uncertainties, including completing requisite clinical activities to support regulatory approvals, market acceptance of the Company's product candidates, if approved, as well as the timing and extent of spending on research and development. There can be no assurance that the Company will ever earn revenue or achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis. Unless and until it does, the Company will need to continue to raise additional capital. Based on its current operating plan, management estimates that its existing cash and cash equivalents, including the proceeds from the IPO, will be

sufficient to fund its operating plan and capital expenditure requirements for at least the next 12 months from the date of issuance of these financial statements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP").

Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates and assumptions, including those related to research and development accrued expenses, valuation of its common stock prior to the IPO, stock-based compensation, valuation of deferred tax assets and uncertain income tax positions. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the amount reported as revenue and expenses that are not readily apparent from other sources. Actual results may differ materially from those estimates.

Segment Information

The Company operates and manages its business as one reportable and operating segment, which is the business of developing therapies for autoimmune and inflammatory diseases. The chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of the Company's long-lived assets are located in the United States. All of the Company's collaboration revenue was derived from a related-party customer headquartered in the United States.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking accounts and money market funds. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Restricted Cash

As of each of December 31, 2023 and 2022, the Company had $0.6 million of long-term restricted cash held as security for the Company's building lease. The entire amount is deposited with a financial institution and held in separate bank accounts.

Available-For-Sale Marketable Securities

Available-for-sale marketable securities as of December 31, 2023, consist of U.S treasury bills with original maturities of greater than 90 days. As the Company's entire investment portfolio is considered available for use in current operations, the Company classifies all investments as available-for-sale and as current assets, even though the stated maturity may be more than one year from the current balance sheet date. The Company carries available-for-sale marketable securities at fair value. Unrealized gains and losses on available-for-sale debt marketable securities are reported in accumulated other comprehensive loss, which is a separate component of stockholders'

deficit. The cost of available-for-sale debt marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. The amortization and accretion are included in interest income together with interest and dividends. The cost of securities sold is based on the specific identification method.

Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. The Company regularly reviews its investment portfolio to determine if any security is impaired, which would require it to record an allowance for credit losses or an impairment charge in the period any such determination is made. In making this judgment, the Company evaluates, among other things, the extent to which the fair value of a security is less than its amortized cost, its intent to sell or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis, the financial condition of the issuer and any changes thereto, and, as necessary, the portion of a decline in fair value that is credit-related. This assessment could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses, allowances for credit losses and impairments on available-for-sale securities, if any, are recorded to interest expense in the statements of operations and comprehensive loss. Interest receivable is recognized in prepaid expenses and other current assets on the balance sheet.

Concentrations of Credit Risk

Cash, cash equivalents, restricted cash and available-for-sale marketable securities are financial instruments that potentially subject the Company to concentrations of credit risk. The Company's cash and restricted cash were deposited with one financial institution, with deposit balances in excess of federally insured limits. As of December 31, 2023, the Company also had investments in money market funds and U.S. Treasury bills, which can be subject to certain credit risks. The Company mitigates the risks by investing in high-grade instruments, limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any material losses on its financial instruments and has full access to and control over all of its cash, cash equivalents and available-for-sale marketable securities.

All of the Company's collaboration revenue was derived from its collaboration, option and license agreement with Gilead Sciences, Inc. (the "Gilead Agreement") (see Note 6).

Other Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on its future financial position or results of operations: the Company's ability to advance the development of its analytics platform and timing and ability to advance its product candidates through preclinical and clinical development; costs and timelines associated with the manufacturing of clinical supplies; regulatory approval, market acceptance of, and reimbursement for, any product candidates the Company may develop; performance of third-party vendors; competition from pharmaceutical or other biotechnology companies with greater financial resources or expertise; protection of intellectual property; litigation or claims against the Company based on intellectual property or other factors; and its ability to attract and retain employees necessary to support its growth.

The Company's business and operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges, such as the effects of the ongoing geopolitical conflicts in Ukraine and in Gaza, tensions in U.S.-China relations, uncertainty in the markets, including disruptions in the banking industry and inflationary trends.

Fair Value Measurement

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The carrying amounts of cash equivalents, prepaid expenses and other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities. Financial instruments, such as money market funds and available-for-sale marketable securities, are measured at fair value at each reporting date (see Note 3).

Deferred Finance Issuance Costs

Deferred finance issuance costs, consisting of legal, accounting and other third-party fees directly relating to in-process equity financings or offerings, are capitalized. The deferred finance issuance costs are offset against offering proceeds upon the completion of the financing or the offering. The Company had $2.5 million and zero deferred finance issuance costs recorded as other non-current assets as of December 31, 2023 and 2022, respectively.

Property and Equipment

Property and equipment are recorded at cost, net of accumulated depreciation and amortization. Depreciation is recorded using the straight-line method over the estimated useful lives of the assets. Property and equipment consisted almost exclusively of assets with useful lives of five years. Leasehold improvements are capitalized and amortized over the shorter of the expected life or lease term. Major replacements and improvements are capitalized, while general repairs and maintenance are expensed as incurred.

Leases

The Company determines whether an arrangement is a lease at inception. Specifically, it considers whether it controls the underlying asset and has the right to obtain substantially all of the economic benefits or outputs from the asset. If the contractual arrangement contains a lease, the Company then determines the classification of the lease, operating or finance, using the classification criteria described in ASC Topic 842, *Leases* ("ASC 842"). Operating and finance lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. Operating lease expense is recognized on a straight-line basis over the lease term. For finance leases, the right-of-use asset is amortized on a straight-line basis over the shorter of the useful life of the asset or the lease term, and interest expense on the lease liability is recorded separately using the interest method.

The Company has elected not to separate lease components from non-lease components for all classes of underlying assets, and instead accounts for the lease and non-lease components as a single component. Variable lease payments are recognized as they are incurred and primarily include common area maintenance, utilities, real estate taxes, insurance and other operating costs that are passed on from the lessor in proportion to the space leased by the Company. The Company does not recognize lease assets and lease liabilities for leases with an original lease term of 12 months or less.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether the transaction should be accounted for as a business combination or an asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether the Company has acquired inputs and processes that have the ability to create outputs which would meet the definition of a business. Significant judgment is required in the application of the screen test to determine whether an acquisition is a business combination or an acquisition of assets.

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 with no alternative future use is charged to research and development expense at the acquisition date.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty of the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses in the statements of operations and comprehensive loss.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, principally property and equipment and operating and finance right-of-use assets, for impairment whenever events or changes in business circumstances indicate the carrying amount of an asset may not be fully recoverable. Recoverability of assets held and used is measured by comparing the carrying amount of an asset to future net cash flows expected to be generated by the asset. If the Company determines that the carrying value of long-lived assets may not be recoverable, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Fair value is determined through various valuation techniques, principally discounted cash flow models, to assess the fair values of long-lived assets. The Company did not record any impairment of long-lived assets during the years ended December 31, 2023 and 2022.

Redeemable Convertible Preferred Stock

The Company records redeemable convertible preferred stock at fair value on the date of issuance, net of issuance costs. The redeemable convertible preferred stock is recorded separate from stockholders' deficit because the shares contain deemed liquidation features that are not solely within the Company's control. The holders of the preferred stock control a majority of the votes of the board of directors of the Company through direct representation. Accordingly, the preferred stock is classified as temporary equity in the Company's balance sheets. The Company has not adjusted the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such stock because it is uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such a deemed liquidation event will occur. In connection with the closing of the IPO in February 2024, all outstanding shares of redeemable convertible preferred stock were converted into shares of common stock on a 1-for-4.5511 basis.

Collaboration Arrangements and Contracts with Customers

In January 2020, the Company entered into the Gilead Agreement (see Note 6). The Company concluded that the Gilead Agreement was in the scope of revenue recognition guidance, ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

In accordance with ASC 606, revenue is recognized when a customer, or licensee, obtains control of promised goods or services (*e.g.*, an intellectual property license or research services). The amount of revenue recognized reflects the consideration that the Company expects to be entitled to receive in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps: (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when or as the Company satisfies a performance obligation.

The terms of revenue agreements may include (i) licenses for the Company's technology or programs, (ii) research and development services and (iii) services or obligations in connection with participation in research or steering committees. Payments to the Company under these arrangements typically include one or more of the following: nonrefundable upfront and license fees, research funding and milestone and other contingent payments to the Company for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

The Company assesses whether the promises in its arrangements with customers, including any options provided to a customer, are considered as distinct performance obligations that should be accounted for separately. Judgment is required to determine whether the license to the Company's intellectual property is distinct from the research and development services or participation on steering committees.

The Company's collaboration and license agreements may include contingent payments related to specified research, development and regulatory milestones and payments related to sales-based milestones and royalties.

Milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting date, the Company re-evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price by using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price in such period of determination. Sales-based milestone payments and royalties are typically payable when annual sales of a covered product reach specified levels and sales occur. When an intellectual property license is determined to be a predominant promise in the arrangement, sales-based milestone payments and royalties are recognized at the later of when the associated performance obligation has been satisfied or when the sales occur. Unlike other contingency payments, such as regulatory milestone payments, sales-based milestone payments and royalties are not included in the transaction price based on estimates at the inception of the contract, but rather, are included when the sales or usage occur.

The transaction price in each arrangement is allocated to the identified performance obligations based on the relative standalone selling price ("SSP") of each distinct performance obligation, which requires judgment. In instances where SSP is not directly observable, such as when a license or service is not sold separately, SSP is determined using information that may include market conditions and other observable inputs. Due to the early stage of the Company's licensed technology, the license of such technology is typically combined with research and development services and steering committee participation as one performance obligation. The Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

In cases when an upfront payment contains material rights for the optional services the Company may provide in the future, the material right is treated as a separate performance obligation. The value allocated to such material right is deferred and recognized as revenue when the performance obligation is satisfied and the optional services are provided.

Contract Liabilities

Funds received in advance are recorded as deferred revenue, which is a contract liability, and are recognized as the related performance obligation is satisfied.

Research and Development Expenses

Research and development expenses are charged to expense as incurred. Research and development expenses include certain payroll and personnel expenses, license fees, laboratory supplies, consulting costs, external contract research and development expenses and allocated overhead, including rent, equipment depreciation and utilities. Advance payments for goods or services for future research and development activities are deferred as prepaid expenses and expensed as the goods are delivered or the related services are performed.

