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, 2024

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 28, 2024, the last business day of the Registrant's most recently completed second quarter, the aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant was approximately $222.1 million.

The number of shares of Registrant's Common Stock outstanding as of March 1, 2025 was 43,214,918.

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 expand internationally;
- 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 clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases. Our goal is to liberate patients from autoimmune diseases through the curative potential of cell therapy. Our approach is supported by our breadth of experience treating patients with our lead product candidate, KYV-101, across more than 15 autoimmune disease indications. This has been documented through the scientific publication of multiple autoimmune case studies, our proprietary dataset of patients treated through named patient forms of compassionate use, our experience in ongoing investigator-initiated trials at leading academic institutions, as well as early clinical data from our ongoing company-sponsored trials illustrating the potential of these therapies to deeply deplete B cells with the aim of achieving durable treatment-free remission. This validation provides us with a clear path to continue advancing KYV-101 through late-stage clinical development and commercialization across two broad areas of autoimmune disease: neuroinflammation and rheumatology.

Our lead program, KYV-101, is an autologous, fully human CD19 CAR T-cell product candidate incorporating highly potent CD28 co-stimulation. KYV-101 is made from an underlying chimeric antigen receptor, or CAR, licensed from the National Institutes of Health, or the NIH. We believe that this uniquely designed CAR in KYV-101 has the potential to deliver a differentiated therapeutic profile in autoimmune disease. In addition to a fully human scFv domain, the CAR in KYV-101 was also designed with a human CD8α hinge and transmembrane domain, a human CD28 costimulatory domain, and a human CD3ζ activation domain. This same 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 similar rates of durable antitumor responses while delivering improved tolerability in the clinic among adult oncology patients, as compared to the CAR used to create Yescarta®. We believe that these differentiated properties of the CAR in KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

Our focused clinical development pipeline includes a pivotal Phase 2 trial of KYV-101 in stiff person syndrome, or SPS, a Phase 2 trial of KYV-101 in myasthenia gravis, or MG, and two multi-center Phase 1/2 trials for patients with lupus nephritis, or LN. We are also harnessing investigator-initiated trials and other Kyverna-sponsored clinical trials, or KYSA trials, including in multiple sclerosis and systemic sclerosis, to inform the next priority indications to advance into late-stage development. Additionally, our pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats, including efficiently expanding into broader autoimmune indications and increasing patient reach with KYV-102 using our proprietary whole blood rapid manufacturing process. We believe our cell therapy approach to autoimmune disease may present a significant advantage over current standard-of-care therapies by aiming for deep B cell depletion, an immune reset and long-term remission in autoimmune diseases.

KYV-101 is currently being evaluated in company-sponsored KYSA trials and investigator-initiated trials in numerous B-cell mediated autoimmune diseases with a prioritized focus in SPS, MG and LN. We have aligned with the FDA on a registrational Phase 2 trial design in SPS, KYSA-8. This KYSA-8 pivotal Phase 2 trial in SPS has enrolled 70% of study participants, with completion of enrollment expected in mid-2025. We also continue to progress our chemistry, manufacturing and controls, or CMC, readiness efforts in a capital-efficient manner in support of an anticipated biologics license application, or BLA, filing with the FDA in 2026. We expect to report topline data from our pivotal Phase 2 trial in SPS in the first half of 2026 and anticipate filing our first BLA with the FDA in 2026.

Our Phase 2 trial in MG, KYSA-6, has completed enrollment of patients in an initial six-patient cohort and we plan to report interim data from this cohort in the second half of 2025. We received Regenerative Medicine Advanced Therapy, or RMAT, designations and Orphan Drug Designations from the FDA for both SPS and MG as well as Orphan Drug Designation from the European Medicines Association in MG. We continue to engage in positive dialogue with the FDA and expect to provide an update on the registrational path for KYV-101 in MG in the first half of 2025.

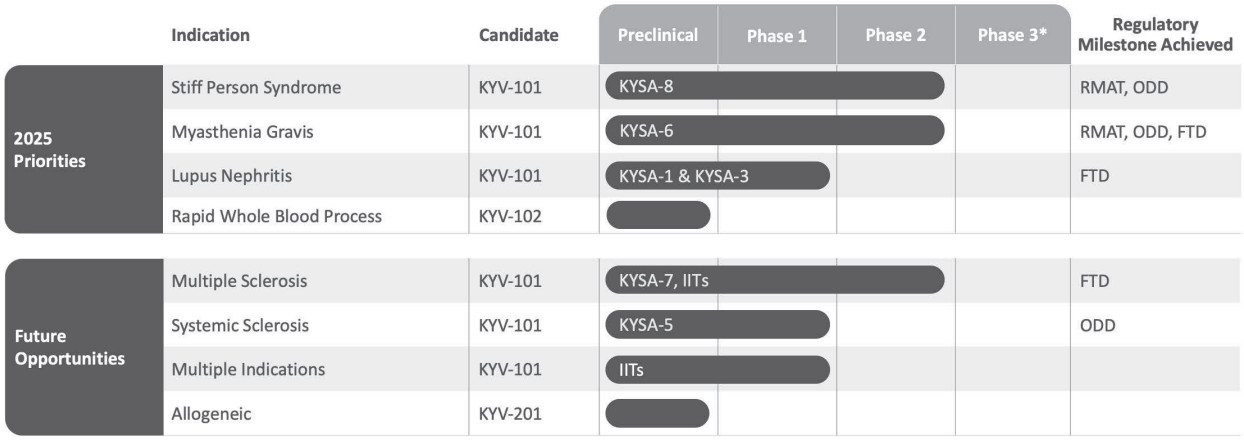
We are also currently advancing two Phase 1/2 trials in LN, KYSA-1 and KYSA-3. We have completed the dose-escalation cohort of KYSA-1 and are now treating patients at the target dose. We expect to report Phase 1 data from both of these trials in the second half of 2025. In November 2024, we presented clinical data at ACR

Convergence 2024 that demonstrated positive sustained efficacy and durability at >6-month follow-up observed in patients with severe LN treated with KYV-101 at the therapeutic dose.