The Company has entered into various agreements with outsourced vendors, clinical manufacturing organizations ("CMOs") and clinical research organizations ("CROs"). The Company makes estimates of accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs.

The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses on the balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly. Payments made under these arrangements in advance of the performance of the related services are recorded as prepaid expenses and other current assets until the services are rendered.

Stock-Based Compensation Expense

The Company accounts for stock-based compensation by measuring and recognizing compensation expense for all stock-based payments based on estimated grant-date fair values. For awards with service-based vesting conditions, the Company recognizes stock-based compensation expense on a straight-line basis over the requisite service or vesting period.

The Company estimates the fair value of stock options using the Black-Scholes option-valuation model. The Black-Scholes model requires the input of subjective assumptions, including expected volatility, expected dividend yield, expected term, risk-free rate of return and the estimated fair value of the underlying common stock on the date of grant. The Company accounts for forfeitures as they occur. The fair value of restricted stock awards granted to employees is valued as of the grant date using the estimated fair value of the Company's common stock.

Foreign Currency Transactions

Transactions denominated in foreign currencies are initially measured in U.S. dollars using the exchange rate on the date of the transaction. Foreign currency denominated monetary assets and liabilities are subsequently remeasured at the end of each reporting period using the exchange rate at that date, with the corresponding foreign currency transaction gain or loss recorded in the statements of operations and comprehensive loss.

Net Loss Per Share Attributable to Common Stockholders

Basic net loss per common share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. For purposes of the diluted net loss per share calculation, the redeemable convertible preferred stock, common stock subject to repurchase, unvested restricted stock units and stock options are considered to be potentially dilutive securities.

Basic and diluted net loss attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and common stock subject to repurchase are considered participating securities. The redeemable convertible preferred stock does not have a contractual obligation to share in the Company's losses, and common stock subject to repurchase is considered an unvested stock-based compensation award for accounting purposes. As such, the net loss is attributed entirely to common stockholders. Because the Company has reported a net loss for the reporting periods presented, the diluted net loss per common share is the same as basic net loss per common share for those periods.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive loss. Other comprehensive loss represents unrealized gains and losses arising during the period on available-for-sale marketable securities.

Income Taxes

The Company accounts for income taxes using the liability method; under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting basis of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain.

In evaluating the ability to recover its deferred income tax assets, the Company considers all available positive and negative evidence, including its operating results, ongoing tax planning and forecasts of future taxable income on a jurisdiction-by-jurisdiction basis. In the event the Company determines that it would be able to realize its deferred income tax assets in the future in excess of their net recorded amount, it would make an adjustment to the valuation allowance that would reduce the provision for income taxes. Conversely, if all or part of the net deferred

tax assets are determined not to be realizable in the future, an adjustment to the valuation allowance would be charged to the provision of income taxes in the period when such determination is made.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Tax positions that meet the more-likely-than-not threshold are measured at the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with the taxing authority. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* to amend the current accounting standard, which requires the measurement of all expected losses to be based on historical experience, current conditions and reasonable and supportable forecasts. For trade receivables, contract assets and other financial instruments, the Company will be required to use a forward-looking expected loss model that reflects probable losses rather than the incurred loss model for recognizing credit losses. The Company adopted this standard effective January 1, 2023, and amended its disclosures and accounting policy as related to available-for-sale marketable securities in accordance with the standard. There were no changes to the Company's operating results, balance sheets and cash flows as a result of the adoption of this standard.

In August 2020, the FASB issued ASU 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"), which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Specifically, ASU 2020-06 simplifies accounting for the issuance of convertible instruments by removing major separation models required under current GAAP. In addition, the ASU removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception and simplifies the diluted earnings per share calculation in certain areas. The Company adopted this standard effective January 1, 2023, which did not have an impact on the Company's financial statements.

New Accounting Pronouncements Not Yet Adopted

In October 2023, the FASB issued ASU 2023-06, Disclosure Improvements: *Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*. This ASU aligns the requirements in the ASC to the removal of certain disclosure requirements set out in Regulation S-X and Regulation S-K, announced by the Securities and Exchange Commission ("SEC"). The effective date for each amended topic in the ASC is either the date on which the SEC's removal of the related disclosure requirement from Regulation S-X or Regulation S-K becomes effective, or on June 30, 2027, if the SEC has not removed the requirements by that date. Early adoption is prohibited. The Company is currently evaluating the impact of the adoption of this standard on its financial statements.

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): *Improvements to Reportable Segment Disclosures*. This ASU requires public entities to disclose information about their reportable segments' significant expenses and other segment items on an interim and annual basis. Public entities with a single reportable segment are required to apply the disclosure requirements in ASU 2023-07, as well as all existing segment disclosures and reconciliation requirements in ASC 280 on an interim and annual basis. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact of the adoption of this standard on its financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*. This ASU requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. ASU 2023-09 is

effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact the adoption of this standard on its financial statements.

3. Fair Value Measurements and Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements, as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

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

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

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

The Company's fair value hierarchy for its cash equivalents and available-for-sale marketable securities measured at fair value on a recurring basis as of December 31, 2023, was as follows (in thousands):

	Fair Value Measurements			
As of December 31, 2023	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents				
Money market funds	$ 29,050	$ 29,050	$ —	$ —
Available-for-sale marketable securities				
U.S. Treasury bills	22,896	—	22,896	—
Total fair value of assets	$ 51,946	$ 29,050	$ 22,896	$ —

The Company's fair value hierarchy for its cash equivalents and available-for-sale marketable securities measured at fair value on a recurring basis as of December 31, 2022, was as follows (in thousands):

	Fair Value Measurements			
As of December 31, 2022	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents				
Money market funds	$ 13,713	$ 13,713	$ —	$ —
Available-for-sale marketable securities				
U.S. Treasury notes	6,378	—	6,378	—
U.S. Treasury bills	7,209	—	7,209	—
Total fair value of assets	$ 27,300	$ 13,713	$ 13,587	$ —

Financial assets measured at fair value on a recurring basis consist of the Company's cash equivalents and available-for-sale marketable securities. Cash equivalents consisted of money market funds, and available-for-sale marketable securities consisted of U.S. Treasury notes and bills. The Company obtains pricing information from its investment manager and generally determines the fair value of available-for-sale marketable securities using standard observable inputs, including reported trades, broker/dealer quotes and bids and/or offers. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

4. Available-for-Sale Marketable Securities

As of December 31, 2023, the Company's available-for-sale marketable securities consisted entirely of debt securities issued by the U.S. Treasury with contractual maturities on various dates through February 2024.

The following table summarizes the amortized cost, unrealized gains and losses and fair value of the Company's available-for-sale marketable securities as of December 31, 2023 (in thousands):

As of December 31, 2023:	Total Amortized Cost	Total Unrealized Gains	Total Unrealized Losses	Total Estimated Fair Value
U.S. Treasury bills	$ 22,892	$ 4	$ —	$ 22,896
Total available for sale marketable securities	$ 22,892	$ 4	$ —	$ 22,896

The following table summarizes the amortized cost, unrealized gains and losses and fair value of the Company's available-for-sale marketable securities as of December 31, 2022 (in thousands):

As of December 31, 2022:	Total Amortized Cost	Total Unrealized Gains	Total Unrealized Losses	Total Estimated Fair Value
U.S. Treasury notes	$ 6,396	$ —	$ (18)	$ 6,378
U.S. Treasury bills	7,217	—	(8)	7,209
Total available for sale marketable securities	$ 13,613	$ —	$ (26)	$ 13,587

As of December 31, 2023 and 2022, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the Company's marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its investments were not significantly impacted by such conditions. For all securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for losses has been recorded. During the years ended December 31, 2023 and 2022, the Company did not recognize any impairment losses on its investments.

As of each of December 31, 2023 and 2022, accrued interest receivable was zero and less than $0.1 million, respectively. The Company's accounting policy is to not measure an allowance for credit losses for accrued interest receivables and to write-off any uncollectible accrued interest receivable as a reversal of interest income in a timely manner, which it considers to be in the period in which the Company determines the accrued interest will not be collected. The Company has not written off any accrued interest receivables for the year ended December 31, 2023.

5. Property and Equipment, Net

Property and equipment, net, consists of the following (in thousands):

	December 31,	
	2023	2022
Laboratory equipment	$ 3,409	$ 3,065
Computer equipment and software	138	138
Furniture and fixtures	622	534
Leasehold improvements	645	456
Property and equipment, gross	4,814	4,193
Less accumulated depreciation	(2,488)	(1,618)
	$ 2,326	$ 2,575

Depreciation expense related to property and equipment was approximately $0.9 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively.

6. Significant Agreements

Gilead Collaboration, Option and License Agreement (Related Party)

In January 2020, the Company entered into the Collaboration, Option and License Agreement (the "Gilead Agreement") with Gilead Sciences, Inc. ("Gilead"). Simultaneously with the entry into the Gilead Agreement, the Company entered into (i) a License Agreement (the "Kite Agreement") with Kite Pharma, Inc. ("Kite"), an affiliate of Gilead (see below), and (ii) a stock purchase agreement, pursuant to which the Company issued to Gilead an aggregate of 6,890,744 shares of its Series A-2 Preferred Stock, of which 4,042,066 shares were issued as consideration under the Kite Agreement (see below).

Pursuant to the Gilead Agreement, the Company and Gilead collaborated to develop potential cell-based therapy products, which could use the SynNotch Technology and the SynNotch intellectual property related thereto, controlled by Gilead through Kite, for the treatment, diagnosis or prevention of autoimmune, inflammatory, or allogeneic stem cell transplant inflammatory diseases (excluding post-transplant infectious diseases), subject to certain exceptions. The Gilead Agreement initially involved the research and development of cell-based products for the treatment, diagnosis or prevention of two indications under two research programs and non-exclusive research licenses, specifically, Crohn's disease, or Program A, and Ulcerative colitis, or Program B. Upon execution of the Gilead Agreement, Gilead paid the Company a one-time, non-refundable and non-creditable payment of $17.5 million.

Pursuant to the Gilead Agreement, the Company also granted Gilead, on a research program-by-program basis, an exclusive option, exercisable at any time during the Option Period for such program, to obtain an exclusive license under such program's intellectual property to develop, manufacture, and commercialize optioned products belonging to such program for a specified fee and on the terms and conditions set out in the Gilead Agreement. For purposes of the foregoing, an Option Period meant, on a program-by-program basis, the period commencing on the date of execution of the Gilead Agreement and ending upon the earlier of (i) the expiration of the review period for such program, and (ii) the ten-year anniversary of the date of execution of the Gilead Agreement.

Unless terminated earlier, the Gilead Agreement was to expire, with respect to each program, (i) upon such program becoming a terminated program, or (ii) on an optioned product-by-optioned product and country-by-country basis, upon the expiration of the royalty term with respect to such optioned product in such country with respect to such program. Gilead had the right to terminate the Gilead Agreement at will, in its sole discretion, in its entirety or on a program-by-program or optioned program-by-optioned program basis at any time upon ninety days' prior written notice to the Company. In addition, either party was able to terminate the Gilead Agreement for uncured material breach by the other party, or upon the occurrence of insolvency-related events of the other party.

The royalty term under the Gilead Agreement continued on an optioned product-by-optioned product and country-by-country basis until the latest of: (i) the date on which there is no valid claim of a program patent; (ii) the expiration of any regulatory exclusivity with respect to such optioned product in the relevant country; and (iii) the ten-year anniversary of the date of the first commercial sale of such optioned product in such country.

The Company concluded that the Gilead Agreement was in the scope of ASC Topic 606. The Company estimated the transaction price as $17.5 million, which was allocated to two performance obligations, Program A and Program B, based on the relative fair value of each program. Other milestone payments were constrained and not included in the transaction price as they were considered not probable as of December 31, 2022. The Company recognized $7.0 million as collaboration revenue during the year ended December 31, 2022. On November 30, 2022, after the completion of research activities under Program A and Program B, Gilead provided the Company with notice that Program A and Program B were terminated. As of December 31, 2023 and 2022, there were no other active programs under the Gilead Agreement and deferred revenue was zero. Deferred revenue as of December 31, 2021 was $7.0 million, which was fully recognized as collaboration revenue during the year ended December 31, 2022.

On October 24, 2023, after agreement by both parties that the Gilead Agreement had no active programs, Gilead provided the Company with 90 days' written notice to terminate the Gilead Agreement, and such termination became effective as of January 22, 2024.

Kite License Agreement (Related Party)

Concurrently with the Gilead Agreement, the Company entered into the Kite Agreement. Pursuant to the Kite Agreement, Kite granted to the Company a ten-year, co-exclusive license for the SynNotch technology primarily used in the Company's own internal research and development programs for the treatment, diagnosis or prevention of autoimmune, inflammatory or allogeneic stem cell transplant inflammatory diseases (excluding post-transplant infectious diseases). Upon expiration of the ten-year co-exclusive license term, the license will become a non-exclusive license through expiration of the related patents.

Kite had licensed certain of the SynNotch technology included in the Kite Agreement pursuant to that certain Amended and Restated Exclusive License Agreement, between The Regents of the University of California and Kite (as successor to Cell Design Labs, Inc.), or the UCSF License Agreement. The Company is responsible for all costs and payments arising under the UCSF License Agreement and as a result of activities under the Kite Agreement, including earned royalties based on a low single-digit percentage of net sales, milestone payments in an aggregate amount of up to $10.8 million and accrued interest payables.

Pursuant to the Kite Agreement, the Company is also obligated to pay mid-teen-and mid-single-digit percentages of annual maintenance fees, minimum annual royalties and patent prosecution costs payable under the UCSF License Agreement during the co-exclusive term and non-exclusive term, respectively. The Company was also obligated to pay a $6.3 million sublicensing fee under the UCSF License Agreement, which the Company agreed to offset with future milestone payments payable by Gilead under the Gilead Agreement.

Unless terminated earlier, the Kite Agreement will expire upon the expiration of all licensed patents and Kite improvement patents therein. The Company has the right to terminate the Kite Agreement at will, in the Company's sole discretion, in its entirety upon 90 days' written notice to Kite. In addition, either party may terminate the Kite Agreement for uncured material breach by the other party, or upon the occurrence of insolvency-related events of the other party.

In January 2020, as a consideration for the license, the Company issued to Gilead an aggregate of 4,042,066 shares of Series A-2 Preferred Stock at a price per share of $0.8776, which was the purchase price paid by other investors in the Series A-2 Preferred Stock financing, for a total of $3.5 million.

The acquisition of the co-exclusive license under the Kite Agreement, including patent rights and know-how, was accounted for as an asset acquisition. As the acquired technology did not have an alternative use for accounting purposes, the license consideration of $3.5 million and the sublicensing fee of $6.3 million was recorded as a research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2020.

As of December 31, 2023 and 2022, the Company recognized the total sublicensing fee of $6.3 million as current accrued license expense—related party, of which $2.5 million became payable as a result of the qualified financing. The Company expects to pay such amount of $2.5 million by mid-2024. The remaining $3.8 million was available to be offset against future milestones payable by Gilead under the Gilead Agreement; however, due to the termination of the Gilead Agreement, there are no future milestones payable to offset the sublicensing fee, and the payment schedule for the remaining $3.8 million of the sublicensing fee has not been agreed to by the Company and Gilead.

The annual maintenance fee, patent prosecution costs and minimal annual royalties are expensed as incurred and were minimal for each of the years ended December 31, 2023 and 2022.

Intellia License and Collaboration Agreement (Related Party)

In December 2021, the Company entered into a License and Collaboration Agreement (the "Intellia Agreement") with Intellia Therapeutics, Inc. ("Intellia") to research and develop an allogeneic CD19-directed CAR cell therapy product (the "CRISPR Product"), suitable for validation through pre-clinical and clinical proof-of-concept clinical trials, including the performance of activities as agreed in the collaboration plan. Pursuant to the Intellia Agreement, Intellia granted to the Company an exclusive, worldwide, sublicensable in multiple tiers, royalty

bearing license under certain of Intellia's intellectual property to research, develop, sell and otherwise exploit the CRISPR Product. The Company is performing the majority of the work under the collaboration plan.

As consideration for the licenses granted to the Company pursuant to the Intellia Agreement, the Company issued to Intellia 3,739,515 shares of its Series B Preferred Stock at a price of $1.8719 per share, which was the price paid by other investors in the Company's Series B Preferred Stock financing, for consideration of $7.0 million. Intellia also purchased 1,602,649 shares of Series B Preferred Stock at a price of $1.8719 per share under the Series B Preferred Stock Purchase Agreement in cash for total proceeds to the Company of $3.0 million. The Company is also obligated to make aggregate milestone payments to Intellia of up to $64.5 million upon the achievement of specified development and regulatory milestones and is obligated to pay to Intellia low to mid-single-digit royalties as a percentage of annual worldwide sales, subject to certain adjustments, and additional potential royalties and milestones to Intellia's licensors. The royalties are payable on a country-by-country basis, commencing upon the first commercial sale of the CRISPR Product in the applicable country and expiring upon the later of (i) 12 years after the first commercial sale or (ii) the expiration of the last-to-expire valid patent claim.

Under the Intellia Agreement, Intellia owns rights, title and interests in and to any intellectual property developed in the course of performance under the Intellia Agreement that is not specifically directed to the CRISPR Product. The Company granted to Intellia certain non-exclusive, royalty-free, fully paid-up, worldwide licenses under the Company's intellectual property solely to perform the activities designated to Intellia under the collaboration, and to research, develop or otherwise exploit any human therapeutic product that is developed or commercialized by Intellia, utilizes or incorporates Intellia intellectual property and that is not the CRISPR Product or any product directed to CD19 or any other B-cell antigen.

In addition, the Company granted Intellia an exclusive option (the "Intellia Option") to enter into a co-development and co-commercialization agreement with the Company for the CRISPR Product, (the "Co-Co Agreement") for a fee payable to the Company. If Intellia exercises the Intellia Option, the Company and Intellia would share equally the regulatory and clinical development expenses associated with obtaining approval of the CRISPR Product in the U.S. and would also share equally all net profits and losses from commercialization of the CRISPR Product in the U.S. If Intellia exercises the Intellia Option, no milestone payments will be due and payable from that time forward and the Company will only pay royalties on sales outside of the U.S. In addition, upon exercise of the Intellia Option, following regulatory approval of the CRISPR Product, Intellia will have exclusive commercialization rights for the CRISPR Product for U.S. administration, subject to the Company's rights to co-promote the CRISPR Product in the U.S., and the Company will retain the sole and exclusive rights to research, develop, or otherwise exploit the CRISPR Product for rest-of-world administration and shall have sole decision-making authority in relation thereto, subject to the parties' obligations to cooperate regarding certain development, regulatory and commercialization strategies.

During the term of the Co-Co Agreement, subject to certain exceptions, neither party will clinically develop or commercialize a cell therapy product directed to CD19 other than the CRISPR Product for use in the treatment or prevention of certain indications set forth in the Intellia Agreement and any additional indication that the parties mutually agree to include (any such product, a Competitive Product); provided, however, that (i) any products for use in any indications that are the subject of a development program or third-party collaboration as of the effective date of the Co-Co Agreement shall not be considered Competitive Products and (ii) any products for use in any additional indications that are the subject of a development program or third-party collaboration as of the date that such additional indications are included in the global development plan shall not be considered Competitive Products.

The Intellia Agreement terminates on a country-by-country basis upon the expiration of the last valid claim within Intellia's patent rights covering the CRISPR Product within such country, unless the agreement is earlier terminated in its entirety by either party for insolvency, by either party for material breach of contract, by Intellia if the Company participates in legal action or proceeding challenging the validity or enforceability of Intellia's patents, or by the execution of the Co-Co Agreement. The Company may terminate the Intellia Agreement in its entirety, or on a country-by-country basis, by providing a written notice after the expiration or termination of the Intellia Option. Following the expiration of the term for a given country, the licenses granted to the Company in such country will automatically become fully paid-up, perpetual, irrevocable and royalty-free licenses.

No milestone payments were probable or payable as of December 31, 2023 and 2022.

Patent License Agreements with the National Institutes of Health

In May 2021, the Company entered into two patent license agreements (the "NIH Agreements") with the National Institutes of Health (the "NIH"), pursuant to which the Company obtained exclusive, worldwide licenses to certain patents to use an anti-CD19 CAR in the Company's autologous and allogeneic CAR T-cell products for the treatment of patients with autoimmune disease. Upfront consideration of $3.3 million for acquired licenses, was paid 50% in July 2021 and the remaining 50% in May 2022 in accordance with the terms of the NIH Agreements.