We anticipate that our current cash, cash equivalents and available-for-sale marketable securities will be sufficient to fund our operations into 2027. In particular, we expect that our cash, cash equivalents and available-for-sale marketable securities will allow us to file a BLA for KYV-101 in SPS, advance a registration-enabling trial in MG, continue advancing our clinical trial program in LN, and identify our next priority indications to advance into late-stage development. Our operating cash burn can vary from quarter to quarter; for example, we made certain one-time investments in our CMC readiness in the second half of 2024, which we expect to continue through the first half of 2025 for an anticipated BLA in 2026. We have also accelerated enrollment in certain of our clinical trials, with completion of enrollment in our pivotal Phase 2 trial in SPS expected in mid-2025. For these reasons, we currently expect our operating cash burn in the first half of 2025 to be higher than our operating cash burn in the second half of 2025. The amounts and timing of our actual expenditures will depend on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the time and cost necessary to conduct our ongoing and planned preclinical studies and clinical trials, the results of our preclinical studies and clinical trials 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.

Our pipeline and programs

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



*Phase 3 may not be required if Phase 2 is registrational
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.
RMAT, Regenerative Medicine Advanced Therapy; ODD, Orphan Drug Designation; FTD, Fast Track Designation

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 conditions. We estimate that there are approximately 8.3 million diagnosed patients with B-cell-driven autoimmune diseases in the United States, the European Union and Japan. 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 require chronic administration and are rarely considered curative. The majority of patients do not respond optimally, if at all, to these therapies.

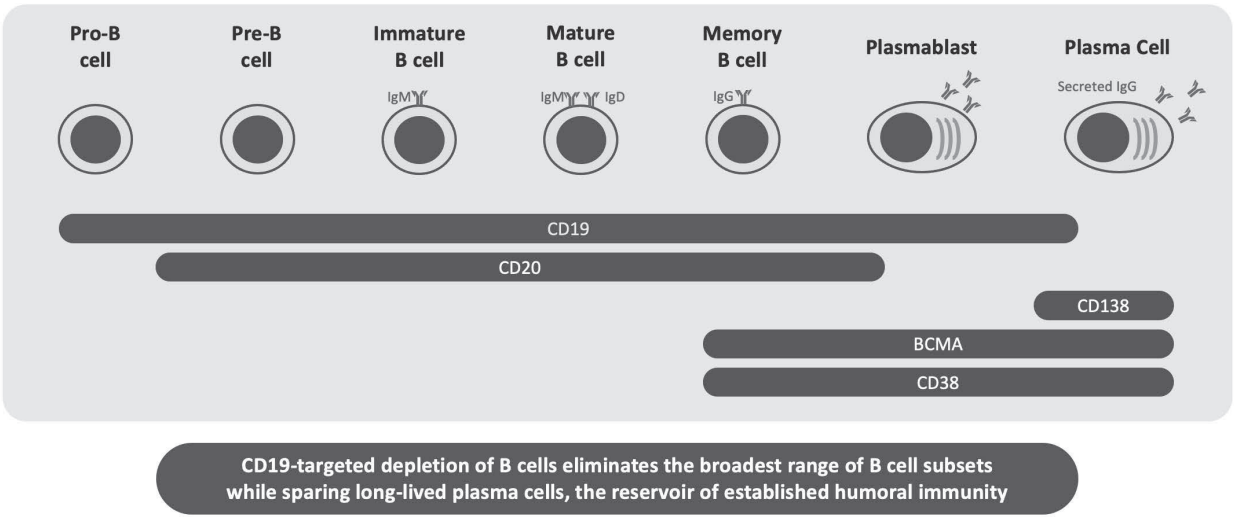
There is a wide spectrum of diseases and symptoms driven by autoimmunity. The presence of autoantibodies, a product of autoreactive B cells, is a hallmark of many of these diseases. Although the identity of the autoantigen targeted and the tissue or organ with the most significant pathology may differ 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 pathogenic B cells.

Our Solution — Cell Therapy to Treat Autoimmune Disease

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

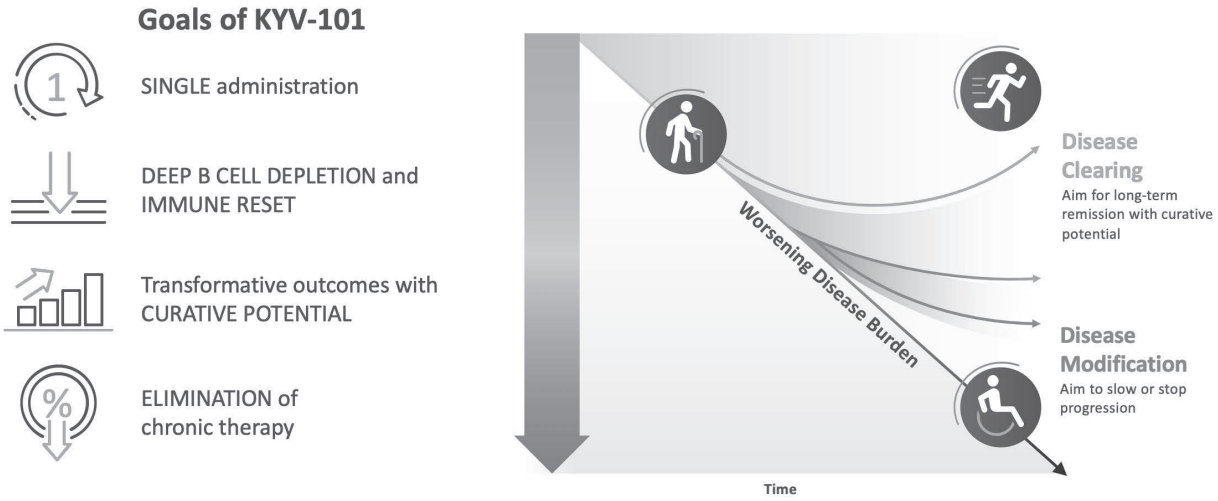
We believe the success of cell therapies such as CAR T-cell therapies in oncology has paved the way for the application of cellular therapies in other therapeutics areas, including autoimmune diseases.