Under the NIH Agreements, commencing in January 2023 and subsequently on January 1 of each calendar year thereafter, the Company is also required to make minimum annual royalty payments of $0.2 million, which shall be credited against any earned royalties due based on a low single-digit percentage of net sales made in a respective year. In addition, benchmark royalties following the completion of certain regulatory-and clinical-related benchmarks are due to the NIH, with the minimum cumulative royalty due for a product reaching FDA approval or foreign-equivalent approval totaling approximately $5.7 million for the autologous patent license agreement and approximately $1.7 million for the allogeneic patent license agreement. Additional benchmark royalties would be payable for a subsequent indication under each NIH Agreement. If the Company enters into a sublicensing agreement, it will be required to pay the NIH a sublicense royalty payment as a percentage of the fair market value of any consideration received for each sublicense granted. The sublicensing percentage starts at a high teens to low twenties percentage if clinical trials for the product have not yet begun and decreases to a mid-single-digit percentage if the product has received FDA approval or foreign-equivalent approval.

Unless terminated sooner, the NIH Agreements remain in effect until the last licensed patent right granted pursuant to the respective agreement expires.

The acquisition of the licenses, including patent rights and know-how, was accounted for as an asset acquisition. As the acquired technology did not have an alternative use for accounting purposes, the consideration of $3.3 million was recorded as research and development expense in the statements of operations and comprehensive loss for the year ended December 31, 2021. No benchmark royalties were probable or payable as of December 31, 2023 and 2022.

7. *Commitments and Contingent Liabilities*

License Agreements

The Company entered into license agreements with the NIH, Intellia and Kite (see Note 6), pursuant to which the Company is required to pay certain milestone payments contingent upon the achievement of specific development and regulatory events. No such milestones were achieved or probable as of December 31, 2023 and 2022. The Company is required to pay royalties on sales of products developed under these agreements. The Company's product candidates were in clinical trials or the pre-clinical stage of development as of December 31, 2023 and 2022, and no such royalties were due.

Legal Contingencies

From time to time, the Company may become involved in legal proceedings arising from the ordinary course of business. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment is required to determine both probability and the estimated amount. Management is not aware of any legal matters that could have a material adverse effect on the Company's financial position, results of operations or cash flows.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims

or been required to defend any action related to its indemnification obligations. As of December 31, 2023 and 2022, the Company does not have any material indemnification claims that were probable or reasonably possible.

Leases

In July 2020, the Company entered into a five-year operating lease agreement for a 17,628 square feet facility in Emeryville, California, which lease term commenced in October 2020. In November 2021, the agreement was amended to extend the lease term for an additional 15 months through January 2027. The amended agreement also provides for an additional 15,736 square feet of space (the "Expansion Space") and includes an option to extend the lease for an additional 36 months. The Company obtained 9,512 square feet of the Expansion Space in January 2022 and the remaining 6,224 square feet in September 2022. The November 2021 lease term extension was accounted for as a lease modification with the right-of-use asset and lease liability being remeasured at the modification date. The two extension space modifications were accounted for as separate leases. The Company does not believe that the option to extend the lease is reasonably certain of being exercised, and therefore did not include it in the computations of the present value of the remaining lease payments at lease commencement. In addition to the base rent, which includes escalating payments over the lease term, the Company pays variable costs related to operating expenses and taxes, which are recognized as incurred.

The Company has multiple leases for laboratory equipment with terms of 36 months that are accounted for as finance leases. Some of the Company's office and lab space were leased under short-term lease agreements during the years ended December 31, 2023 and 2022.

Components of the lease expense for the years ended December 31, 2023 and 2022, were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Operating lease cost	$ 2,429	$ 2,076
Finance lease cost:		
Amortization of right-of-use assets	838	276
Interest on lease liabilities	187	65
Short-term lease cost	1	92
Variable lease cost	970	850
Total lease expense	$ 4,425	$ 3,359

Supplemental cash flow information related to leases was as follows for the years ended December 31, 2023 and 2022 (in thousands):

	Year Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 2,384	$ 1,736
Operating cash flows from finance leases	187	65
Financing cash flows from finance leases	781	249
Right-of-use assets obtained in exchange for lease obligations upon inception of lease (noncash):		
Operating leases	—	4,454
Finance leases	975	1,872

The following is a schedule by year of future payments of the Company's lease liabilities as of December 31, 2023 (in thousands):

	Operating Leases	Finance Leases
2024	$ 2,507	$ 1,098
2025	2,619	828
2026	2,821	147
2027	238	—
Total lease payments	8,185	2,073
Less interest	(983)	(196)
Total lease liability balance	7,202	1,877
Less: current portion	(1,964)	(956)
Non-current lease liabilities	$ 5,238	$ 921

The weighted-average remaining lease term and discount rate related to the Company's operating lease liabilities as of December 31, 2023, were 3.1 years and 8%, respectively. The weighted-average remaining lease term and discount rate related to the Company's finance lease liabilities as of December 31, 2023, were 2.0 years and 11%, respectively. The weighted-average remaining lease term and discount rate related to the Company's operating lease liabilities as of December 31, 2022, were 4.1 years and 8%, respectively. The weighted-average remaining lease term and discount rate related to the Company's finance lease liabilities as of December 31, 2022, were 2.6 years and 10%, respectively. The discount rates were based on the Company's estimate of its incremental borrowing rate, as the discount rates implicit in the leases could not be readily determined. As the Company does not have any outstanding debt, the Company estimated the incremental borrowing rate based on its estimated credit rating and available market information.

8. Redeemable Convertible Preferred Stock

As of December 31, 2023 and 2022, the Company's certificate of incorporation authorized the Company to issue up to 114,556,997 and 97,462,067 shares of redeemable convertible preferred stock, respectively, at a par value of $0.00001 per share.

In January 2022, the Company amended its Series B Preferred Stock Purchase Agreement and issued additional 6,410,597 shares of Series B redeemable convertible preferred stock ("Series B Preferred Stock") to new investors for an aggregate cash consideration of $12.0 million at a purchase price of $1.8719 per share. Issuance costs were less than $0.1 million, which were recorded as a reduction to the proceeds received.

In June 2023 and July 2023, the Company issued 32,052,994 additional shares of Series B Preferred Stock to existing and new investors for an aggregate cash consideration of $60.0 million at a price per share of $1.8719, net of $0.1 million issuance costs.

In connection with the IPO in February 2024, all outstanding shares of the Company's redeemable convertible preferred stock automatically converted into 25,171,265 shares of common stock. Subsequent to the closing of the IPO, there were no shares of redeemable convertible preferred stock outstanding.

Redeemable convertible preferred stock as of December 31, 2023 and 2022, consisted of the following (in thousands, except shares):

	December 31, 2023			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series A-1 redeemable convertible preferred stock	8,803,542	8,803,542	$ 7,726	$ 7,696
Series A-2 redeemable convertible preferred stock	24,552,546	24,552,546	21,547	21,490
Series B redeemable convertible preferred stock	81,200,909	81,200,909	152,000	151,388
Total redeemable convertible preferred stock	114,556,997	114,556,997	$ 181,273	$ 180,574

	December 31, 2022			
	Shares Authorized	Shares Issued and Outstanding	Aggregate Liquidation Preference	Net Carrying Value
Series A-1 redeemable convertible preferred stock	8,803,542	8,803,542	$ 7,726	$ 7,696
Series A-2 redeemable convertible preferred stock	24,552,546	24,552,546	21,547	21,490
Series B redeemable convertible preferred stock	64,105,979	49,147,915	92,000	91,488
Total redeemable convertible preferred stock	97,462,067	82,504,003	$ 121,273	$ 120,674

As of December 31, 2023, the holders of the Company's Series A-1 redeemable convertible preferred stock ("Series A-1 Preferred Stock"), Series A-2 redeemable convertible preferred stock ("Series A-2 Preferred Stock") and Series B Preferred Stock had various rights and preferences, including the following:

Liquidation Preference

Upon any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, or any other deemed liquidation event, before any distribution or payment made to the holders of any common stock of the Company (the "Common Stock"), Series A-1 Preferred Stock or A-2 Preferred Stock, the holders of Series B Preferred Stock are entitled to be paid out of the proceeds or assets of the Company an amount equal to the greater of (i) the original issue price of $1.8719 per share, plus any declared and unpaid dividends on each such share, or (ii) such amount per share as would have been payable had all shares of Series B Preferred Stock been converted into Common Stock prior to such liquidation. If, upon any such liquidation event, the assets of the Company are insufficient to make payment of the liquidation preference in full to all holders of Series B Preferred Stock, such assets will be distributed among the holders of Series B Preferred Stock ratably in proportion to the full preferential amount that each such holder is entitled to receive.

After the payment of the full liquidation preference of the holders of Series B Preferred Stock, the holders of Series A-1 Preferred Stock and A-2 Preferred Stock are entitled to be paid out of the proceeds or assets of the Company an amount equal to the greater of (i) the original issue price of $0.8776 per share, plus any declared and unpaid dividends on each such share, or (ii) such amount per share as would have been payable had all shares of Series A-1 Preferred Stock and A-2 Preferred Stock been converted into Common Stock prior to such liquidation. If, upon any such liquidation event, after payment of the full liquidation preference of Series B Preferred Stock, the assets of the Company are insufficient to make payment of the liquidation preference in full to all holders of Series A-1 Preferred Stock and A-2 Preferred Stock, such assets will be distributed among the holders of Series A-1 Preferred Stock and A-2 Preferred Stock ratably in proportion to the full amount that each such holder is entitled to receive.

After the payment of the full liquidation preference of the redeemable convertible preferred stock, the remaining assets of the Company legally available for distribution, if any, will be distributed ratably to the holders of Common Stock.

Conversion

Shares of redeemable convertible preferred stock are convertible into Common Stock at the option of the holder at a conversion ratio that equals to the original issue price for such series, adjusted for any anti-dilution adjustments, divided by the conversion price for such series, in effect on the date of the conversion. The conversion price as adjusted for the reverse stock split is $3.9941 per share for both the Series A-1 Preferred Stock and the Series A-2 Preferred Stock and $8.5193 per share for the Series B Preferred Stock.