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:



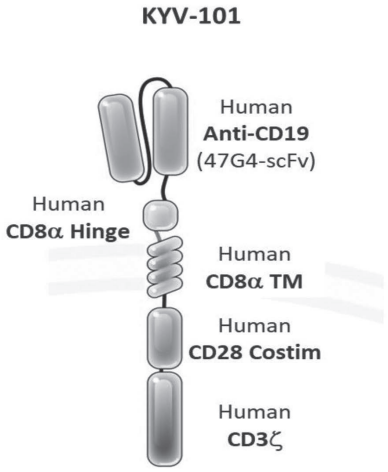
KYV-101 is a Fundamentally Different Approach

CD19 CAR T-cell therapy has demonstrated the ability to deeply deplete B cells in blood and tissues while disrupting B cell follicular architecture, with the potential to clear disease by resetting disease-contributing B cells. We believe that KYV-101's unique design with CD28 costimulation is optimal for autoimmunity, enabling the potential for disease clearance through deep B-cell depletion and immune reset while eliminating the need for chronic therapy. The following figure illustrates these disease clearing goals of KYV-101, potentially achieved with a single administration, representing a major paradigm shift compared with current standard of care disease modifying agents that may slow progression with chronic administration, but are not administered with curative intent.



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

KYV-101 is created using a fully human CAR, referred to as Hu19-CD828Z, that was designed with highly potent CD28 costimulation and reduced cytokine release to improve tolerability, resulting in the potential for an overall improved therapeutic profile. The following illustration shows the structure of the CAR in KYV-101:



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 antitumor results and durable response observed with Hu19-CD828Z CAR T cells were comparable to results previously observed at the same clinic with the CD28-containing FMC63-CD28Z CAR in Yescarta®, but there were marked differences in the adverse event profiles for these two CAR T cells. 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. Patients treated with Hu-19-CD828Z CAR T cells were also 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. We believe that this improved therapeutic profile has the potential to be critical for the application of CAR T-cell therapies in indications such as autoimmune diseases.

Additionally, the Hu19-CD828Z CAR in KYV-101 contains a fully human anti-CD19 single-chain fragment variable, or scFV, domain. By contrast, all five of the currently approved CD19 CAR T-cell therapies, Kymriah®, Yescarta®, Tecartus®, Breyanzi® and Aucatzyl® incorporate the scFv portion of murine antibodies as their

antigen-recognition domains. These murine domains can lead to anti-murine immune responses in treated patients, which results in increased clearance of therapeutic CAR T cells, limiting their expansion and persistence.

The combination of autologous patient cells, our 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 CAR in KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

Clinical Results of KYV-101 in Autoimmune Disease

We have explored the potential of KYV-101 in more than 15 autoimmune indications through a combination of Kyverna-sponsored clinical trials, investigator-initiated clinical trials and named patient activities by individual physicians through a form of compassionate use outside of our sponsored clinical trials. Our KYSA trials include trials with registrational intent and for which we may issue milestone guidance. Our investigator-initiated clinical trials, or IITs, are single-center trials at leading academic centers which help us explore future potential indications.

From May 2023 to December 2024 we supplied KYV-101 in named patient activities for the treatment of 40 patients in Germany through "Individueller Heilversuch", or IH, which is a form of compassionate use treatment for an individual patient, where a procedure or treatment that has not received marketing authorization may be used for the expected benefit of a patient who has exhausted all available treatment options, under the discretion of the treating physician. The primary goal of these compassionate use treatments is not to assess the effectiveness, but rather to provide a treatment option to patients who have exhausted all other options. While we do not anticipate that we will continue supplying KYV-101 for additional IH activities in Germany outside of formal clinical trials in 2025, this experience has guided our clinical development and commercialization strategy into a prioritized portfolio of indications.

Through this breadth of experience, we have identified three priority indications for our focused clinical development pipeline: SPS, MG, and LN. In all three of these indications, the first patients treated at the KYV-101 therapeutic dose of 1×10^8 CAR T cells/μL reported durable remissions of greater than one year and required no ongoing treatment with immunosuppressants or glucocorticoids as of January 2025. The figure below summarizes the reported experience in these first three patients.

Observed Durable Remissions at Therapeutic Dose of KYV-101 Across Priority Indications

Stiff Person Syndrome (SPS) Disease Background

SPS is a rare, progressive neuroinflammatory autoimmune disease causing debilitating muscle stiffness in the torso, arms, and legs, impacting the ability to walk or move. The majority of patients with SPS have antibodies to GAD65 or the glycine receptor, which impact the interaction between nerves and muscles, causing the stiffness and lack of mobility. Patients typically present with muscle spasms and stiffness, resulting in difficulty turning and bending. When stiffness is severe, the patients' posture resembles a statue. Patients can also have breathing and other

muscle groups impacted such as speech and swallowing. Stiffness, rigidity and spasms impacting a patient's trunk and limbs cause 80% of patients to lose mobility.