Each share of redeemable convertible preferred stock is automatically convertible into shares of Common Stock at the then-effective conversion ratio immediately upon (i) the vote or written consent of the holders of at least 60% of the outstanding shares of redeemable convertible preferred stock, or (ii) the closing of a firm-commitment underwritten public offering with gross proceeds to the Company of at least $50.0 million and a public offering price which is at least $10.65 per share, adjusted for any anti-dilution adjustments.

Dividends

The holders of Series A-1 Preferred Stock, Series A-2 Preferred Stock and Series B Preferred Stock are entitled to receive cash dividends at a rate of 8% per annum when and if declared by the board of directors of the Company (the "Board of Directors"). These dividends shall be non-cumulative and be paid prior and in preference to the holders of Common Stock.

After payment of dividends to the holders of redeemable convertible preferred stock, any additional dividends shall be distributed among all holders of Common Stock and redeemable convertible preferred stock ratably (on an as-if-converted to Common Stock basis). No dividends have been declared or paid to date.

Voting Rights

Each holder of redeemable convertible preferred stock is entitled to the number of votes equal to the number of shares of Common Stock into which such shares of Preferred Stock held by such holder could then be converted. The holders of redeemable convertible preferred stock vote together with the holders of Common Stock as a single class and on an as-converted to Common Stock basis.

For as long as at least 4,000,000 shares of the Series A-1 Preferred Stock remain outstanding, the holders of the Series A-1 Preferred Stock, voting as a separate class, are entitled to elect two members of the Board of Directors. For as long as at least 4,000,000 shares of the Series A-2 Preferred Stock remain outstanding, the holders of the Series A-2 Preferred Stock, voting as a separate class, are entitled to elect one member of the Board of Directors. For as long as at least 10,000,000 shares of the Series B Preferred Stock remain outstanding, the holders of the Series B Preferred Stock, voting as a separate class, are entitled to elect one member of the Board of Directors. The remaining members of the Board of Directors are elected by the holders of redeemable convertible preferred stock and Common Stock, voting together as a single class on an as-converted basis.

Redemption

The redeemable convertible preferred stock is recorded in mezzanine equity because while it is not mandatorily redeemable, it will become redeemable at the option of the holders of the redeemable convertible preferred stock upon the occurrence of certain deemed liquidation events that are considered not solely within the Company's control.

9. Common Stock

As of December 31, 2023, the Company was authorized to issue 140,492,016 shares of Common Stock at a par value of $0.00001 per share. There were 1,250,103 shares of Common Stock legally issued and outstanding at December 31, 2023, with 8,125 shares subject to repurchase due to remaining vesting requirements. The holders of Common Stock are entitled to dividends as declared by the Board of Directors, subject to the rights of holders of all classes of stock outstanding having priority rights as to dividends. The holder of each share of common stock is entitled to one vote.

As of December 31, 2023 and 2022, Common Stock reserved for future issuance was as follows:

	December 31,	
	2023	2022
Redeemable convertible preferred stock	25,171,265	18,128,357
Outstanding stock option awards (349,321 shares issued in connection with the early exercised options for a non-recourse promissory note are excluded from shares reserved for issuance)	3,960,713	2,338,346
Shares available for future options grants	487,673	22,394
Total shares reserved for future issuance	**29,619,651**	**20,489,097**

Common Stock Issued to a Founder

In September 2018, the Company issued 120,849 shares of Common Stock to a founder of the Company at a purchase price of $0.02 per share. The price was based on an estimate of the fair value of the Common Stock on the grant date. Shares vest monthly over a four-year period starting in May 2019. The Company has the right to repurchase unvested shares at the purchase price if the founder's services to the Company are terminated. All shares were vested during the year ended December 31, 2022, and there are no unvested shares as of December 31, 2023 and 2022.

Early Exercise of Options for a Promissory Note

In December 2022, the Company's chief executive officer (the "CEO"), a related party, early exercised options for 349,321 shares of Common Stock in exchange for a partial recourse promissory note receivable with the principal amount of $1.1 million. The note bears interest of 4.27% per annum and is due in December 2027. For accounting purposes, the promissory note was determined to be non-recourse and, as such, the issuance of the promissory note and subsequent early exercise of stock options are considered non-substantive and will not be recorded in the financial statements until the promissory note is repaid. The issuance of the promissory note modified the terms of the related stock options. The modification did not result in additional compensation expense and the Company continues to recognize stock-based compensation expense for these exercised stock options based on their original grant-date fair value. While the issued shares are not considered outstanding for accounting purposes, they are legally issued and have voting and dividends rights. The shares are included in common stock on the statement of redeemable convertible preferred stock and stockholders' deficit as of December 31, 2023 and 2022, and are not included in the calculation of net loss per share attributable to common stockholders for the year ended December 31, 2023 and 2022.

On January 12, 2024, the Company and the CEO entered into a note forgiveness letter, pursuant to which the promissory note and all accrued interest thereon in an aggregate amount of $1.1 million were forgiven.

10. Stock Option Plan

In 2019, the Company adopted the 2019 Stock Plan (the "2019 Plan"), which provides for stock awards to employees, directors and consultants of the Company. Awards issuable under the 2019 Plan include incentive stock options ("ISO"), non-statutory stock options ("NSO"), restricted stock units, stock grants and stock purchase awards. As of December 31, 2023, only ISOs and NSOs had been granted under the 2019 Plan. As of December 31,

2023, 5,577,776 shares of Common Stock have been authorized for issuance and 487,673 shares are available for future grant under the 2019 Plan.

Options to purchase Common Stock may be granted at a price not less than the fair market value as established by the Board of Directors in the case of both NSOs and ISOs. Stock option grants under the 2019 Plan generally vest over four years. All options expire no later than ten years from the date of grant. The exercise price of ISOs granted to an employee who owns more than 10% of the voting power of all classes of stock of the Company shall be no less than 110% of the estimated fair market value of the underlying Common Stock on the grant date, and the contractual term is no longer than five years.

A summary of option activity under the 2019 Plan is as follows:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022 *	2,687,667	$ 3.33	9.34	$ 673
Options granted	2,099,492	$ 4.77		
Options exercised	(242,566)	$ 2.66		
Options cancelled and forfeited	(234,559)	$ 3.03		
Outstanding at December 31, 2023 *	4,310,034	$ 4.09	9.09	$ 11,810
Exercisable at December 31, 2023 **	2,019,218	$ 3.42	8.53	$ 6,887
Vested and expected to vest at December 31, 2023	4,310,034	$ 4.09	9.09	$ 11,810

* Excludes 349,321 shares of Common Stock issued in connection with the early exercised options for a non-recourse promissory note, which are not considered substantive for accounting purposes (see Note 9)
** Includes 1,236,066 shares of unvested stock options for which a holder has the right to early exercise such option as of December 31, 2023.

Aggregate intrinsic value represents the difference between the fair value of the underlying Common Stock and the exercise price. The weighted-average grant date fair value of options granted for the years ended December 31, 2023 and 2022, was $4.39 and $2.73, respectively. The weighted-average grant date fair value of options vested for the years ended December 31, 2023 and 2022 was $2.31 and $1.67, respectively. As of December 31, 2023, total unrecognized stock-based compensation expense was $12.5 million, which is expected to be recognized over a weighted-average period of 3.5 years. The intrinsic value of options exercised during 2023 and 2022 was $1.0 million and $0.1 million, respectively, and is calculated based on the difference between the exercise price and the fair value of Common Stock as of the exercise date.

Early Exercise of Employee Options

Certain employees received stock options that allow for exercise of the stock option prior to vesting. The shares of Common Stock issued upon an early exercise that have not yet vested are subject to repurchase by the Company in the event of termination of the holder's continuous status as a service provider, at the price paid by the holder.

Proceeds from the early exercise of stock options are recorded as repurchase liability, and as shares vest, they are recognized as additional paid-in capital in the balance sheets. Shares purchased by employees pursuant to the early exercise of stock options are not deemed, for accounting purposes, to be issued until those shares vest according to their respective vesting schedules, and the Company recognizes stock-based compensation expense related to these options as they continue to vest. As of each of December 31, 2023 and 2022, there was $0.1 million repurchase liability related to the unvested shares. As of December 31, 2023 and 2022, 8,125 and 105,629 common stock shares, respectively, remained subject to the right of repurchase as a result of the early exercise of stock options and are included in common shares outstanding. Early exercises as of December 31, 2023 exclude 349,321

shares of Common Stock issued in connection with the early exercised options for a non-recourse promissory note, which are not considered substantive for accounting purposes.

Stock-Based Compensation Expense

The Black-Scholes option pricing model, used to estimate fair value of stock-based awards, requires the use of the following assumptions:

- *Fair value of Common Stock.* The fair market value of Common Stock is determined by the Board of Directors with assistance from management and external valuation experts. The approach to estimating the fair market value of Common Stock is consistent with the methods outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation* (the "Practice Aid").

  In accordance with the Practice Aid, the Company determined the hybrid method was the most appropriate method for determining the fair value of the Common Stock based on the Company's stage of development and other relevant factors. The hybrid method is a probability-weighted expected return method ("PWERM"), where the equity value in one or more scenarios is calculated using an option pricing model ("OPM"). The Company determined this was the most appropriate method for determining the fair value of the Common Stock based on the Company's stage of development and other relevant factors. The PWERM is a scenario-based analysis that estimates the value per share of the Common Stock based on the probability-weighted present value of expected future equity values for the Common Stock, under various possible future liquidity event scenarios, considering the rights and preferences of each class of shares, and discounted for a lack of marketability. Under the hybrid method, an OPM was utilized to determine the fair value of the Common Stock in certain of the PWERM scenarios (capturing situations where the Company's development path and future liquidity events were difficult to forecast), and potential exit events were explicitly modeled in the other PWERM scenarios. A discount for lack of marketability was applied to the value derived under each scenario to account for a lack of access to an active public market to estimate the Common Stock fair value.
- *Expected Term.* The expected term of options granted represents the period of time that the options are expected to be outstanding. Due to the lack of historical exercise history, the expected term of the Company's employee stock options has been determined by calculating the midpoint of the contractual term of the options and the weighted-average vesting period. Grants to nonemployees are based on the contractual term.
- *Expected Volatility.* The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have any trading history for the Common Stock. The Company will continue to analyze the historical stock price volatility and expected term assumption as more historical data for the Common Stock becomes available.
- *Risk-Free Interest Rate.* The risk-free interest rate assumption is based on the U.S. Treasury instrument whose term was consistent with the expected term of the Company's stock options.
- *Dividends.* The Company has not paid any cash dividends on Common Stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

The fair value of options granted to employees and nonemployees was estimated at the grant date using the following assumptions for the years ended December 31, 2023 and 2022, respectively:

	Year ended December 31,	
	2023	2022
Employees		
Expected volatility	91% - 95%	92% - 97%
Expected dividend yield	—%	—%
Expected term (in years)	5.9 - 6.2	6.0 - 6.1
Risk-free interest rate	3.6% - 4.7%	1.8% - 3.9%
Non-Employees		
Expected volatility	94%	90% - 92%
Expected dividend yield	—%	—%
Expected term (in years)	6.2	10.0
Risk-free interest rate	4.6%	1.8% - 2.8%

The following table presents the classification of stock-based compensation expense related to stock options granted to employees and nonemployees (in thousands):

	Year ended December 31,	
	2023	2022
Research and development	$ 792	$ 397
General and administrative	1,428	532
Total stock-based compensation expense	$ 2,220	$ 929

11. Defined Contribution plan

The Company sponsors a 401(k) plan (the "401(k) Plan"), which stipulates that eligible employees can elect to contribute to the 401(k) Plan, subject to certain limitations of eligible compensation. The Company may match employee contributions in amounts to be determined at the Company's sole discretion. The Company made no matching contributions during the years ended December 31, 2023 and 2022.