The prevalence of SPS is estimated to be between 2,000 and 6,000 cases in the United States, with between 1,500 and 2,500 treated off-label with immunomodulatory therapy. It is estimated that 85% of these patients continue to progress with active disease. Walking speed, which we have selected as the primary endpoint for our KYSA-8 pivotal Phase 2 trial, is a holistic functional measure of stiffness and disability in SPS patients. The timed 25-foot walk test, or T25FW, is a validated tool to assess walking ability in clinical trials that has been used to measure stiffness and loss of mobility in SPS.

Current Treatment Paradigm

There are no FDA-approved therapies for SPS. Current therapies span four categories: symptomatic treatments such as muscle relaxants, anti-seizure medications, painkillers, and anti-inflammatory agents; off-label use of immunosuppressants and intravenous immunoglobulin, or IVIG; physical, speech and occupational therapy and other forms of supportive care; and psychiatric therapy including anti-depressants and anxiolytics. For patients who receive off-label use of immunosuppressants and IVIG, up to 85% have no response or eventually fail therapy.

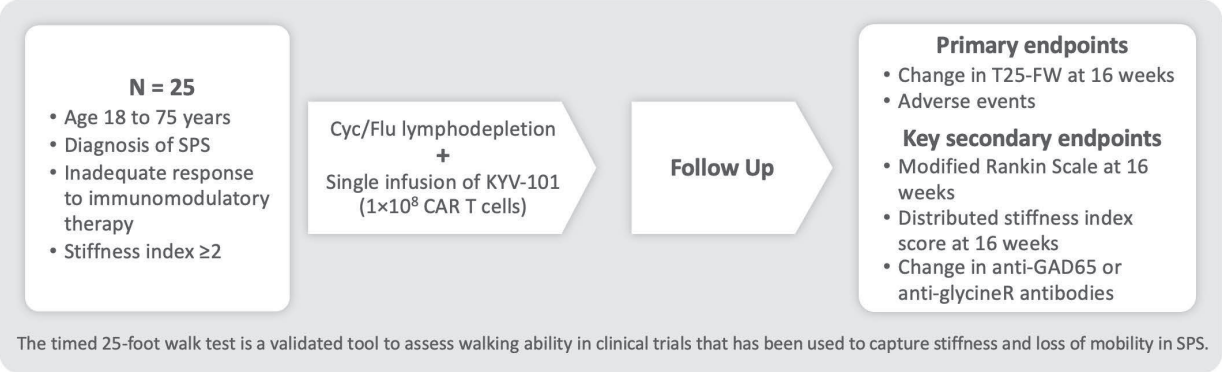
We believe that a therapy that deeply depletes pathogenic B cells to reset the immune system may provide durable benefits for patients with SPS without the need for chronic treatment.

KYV-101 Clinical Development in SPS

We have aligned with the FDA on a registrational Phase 2 trial design in SPS, KYSA-8, and we have enrolled 70% of study participants in this KYSA-8 pivotal Phase 2 trial in which we intend to enroll 25 adult patients with SPS. Our primary endpoint is change from baseline in the T25FW at 16 weeks after treatment. Secondary endpoints include evaluating other efficacy scores, including the Modified Rankin Scale, or mRS, Stiffness Index, and Hauser Ambulation Index as well as disease-related biomarkers such as autoantibody titers.

We received RMAT designation from the FDA for the treatment of SPS in July 2024 and Orphan Drug Designation from the FDA for the treatment of SPS in August 2024. We expect to complete enrollment in KYSA-8 in the first half of 2025 and we expect to report top-line results from KYSA-8 in the first half of 2026, with the intention of filing a BLA for SPS in 2026. The following figure shows the design for our KYSA-8 pivotal Phase 2 trial in SPS:

KYSA-8 pivotal Phase 2 trial in SPS: open-label, single-arm, multicenter study; Natural History comparator



We chose SPS as the lead indication for our clinical development program because of the significant unmet need, with currently no FDA-approved therapies. There is a high cost burden from chronic immunosuppressants, supportive care and hospital visits in this patient population. Up to 85% of patients have no response to or eventually fail off-label immunosuppressants and IVIG. We also believe that there is a significant first-mover advantage in bringing CAR T-cell therapy to neuromuscular diseases, including the opportunity to address a prevalent patient pool, establish price, build brand loyalty, and launch with a focused commercial infrastructure. For these reasons, we

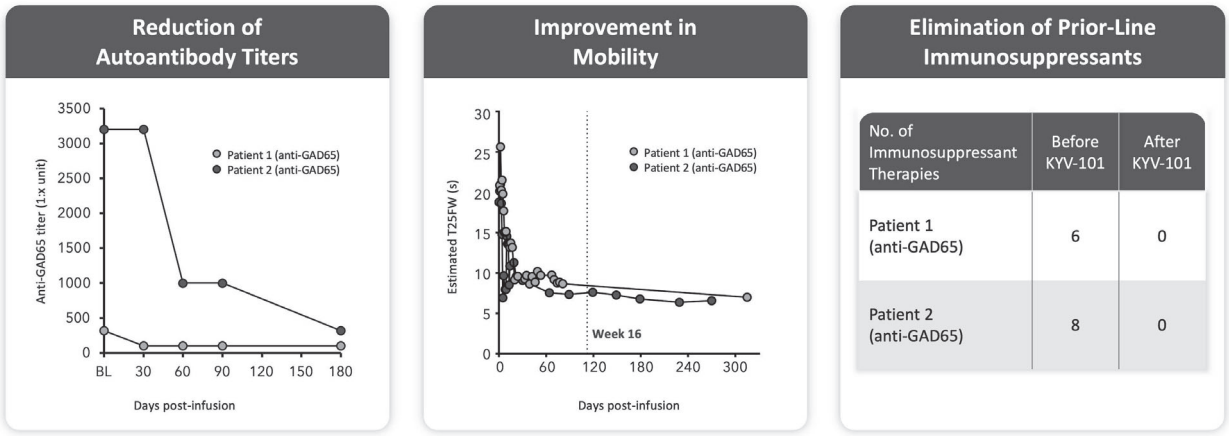
believe that SPS is the ideal indication to advance as the tip of the spear for our clinical development program, with the potential to unlock significant opportunity in larger indications in neuroinflammatory disease, as well as in autoimmune disease more broadly.