12. Net Loss Per Share Attributable to Common Stockholders

The following table sets forth the computation of basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Year ended December 31,	
	2023	2022
Numerator:		
Net loss attributable to common stockholders	$ (60,366)	$ (28,893)
Denominator:		
Weighted average shares used in computing basic and diluted net loss per share	673,622	455,478
Net loss per share attributable to common stockholders, basic and diluted:	$ (89.61)	$ (63.43)

The potential shares of Common Stock that were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have had an antidilutive effect were as follows:

	As of December 31,	
	2023	2022
Redeemable convertible preferred stock, as converted	25,171,265	18,128,357
Options issued and outstanding	3,960,713	2,338,346
Unvested early exercised common stock options	8,125	454,950
Vested early exercised common stock options exercised for non-recourse promissory note (Note 10)	349,321	-
	29,489,424	20,921,653

13. Income Taxes

The Company has recorded no income tax expense for the years ended December 31, 2023 and 2022. All the Company's taxable losses were generated in the U.S.

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

	Year Ended December 31,	
	2023	2022
Income tax computed at federal statutory rate	21.00%	21.00%
State taxes	6.6%	6.3%
Other permanent differences	(0.8)%	0.0%
Research credits	1.1%	1.1%
Stock-based compensation	(0.6)%	(0.3)%
State uncertain tax positions	(5.9)%	(7.4)%
Change in valuation allowance	(21.4)%	(20.7)%
Effective income tax rate	—%	—%

Significant components of the Company's deferred tax assets for federal and state income taxes are as follows (in thousands):

Deferred Tax Assets:

	Year Ended December 31,	
	2023	2022
Net operating loss carry forwards	$ 10,807	$ 6,848
Capitalized research and development expenditures	13,327	5,281
Reserves and accruals	816	407
Lease liabilities	2,091	2,563
Research credits	1,714	675
Stock-based compensation	216	157
Accrued license	1,814	1,804
License and upfront fees	2,936	3,569
Other	83	94
Total gross deferred tax assets	33,804	21,398
Less: Valuation allowance	(31,772)	(18,832)
Total deferred tax assets	$ 2,032	$ 2,566
Deferred tax liabilities		
Property and equipment	(147)	(195)
Lease right-of-use assets	(1,885)	(2,371)
Total gross deferred tax liabilities	(2,032)	(2,566)
Net deferred tax assets	$ —	$ —

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The Company has reviewed its positive and negative evidence and has concluded that it is more likely than not that the net deferred tax assets will not be realized due to the cumulative losses incurred since inception; therefore, the Company continues to maintain a valuation allowance. The valuation allowance increased by $12.9 million and $6.0 million during the years ended December 31, 2023 and 2022, respectively.

The Company has net operating loss carryforwards for federal and state income tax purposes of $48.8 million and $103.2 million, respectively, as of December 31, 2023. The federal net operating loss carryforwards are not subject to expiration but are limited to 80% of the taxable income in the year the carryforward is used. State net operating loss carryforwards, if not utilized, will expire in various amounts 2036 through 2043.

As of December 31, 2023, the Company has federal and state research and development credit carryforwards of approximately $1.3 million and $0.9 million, respectively. The federal credits will expire in various amounts 2041 through 2042 and the state credits can be carried forward indefinitely.

Utilization of some of the federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. The Company has performed a Section 382 study as of December 31, 2023 and expects approximately $2.0 million of federal net operating losses and $1.9 million California net operating losses to be worthless due to Section 382 limitations.

The Tax Cuts and Jobs Act of 2017 contains a provision that requires the capitalization of Section 174 costs incurred in years beginning on or after January 1, 2022. Section 174 costs are expenditures that represent research and development costs that are incidental to the development or improvement of a product, process, formula, invention, computer software or technique. This provision changes the treatment of Section 174 costs such that the expenditures are no longer allowed as an immediate deduction but rather must be capitalized and amortized over five years for domestic research and development and fifteen years for foreign research and development.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits during the year ended December 31, 2023 and 2022, is as follows (in thousands):

	Year Ended December 31, 2023	Year Ended December 31, 2022
Beginning balance	$ 3,600	$ 732
Increase in tax positions in prior periods	184	118
Increase in tax positions in the current period	4,611	2,750
Ending balance	$ 8,395	$ 3,600

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized, due to the valuation allowance. The Company has elected to include interest and penalties as a component of tax expense. During the years ended December 31, 2023 and 2022, the Company did not recognize accrued interest and penalties related to unrecognized tax benefits.

The Company files tax returns in the U.S., California and other various states. The Company is not currently under examination in any of these jurisdictions and all its tax years remain effectively open to examination due to net operating loss carryforwards.

14. Related Party Transactions

For the year ended December 31, 2023, the Company recorded less than $0.1 million to deferred offering costs related to an advisory services agreement with one of its board members.

In July 2023, the Company issued 4,006,624 shares of Series B Preferred Stock at a price of $1.8719 per share, which was the price paid by other investors, to Gilead, a related party.

On December 30, 2023, the Company's CEO exercised 58,220 stock options with a $3.15 exercise price per share under the 2019 Plan. As of December 31, 2023, in connection with this transaction, the Company recognized $0.2 million to prepaid and other assets related to unpaid exercise price and related taxes. The payment for exercised options was received on January 8, 2024.

15. Subsequent Events

Amendment and Restatement of the Certificate of Incorporation; Adoption of 2024 Equity Incentive Plan and 2024 Employee Stock Purchase Plan

On January 24, 2024, the Board adopted, and on January 30, 2024, the Company's stockholders approved, an amendment and restatement of the Company's certificate of incorporation to be in effect immediately prior to the closing of the IPO, and the 2024 Equity Incentive Plan ("2024 Plan") and 2024 Employee Stock Purchase Plan ("ESPP"). The amended and restated certificate of incorporation went into effect on February 12, 2024 and provided for an increase in the authorized number of shares to 490,000,000 shares of common stock and 10,000,000 shares of preferred stock. The 2024 Plan and the ESPP each became effective on February 6, 2024, the date immediately preceding the date upon which the Company's registration statement for the IPO was declared effective by the SEC. 4,215,000 shares and 422,000 shares were initially reserved for initial issuance under the 2024 Plan and the ESPP, respectively, which will increase as defined in the plans. The 2024 Plan is a successor to the 2019 Plan. Once the 2024 Plan became effective, no further grants will be made under the 2019 Plan.

Office Lease

In February 2024, the Company entered into an agreement to lease approximately 35,000 square feet of office space in Emeryville, California through February 2027. The lease commenced on February 28, 2024. Monthly rent payments are approximately $0.1 million. There is no renewal option for this lease.

Exhibit 4.2

Description of Securities of Kyverna Therapeutics, Inc.

The following is a summary of the material terms of the capital stock of Kyverna Therapeutics, Inc. , or we, us, our, or the Company, as well as other material terms of our amended and restated certificate of incorporation and amended and restated bylaws and certain provisions of Delaware law. This summary does not purport to be complete and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K, to which this exhibit is a part.

Our authorized capital stock consists of 490,000,000 shares of common stock, $0.00001 par value per share, and 10,000,000 shares of undesignated preferred stock, $0.00001 par value per share. Our board of directors is authorized, without stockholder approval except as required by the rules and listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock.

Common Stock

Dividend Rights

Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine.

Voting Rights

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66-2/3% of the voting power of all of the then outstanding capital stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms.

No Preemptive or Similar Rights

Our common stock is not entitled to preemptive rights, and is not subject to conversion, redemption, or sinking fund provisions.

Right to Receive Liquidation Distributions

If we become subject to a liquidation, dissolution or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our common stock and any participating preferred stock outstanding at that time, subject to prior satisfaction of all outstanding debt and liabilities and the preferential rights of and the payment of liquidation preferences, if any, on any outstanding shares of preferred stock.

Fully Paid and Non-Assessable

All of the outstanding shares of our common stock are fully paid and non-assessable.

Preferred Stock

Our board of directors is authorized, subject to limitations prescribed by Delaware law, to issue up to 10,000,000 preferred stock in one or more series, to establish from time to time the number of shares to be included in each series, and to fix the designation, powers, preferences, and rights of the shares of each series and any of its

qualifications, limitations or restrictions, in each case without further vote or action by our stockholders. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of our company or other corporate action and might adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. We have no current plan to issue any shares of preferred stock.

Registration Rights

Investors' Rights Agreement

In November 2021, in connection with the initial issuance and sale of our Series B preferred stock, we entered into an Amended and Restated Investors' Rights Agreement, as subsequently amended, or the Rights Agreement. The Rights Agreement grants certain rights to the holders of our then-outstanding convertible preferred stock, including certain registration rights with respect to the registrable securities held by them.

The holders of an aggregate of 25,171,265 shares of our common stock are entitled to these demand, piggyback and Form S-3 registration rights pursuant to the Rights Agreement. We will pay the registration expenses, other than the underwriting discounts and selling commissions, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than February 12, 2029 (the date that is five years after the completion of our initial public offering), or with respect to any particular holder, at such time that such holder can sell its shares under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act, without limitation during any three-month period.

Demand Registration Rights

The holders of an aggregate of 25,171,265 shares of our common stock are entitled to certain demand registration rights pursuant to the Rights Agreement. At any time beginning August 10, 2024 (the date that is 180 days after the completion of our initial public offering), the holders of a majority of the registrable securities then outstanding may request that we register all or a portion of their shares. Such request for registration must cover at least 40% of the registrable securities then outstanding with an anticipated aggregate offering price of at least $15.0 million.

Piggyback Registration Rights

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, certain holders of registrable securities will be entitled to certain piggyback registration rights pursuant to the Rights Agreement allowing such holders to include their shares in such registration, subject to certain marketing and other limitations. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to: (i) a demand registration; (ii) the registration of securities relating to the sale or grant of securities to employees to a stock option, stock purchase, equity incentive or similar plan; (iii) the registration of securities relating to a SEC Rule 145 transaction; (iv) the registration of securities on any form that does not include substantially the same information as would be required on a Form S-1 or Form S-3; or (v) the registration of common stock that is being registered that is issuable upon conversion of debt securities that are also being registered, then holders of these shares are entitled to notice of the registration and have the right to include their shares in the registration, subject to limitations that the underwriters may impose on the number of shares included in the offering.

S-3 Registration Rights

The holders of an aggregate of 25,171,265 shares of our common stock are entitled to certain Form S-3 registration rights pursuant to the Rights Agreement. Such holders of registrable securities can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and such holders hold registrable securities in an anticipated aggregate offering amount of at least $5.0 million, net of applicable selling expenses. We will not be required to effect a registration on Form S-3 within 60 days of a registration initiated by us, to effect more than two registrations on Form S-3 within any 12-month period or to effect any registration that our board of directors deems in good faith to be materially detrimental to our company and our stockholders, subject to certain limitations.

Election and Removal of Directors; Vacancies

The exact number of directors will be fixed from time to time by resolution of our board of directors. Directors will be elected by a plurality of the votes of the shares of our capital stock present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

No director may be removed except for cause, and directors may be removed for cause only by an affirmative vote of shares representing not less than 66-2/3% of the then-outstanding shares then entitled to vote at an election of directors.

Any vacancy occurring on our board of directors and any newly created directorship may be filled only by a majority of the remaining directors in office.

Staggered Board

Our board of directors is divided into three classes serving staggered three-year terms. At each annual meeting of stockholders, directors will be elected to succeed the class of directors whose terms have expired. This classification of our board of directors could have the effect of increasing the length of time necessary to change the composition of a majority of our board of directors. In general, at least two annual meetings of stockholders will typically be necessary for stockholders to effect a change in a majority of the members of our board of directors.

Limitation on Action by Written Consent

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that holders of our common stock will not be able to act by written consent without a meeting.

Stockholder Meetings

Our amended and restated certificate of incorporation and our amended and restated bylaws provide that special meetings of our stockholders may be called only by the chairperson of our board of directors, our chief executive officer (or president, in the absence of a chief executive officer) or a majority of the directors. Our amended and restated certificate of incorporation and our amended and restated bylaws specifically deny any power of any other person to call a special meeting.

Amendment of Certificate of Incorporation

The provisions of our amended and restated certificate of incorporation under Part B of Article V, Article VI, Article VII, Article VIII, Article IX, Article X and Article XI may be amended only by the affirmative vote of holders of at least 66-2/3% of the voting power of our then-outstanding shares of capital stock. The affirmative vote of holders of at least a majority of the voting power of our outstanding shares of capital stock will generally be required to amend other provisions of our amended and restated certificate of incorporation.

Amendment of Bylaws

The provisions of our amended and restated bylaws may be amended or repealed, and new bylaws may be adopted by (i) our board of directors, with the affirmative vote of a majority of directors present at any regular or special meeting of our board of directors called for that purpose, or (ii) our stockholders, with the affirmative vote of holders of at least 66-2/3% of the voting power of our then-outstanding shares of capital stock.

Other Limitations on Stockholder Actions

Our amended and restated bylaws impose some procedural requirements on stockholders who wish to:

- make nominations in the election of directors;
- propose that a director be removed;
- propose any repeal or change in our amended and restated bylaws; or
- propose any other business to be brought before an annual or special meeting of stockholders.

Under these procedural requirements, in order to bring a proposal before a meeting of stockholders, a stockholder must deliver timely notice of a proposal pertaining to a proper subject for presentation at the meeting to our corporate secretary along with the following:

- a description of the business or nomination to be brought before the meeting and the reasons for conducting such business at the meeting;
- the stockholder's name and address;
- any material interest of the stockholder in the proposal;
- the number of shares beneficially owned by the stockholder, the date or dates such shares were acquired and the investment intent of such acquisition;
- any pledge by the stockholder with respect to such shares; and
- the names and addresses of all persons with whom the stockholder is acting in concert, any material interest of those persons in the proposal, the number of shares beneficially owned by those persons, the date or dates such shares were acquired and the investment intent of such acquisition, any pledge by those persons with respect to such shares, and a description of all arrangements and understandings, existing presently or existing during the prior twenty-four months, between or among the stockholder and/or those persons.

To be timely, a stockholder must generally deliver notice:

- in connection with an annual meeting of stockholders, not less than 90 nor more than 120 days prior to the date on which the annual meeting of stockholders was held in the immediately preceding year, but in the event that the date of the annual meeting is more than 30 days before or more than 60 days after the anniversary date of the preceding annual meeting of stockholders, a stockholder notice will be timely if received by us not later than the 120th day prior to the date of the annual meeting and not later than (i) the 90th day prior to such annual meeting or; (ii) if later, the 10th day following the day on which we first publicly announce the date of the annual meeting; or
- in connection with the election of a director at a special meeting of stockholders, during the period not less than 90 nor more than 120 days prior to the date of the special meeting, or, if later, the 10th day following the day on which public disclosure of such special meeting was first made.

In order to submit a nomination for our board of directors, a stockholder must also submit all information with respect to the nominee that would be required to be included in a proxy statement, as well as other information. If a stockholder fails to follow the required procedures, the stockholder's proposal or nominee will be ineligible and will not be voted on by our stockholders.

Limitation of Liability of Directors and Officers

Our amended and restated certificate of incorporation provides that no director will be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except as required by applicable law, as in effect from time to time. Section 102(b)(7) of the General Corporation Law of the State of Delaware, or the DGCL, permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's or officer's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- as a director, unlawful payments of dividends or unlawful stock repurchases or redemptions;
- as an officer, derivative claims brought on behalf of the corporation by a stockholder; or
- any transaction from which the director or officer derived an improper personal benefit.

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages against a director for breach of fiduciary duty as a director, including breaches resulting from grossly negligent behavior, except in the situations described above.

Our amended and restated certificate of incorporation also provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our director or officer, or served any other enterprise at our request as a director or officer. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

Forum Selection

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on behalf of us; (ii) any action asserting a claim of breach of fiduciary duty owed to us or our stockholders by any director, officer or other employee of our company; (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation and our amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. This provision would not apply to claims brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

Furthermore, our amended and restated certificate of incorporation also provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to the foregoing forum selection provisions.

Our exclusive forum provision will not relieve us of our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

The enforceability of similar federal court choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find this type of provision to be inapplicable or unenforceable. If a court were to find either of the choice of forum provisions contained in our amended and restated certificate of incorporation or our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

The choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with our company or our directors, officers or other employees, which may discourage such lawsuits against our company and our directors, officers and other employees and result in increased costs for investors to bring a claim.

Anti-Takeover Provisions

Certain provisions of Delaware law, along with our amended and restated certificate of incorporation and our amended and restated bylaws, may have the effect of delaying, deferring, or discouraging (i) acquiring control of our company by means of a proxy contest, tender offer or otherwise; or (ii) removing our incumbent officers and directors. These provisions, as well as our ability to issue preferred stock, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of our company to first negotiate with our board of directors. However, these provisions could have the effect of delaying, discouraging or preventing attempts to acquire us, which could deprive our stockholders of opportunities to sell their shares of our common stock at prices higher than prevailing market prices.

Delaware Law

We are governed by the provisions of Section 203 of the DGCL. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales, or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A. The transfer agent and registrar's address is 150 Royall Street, Canton, Massachusetts 02021.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol "KYTX".

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-276952) of Kyverna Therapeutics, Inc. of our report dated March 26, 2024, relating to the financial statements, which appears in this Annual Report on Form 10-K.

/s/ BDO USA, P.C.
San Diego, California
March 26, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Peter Maag, Ph.D., hereby certify that:

(1) I have reviewed this Annual Report on Form 10-K of Kyverna 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(s) 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)) 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) 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

(c) 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(s) 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 26, 2024

By: /s/ Peter Maag, Ph.D.

Peter Maag, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ryan Jones, hereby certify that:

(1) I have reviewed this Annual Report on Form 10-K of Kyverna 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(s) 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)) 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) 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

(c) 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(s) 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 26, 2024

By: /s/ Ryan Jones

Ryan Jones
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Kyverna Therapeutics, Inc. (the "Company") for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 26, 2024

By: /s/ Peter Maag, Ph.D.
Peter Maag, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided by the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Kyverna Therapeutics, Inc. (the "Company") for the period ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, to my knowledge that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 26, 2024

By: /s/ Ryan Jones

Ryan Jones
Chief Financial Officer
(Principal Financial Officer)

A signed original of this written statement required by Section 906 has been provided by the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report, is not deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 97

KYVERNA THERAPEUTICS, INC.

CLAWBACK POLICY

Adopted January 24, 2024

The Board of Directors (the "**Board**") of Kyverna Therapeutics, Inc. (the "**Company**") believes that it is in the best interests of the Company and its stockholders to adopt this Clawback Policy (this "**Policy**"), which provides for the recovery of certain incentive compensation in the event of an Accounting Restatement (as defined below). This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated under the Exchange Act ("**Rule 10D-1**") and Nasdaq Listing Rule 5608 (the "**Listing Standards**").