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

In total, as of October 31, 2024, three patients with SPS have been treated with KYV-101 on a named patient basis through IH, a form of compassionate use. While we do not expect to be able to use the efficacy 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.

The results of the first SPS patient treated with KYV-101 on a named patient basis have been published in *PNAS* in June 2024. We also reported the results observed in the first two SPS patients treated on a named patient basis in a company symposium at ECTRIMS in September 2024. These two SPS patients represent all SPS patients treated on a named patient basis who did not have comorbidities that would have excluded them from the KYSA-8 trial, and therefore we believe their results may be most helpful to understanding the potential of KYV-101 in SPS. In both patients, KYV-101 treatment resulted in a reduction of pathogenic autoantibody levels. Both patients demonstrated improvements in T25FW measurements by week 16 estimated from measurements of walking speed by the treating physicians originally measured in meters per second. These improvements in walking were stable and durable over time. Treatment with immunosuppressants was eliminated in both patients, with no immunosuppressive therapies being used at greater than 180 days of follow-up for all three patients. Measurements exclude physiologic replacement steroids at doses of ≤7.5 mg/day. A third SPS patient treated with KYV-101 on a named patient basis was affected with severe and refractory progressive encephalomyelitis with rigidity and myoclonus, or PERM, and therefore would be excluded from our KYSA-8 trial. PERM is a rare condition affecting approximately 5% of SPS patients. The results in the first two SPS patients who would not be excluded from KYSA-8 are shown in the below graphs:

KYV-101 in SPS: Kyverna Experience at Therapeutic Dose in Initial 2 Compassionate Use Patients



Myasthenia Gravis (MG) Disease Background

MG is an autoimmune disorder associated with progressive muscle weakness and increased mortality risk. 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. 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, leading to death in approximately 2% to 5% of cases. Patients in crisis often require intubation and mechanical ventilation. The prevalence of MG is estimated to be 1 in 5,000, with up to 80,000 to 100,000 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

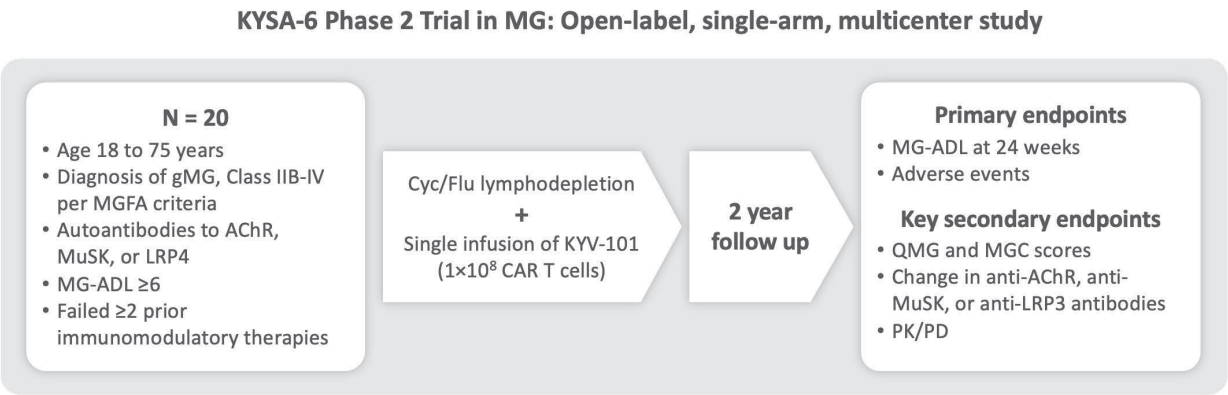
Early-stage MG is symptomatically treated by the use of acetylcholinesterase inhibitors, which block the breakdown of acetylcholine, compensating for some of the loss of receptors due to the autoimmune antibodies targeting AchR. As the disease progresses, patients are typically treated with immunomodulatory agents including immunosuppressive therapies such as steroids or methotrexate, rituximab, IVIG, FcRn blockers, and complement inhibitors. These therapies are chronically administered and often have transient impacts.

We believe that a therapy that deeply depletes pathogenic B cells to reset the immune system may provide durable benefits for patients with MG without the need for chronic treatment.

KYV-101 Clinical Development in MG

We have completed enrollment of an initial cohort of six patients in our KYSA-6 Phase 2 single-arm, open-label, multicenter, global trial in adult patients with MG. Primary endpoints are myasthenia gravis activities of daily living score, or MG-ADL, at 24 weeks and incidence and severity of adverse events and laboratory abnormalities. Secondary endpoints include evaluating other efficacy scores and disease-related biomarkers. We expect to report results from this initial six-patient Phase 2 cohort of KYSA-6 in the second half of 2025.

We received RMAT designation from the FDA for the treatment of MG in August 2024, Orphan Drug Designation from the FDA for the treatment of MG in April 2024, and Orphan Drug Designation from the EMA for the treatment of MG in November 2024. We expect to confirm the registrational path for KYV-101 in MG with regulators in the first half of this 2025. Our current KYSA-6 Phase 2 trial design for which we have completed enrollment of an initial cohort of six patients is shown below:

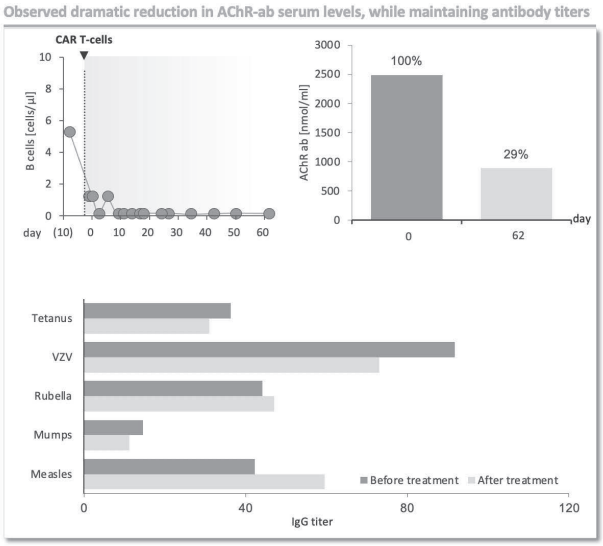


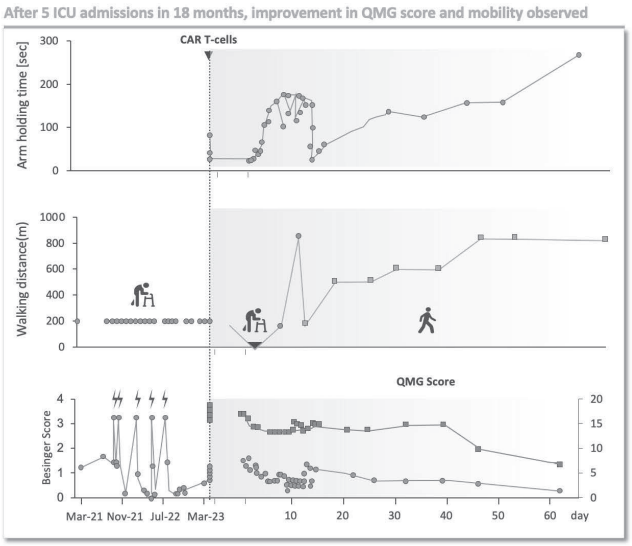
gMG: generalized myasthenia gravis; MGFA: Myasthenia Gravis Foundation of America; AchR: Acetylcholine Receptor; MuSK: Muscle-Specific Kinase; LRP4: Low-density lipoprotein receptor-related protein 4; MG-ADL: myasthenia gravis Activities of Daily Living; QMG: Quantitative Myasthenia Gravis; MGC: Myasthenia Gravis Composite

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 through IH, a form of compassionate use, 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 18 months prior to KYV-101 infusion. 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. At greater than 19 months of follow-up from treatment with KYV-101, this patient continues to report durable remission and require no ongoing treatment with immunosuppressants or glucocorticoids.

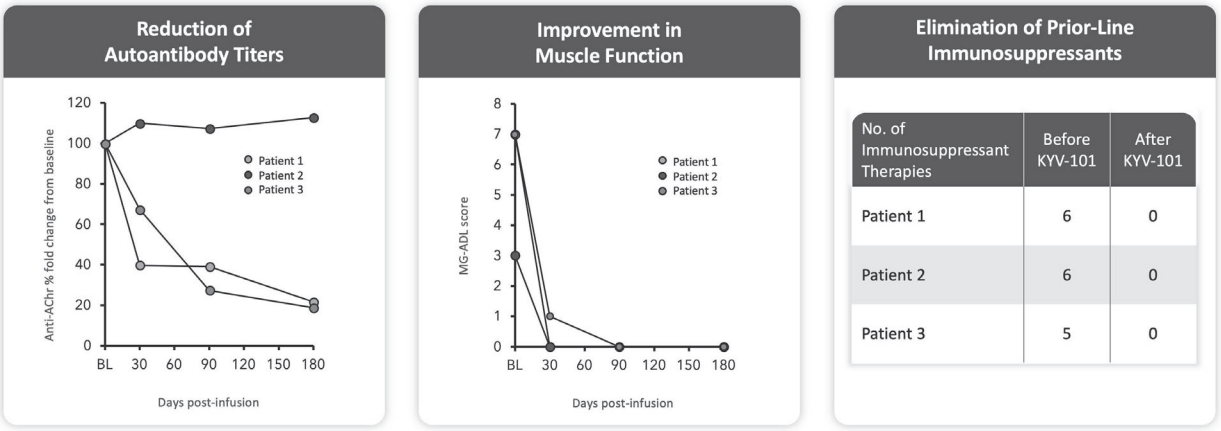




The results from this first patient and two additional MG patients treated with KYV-101 on a named patient basis were reported at a company symposium at ECTRIMS in September 2024. These are the first three MG patients treated with KYV-101 who did not have comorbidities that would have excluded them from the KYSA-6 trial. We believe that the results from these first three patients who would not be excluded from the KYSA-6 study may be most helpful to understanding the potential of KYV-101 in MG. While we do not expect to be able to use the efficacy 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.