1. ADMINISTRATION

Unless otherwise determined by the Board, the Compensation Committee of the Board (the "**Compensation Committee**") (or another committee of the Board) shall administer this Policy (the Board or such committee charged with administration of this Policy, the "**Administrator**"). The Administrator is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy. Any determinations made by the Administrator shall be final and binding on all affected individuals and need not be uniform with respect to each individual covered by this Policy. In the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board, as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to any legal limitation, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

2. DEFINITIONS

As used in this Policy, the following definitions shall apply:

- "**Accounting Restatement**" means an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under the 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.

- "**Administrator**" has the meaning set forth in Section 1 hereof.

- "**Applicable Period**" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare an Accounting Restatement, as well as any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period that comprises a period of at least nine months shall count as a completed fiscal year). The "**date on which the Company is required to prepare an Accounting Restatement**" is the earlier to occur 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 each case regardless of if or when the restated financial statements are filed.

- "**Code**" means the U.S. Internal Revenue Code of 1986, as amended. Any reference to a section of the Code or regulation thereunder includes such section or regulation, any valid regulation or other official guidance promulgated under such section, and any comparable or future legislation or regulation amending, supplementing or superseding such section or regulation.

- "**Compensation Committee**" has the meaning set forth in Section 1 hereof.

- "**Covered Executives**" means the Company's current and former executive officers, as determined by the Administrator in accordance with the definition of executive officer set forth in Rule 10D-1 and the Listing Standards; *provided that* executive officers for purposes of this Policy shall include at a minimum executive officers identified pursuant to 17 C.F.R. 229.401(b).

- "**Effective Date**" has the meaning set forth in Section 9 hereof.

- "**Erroneously Awarded Compensation**" has the meaning set forth in Section 5 hereof.

- A "**Financial Reporting Measure**" is any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure. Financial Reporting Measures include but are not limited to the following (and any measures derived from the following): Company stock price; total shareholder return ("**TSR**"); revenues; net income; operating income; profitability of one or more reportable segments; financial ratios (e.g., accounts receivable turnover and inventory turnover rates); earnings before interest, taxes, depreciation and amortization; funds from operations and adjusted funds from operations; liquidity measures (e.g., working capital and operating cash flow); return measures (e.g., return on invested capital and return on assets); earnings measures (e.g., earnings per share); sales per square foot or same store sales, where sales is subject to an Accounting Restatement; revenue per user, or average revenue per user, where revenue is subject to an Accounting Restatement; cost per employee, where cost is subject to an Accounting Restatement; any of such financial reporting measures relative to a peer group, where the Company's financial reporting measure is subject to an Accounting Restatement; and tax basis income. A Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the Securities and Exchange Commission (the "**SEC**") to constitute a Financial Reporting Measure.

- "**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. Incentive-Based Compensation is "**received**" for purposes of this Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period.

- "**Nasdaq**" means The Nasdaq Stock Market LLC.

3. Covered Executives; Incentive-Based Compensation

This Policy applies to Incentive-Based Compensation received by a Covered Executive: (a) after beginning services as a Covered Executive; (b) if that person served as a Covered Executive at any time during the performance period for such Incentive-Based Compensation; and (c) while the Company had a listed class of securities on a national securities exchange.

4. Required Recoupment of Erroneously Awarded Compensation in the Event of an Accounting Restatement

If the Company is required to prepare an Accounting Restatement, the Company shall promptly demand in writing and recoup the amount of any Erroneously Awarded Compensation received by any Covered Executive, as calculated pursuant to Section 5 hereof, during the Applicable Period. Recovery under this Policy with respect to a Covered Executive shall not require a finding of any misconduct by such Covered Executive or that the Covered Executive was responsible for the accounting error leading to an Accounting Restatement. If a Covered Executive fails to repay Erroneously Awarded Compensation that is owed to the Company under this Policy, the Company shall take all appropriate action to recover such Erroneously Awarded Compensation from the Covered Executive,

and the Covered Executive shall be required to reimburse the Company for all expenses (including legal expenses) incurred by the Company in recovering such Erroneously Awarded Compensation.

5. Erroneously Awarded Compensation: Amount Subject to Recovery

The amount of "**Erroneously Awarded Compensation**" subject to recovery under this Policy, as determined by the Administrator, is the amount of Incentive-Based Compensation received by the Covered Executive that exceeds the amount of Incentive-Based Compensation that otherwise would have been received by the Covered Executive had such compensation been determined based on the restated amounts in the Accounting Restatement.

Erroneously Awarded Compensation shall be determined by the Administrator without regard to any taxes paid by the Covered Executive in respect of the Erroneously Awarded Compensation.

For Incentive-Based Compensation based on stock price or TSR, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculations directly from the information in the Accounting Restatement: (a) the Administrator shall determine the amount of Erroneously Awarded Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive-Based Compensation was received; and (b) the Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq.

6. Method of Recoupment

The Administrator shall determine, in its sole discretion, the timing and method for promptly recouping Erroneously Awarded Compensation hereunder, which may include without limitation (a) seeking reimbursement of all or part of any cash or equity-based award, (b) cancelling prior cash or equity-based awards, whether vested or unvested or paid or unpaid, (c) cancelling or offsetting against any planned future cash or equity-based awards, (d) forfeiture of deferred compensation, subject to compliance with Section 409A of the Code and the regulations promulgated thereunder and (e) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effect recovery under this Policy from any amount otherwise payable to the Covered Executive, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by the Covered Executive.

The Company is authorized and directed to recoup Erroneously Awarded Compensation in compliance with this Policy unless the Administrator determines that recovery would be impracticable for one or more of the following reasons only, and subject to the following procedural and disclosure requirements:

- The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered. Before concluding that the expense of recovery would exceed the recoverable amount, the Administrator must make a reasonable attempt to recover any Erroneously Awarded Compensation, document such reasonable attempt(s) and provide that documentation to Nasdaq;

- Recovery would violate home country law of the issuer where that law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on a violation of the home country law of the issuer, the Administrator must satisfy the applicable opinion and disclosure requirements of Rule 10D-1 and the Listing Standards; or

- Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations promulgated thereunder.

7. No Indemnification of Covered Executives

Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Covered Executive, the Company shall not indemnify any Covered Executives against (a) the loss of any Erroneously Awarded Compensation, including any payment or reimbursement for the cost of third-party insurance purchased by any Covered Executives to fund potential clawback obligations under this Policy, or (b) any claims relating to the Company's enforcement of its rights under this Policy.

8. Administrator Indemnification

Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

9. Effective Date; Retroactive Application

This Policy shall be effective as of February 7, 2024 (the "**Effective Date**"). The terms of this Policy shall apply to any Incentive-Based Compensation that is received by Covered Executives on or after the Effective Date, even if such Incentive-Based Compensation was approved, awarded, granted or paid to Covered Executives prior to the Effective Date. Without limiting the generality of Section 6 hereof, and subject to applicable law, the Administrator may effectuate recovery under this Policy from any amount of compensation approved, awarded, granted, payable or paid to a Covered Executive prior to, on or after the Effective Date.

10. Amendment; Termination

The Board or the Compensation Committee may amend, modify, supplement, rescind or replace all or any portion of this Policy at any time and from time to time in its discretion, and shall amend this Policy as it deems necessary to comply with applicable law or any rules or standards adopted by a national securities exchange on which the Company's securities are listed. Notwithstanding anything in this Section 10 to the contrary, no amendment or other modification of this Policy shall be effective if such amendment or other modification would (after taking into account any actions taken by the Company contemporaneously with such amendment or other modification) cause the Company to violate any federal securities laws, SEC rule or the rules of any national securities exchange or national securities association on which the Company's securities are listed.

11. Other Recoupment Rights; Company Claims

The Board intends that this Policy be applied to the fullest extent of the law. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company under applicable law or pursuant to the terms of any similar policy in any employment agreement, equity award agreement or similar agreement and any other legal remedies available to the Company. This Policy is also in addition to (and not in lieu of) any right of repayment, forfeiture or right of offset against any employees that is required pursuant to any statutory repayment requirement (regardless of whether implemented at any time prior to or following the adoption or amendment of this Policy), including Section 304 of the Sarbanes-Oxley Act of 2002 ("**Section 304**"). Any amounts paid to the Company pursuant to Section 304 shall be considered in determining any amounts recovered under this Policy. The Compensation Committee may require that any employment agreement, equity award agreement or any other agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. The application and enforcement of this Policy do not preclude the Company from taking any other action to enforce a Covered Executive's obligations to the Company, including termination of employment or institution of legal proceedings.

Nothing contained in this Policy, and no recoupment or recovery as contemplated by this Policy, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Executive (including reimbursement of legal fees incurred by or on behalf of the Company or any of its affiliates) arising out of or resulting from any actions or omissions by the Covered Executive.

12. Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

13. Exhibit Filing Requirement

A copy of this Policy and any amendments thereto shall be filed as an exhibit to the Company's annual report on Form 10-K.

14. Governing Law; Venue

This Policy and all rights and obligations hereunder shall be governed by and construed in accordance with the internal laws of the State of Delaware, excluding any choice of law rules or principles that may direct the application of the laws of another jurisdiction. All actions arising out of or relating to this Policy shall be heard and determined exclusively in the Court of Chancery of the State of Delaware or, if such court declines to exercise jurisdiction or if subject matter jurisdiction over the matter that is the subject of any such legal action or proceeding is vested exclusively in the U.S. federal courts, the U.S. District Court for the District of Delaware.

15. Interpretation

If any provision of this Policy or the application of such provision to any Covered Executive 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 the application of such provision) valid, legal or enforceable.

Clawback Policy Acknowledgment

I, the undersigned, agree and acknowledge that I am fully bound by, and subject to, all of the terms and conditions of Kyverna Therapeutics, Inc.'s Clawback Policy (as may be amended, restated, supplemented or otherwise modified from time to time, the "**Policy**"). In the event of any inconsistency between the Policy and the terms of any employment or similar agreement to which I am a party, or the terms of any compensation plan, program or agreement under which any compensation has been granted, awarded, earned or paid, the terms of the Policy shall govern. The Policy will apply both during and after my employment with the Company. In the event it is determined by the Administrator that any amounts granted, awarded, earned or paid to me must be forfeited or reimbursed to the Company, I will promptly take any action necessary to effectuate such forfeiture and/or reimbursement. Any capitalized terms used in this Acknowledgment without definition shall have the meaning set forth in the Policy.

By: _____ _____
[Name] Date
[Title]