The results observed in these three MG patients are shown in the below graphs. In two of the three patients, KYV-101 treatment resulted in a reduction of AchR autoantibody levels. In all three patients, MG-ADL scores improved substantially, from 3 in one patient and 7 in two patients to zero within 30 to 90 days after KYV-101 treatment. These improvements were stable and durable over time. Treatment with immunosuppressants was eliminated in all three patients, with no immunosuppressive therapies being used at greater than 180 days of follow-up for all three patients. Measurements exclude physiologic replacement steroids at doses of ≤7.5 mg/day.

KYV-101 in MG: Kyverna Experience at Therapeutic Dose in Initial 3 Compassionate Use Patients



No. of Immunosuppressant Therapies	Before KYV-101	After KYV-101
Patient 1	6	0
Patient 2	6	0
Patient 3	5	0

Lupus Nephritis (LN) Disease Background

Lupus nephritis is a type of kidney disease that develops in about half of adult patients with systemic lupus erythematosus, or 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. In LN, 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. LN patients can experience fatigue, hypertension, blood and excessive protein in their urine, osteoporosis and edema. Up to 50% of SLE patients will develop LN, and 30% of LN patients will develop end-stage kidney disease and require dialysis or transplant.

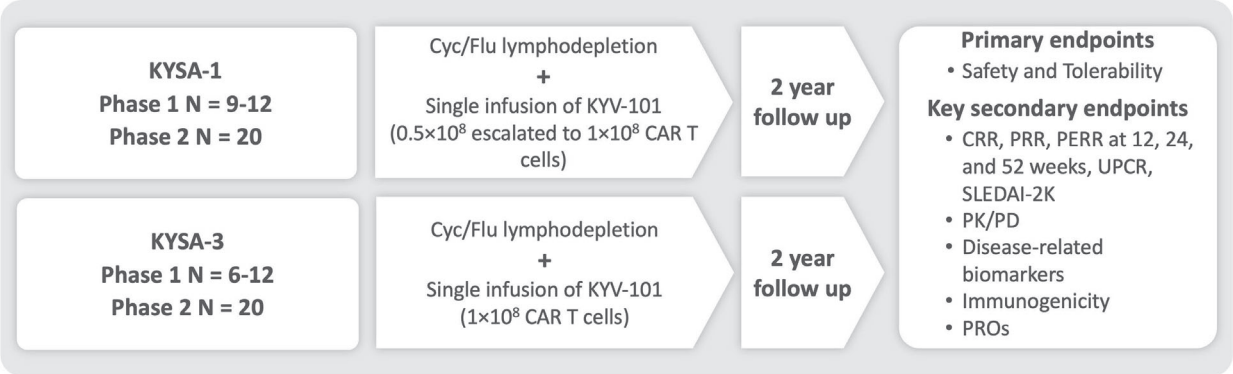
Current treatments for LN focus on minimizing permanent kidney damage. Newer recommendations from the ACR recommend triple therapy with immunosuppressant agents with a combination of a glucocorticoid, mycophenolate, and belimumab, marketed as Benlysta®, or a calcineurin inhibitor. Many patients fail to achieve complete remissions with approved therapies and treatment options for refractory patients are limited. LN can progress aggressively, requiring prompt treatment to avoid permanent kidney damage which can arise following a single disease flare. Long-term high-dose immunosuppression for the treatment of lupus nephritis is associated with significant treatment toxicity.

There are an estimated 70,000 to 100,000 SLE patients in the United States that are diagnosed with lupus nephritis. We estimate that there are up to 40,000 LN patients in the United States with Class II, III or IV LN that are refractory to current therapies.

KYV-101 Clinical Development in LN

We are currently advancing two clinical trials in patients with LN, KYSA-1 and KYSA-3. KYSA-1 is an open-label, multicenter, U.S.-based dose escalation trial in adult patients with refractory lupus nephritis for which we have completed the dose escalation cohort. 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. The Phase 1 primary endpoints of KYSA-3 are the incidence of adverse events and laboratory abnormalities and the frequency of dose-limiting toxicities. Secondary endpoints include evaluating disease-related biomarkers, efficacy, including CRR and time to CRR, and immunogenicity. In total, we have enrolled 9 patients across KYSA-1 and KYSA-3, of which 6 are at the therapeutic dose. We believe that the data from these 9 patients will be sufficient to inform the next stage of our clinical development in LN. Our current KYSA-1 and KYSA-3 clinical trial designs in LN are shown below.

KYSA-1 and KYSA-3 Phase 1/2 Trials in LN: Open-label, single-arm, multicenter studies



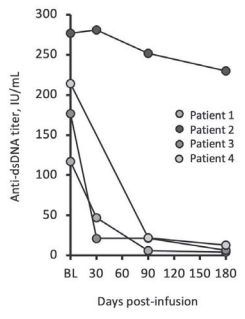
CRR: Clinical Response Rate; PRR: Partial Renal Response; PERR: Primary Efficacy Renal Response; UPCR: urine protein-to-creatinine ration; SLEDAI-2K: the Systemic Lupus Erythematosus Disease Activity Index 2000; PROs: Patient Reported Outcomes

Early results available as of October 31, 2024 in four patients with LN treated with the therapeutic dose of KYV-101, including one patient treated on a named patient basis, one patient treated on a single-patient IND, and two patients treated in the KYSA-3 clinical trial, were reported at a company symposium at ACR in November 2024. While we do not expect to be able to use the efficacy results from named patient case reports in our application for marketing approval to the FDA or other foreign regulatory agencies, we believe that these results address our mission to prioritize patient needs while providing us insight to help de-risk future Kyverna-sponsored clinical trials.

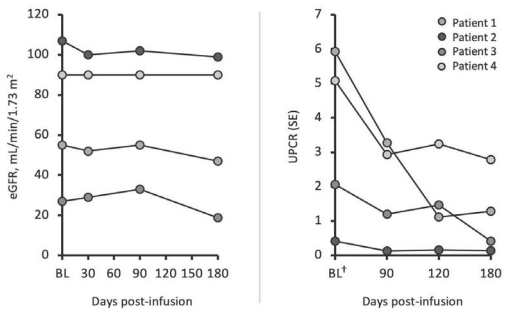
The results observed in these first four LN patients are shown in the below graphs. In all four patients, KYV-101 treatment resulted in a reduction of dsDNA autoantibody levels. KYV-101 treatment also stabilized kidney function for all four patients, measured as no substantial change in estimated glomerular filtration rate and a reduction of urinary protein-to-creatinine ratio, that improved to below 0.5 g/g in two patients, consistent with criteria for CRR. Treatment with immunosuppressants was eliminated in all four patients, with no immunosuppressive therapies being used at greater than 180 days of follow-up for all four patients. Measurements exclude physiologic replacement steroids at doses of ≤7.5 mg/day.

KYV-101 in LN: Kyverna Experience at Therapeutic Dose in Initial 4 Patients

Reduction of Autoantibody Titers



Stabilization of Kidney Function



Elimination of Prior-Line Immunosuppressants

Patient	Before KYV-101	After KYV-101
Patient 1	3	0
Patient 2	7	0
Patient 3	6	0
Patient 4	4	0

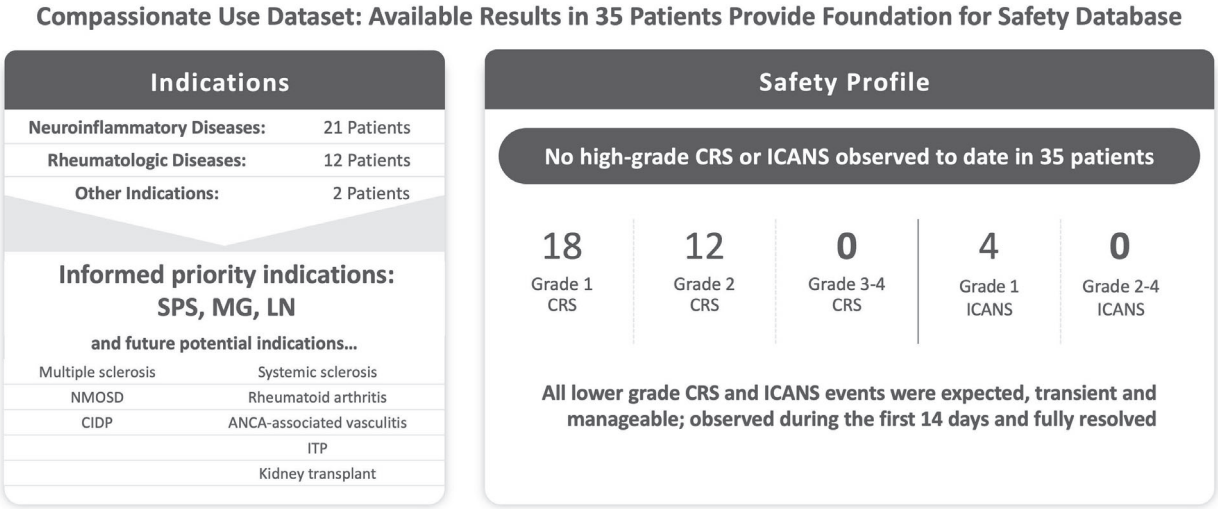
Clinical Applications of KYV-101 in Other Indications

Kyverna's additional KYSA studies, KYSA-5 in systemic sclerosis and KYSA-7 in multiple sclerosis, as well as IITs across numerous other autoimmune diseases, are exploring additional opportunities for KYV-101 beyond our priority indications. Data from these efforts will inform selection of the next priority indication(s) to accelerate into late-stage development.

KYV-101 Safety Experience in Autoimmune Patients

From May 2023 to December 2024 we supplied KYV-101 in named patient activities for the treatment of 40 patients across 9 sites in Germany through IH, which is a form of compassionate use treatment for an individual patient, where a procedure or treatment that has not received marketing authorization may be used for the expected benefit of a patient who has exhausted all available treatment options, under the discretion of the treating physician. The primary goal of these compassionate use treatments is not to assess the effectiveness, but rather to provide a treatment option to patients who have exhausted all other options.

This named patient experience provides us with a dataset to anchor our clinical development strategy and we believe supports the potential for a differentiated safety profile. In our compassionate use results summarized at a company symposium at ACR in November 2024, we reported that we observed no high-grade ICANS or CRS following treatment with KYV-101 across all 35 patients with at least 28 days of follow-up as of October 31, 2024. Lower-grade CRS and ICANS events were expected, transient and manageable. All events were observed during the first 14 days and fully resolved. Such data are not obtained using a single protocol or designed to be aggregated or reported as study results, and may be highly variable. 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.



Manufacturing Capabilities and Industrialization of Autologous CAR T-cell Therapies

We have developed a robust manufacturing process for KYV-101 and partnered with ElevateBio Base Camp, Inc., or Elevate, and WuXi ATU Advanced Therapies Inc, or WuXi, two experienced contract development and manufacturing organizations, to generate KYV-101 for our Kyverna-sponsored clinical trials, investigator-initiated trials and named patient activities. We also continue to progress our CMC readiness efforts in a capital-efficient manner to support a potential BLA filing in 2026.

In parallel, we are developing Ingenui-T, a whole blood, rapid manufacturing process designed to improve patient access to CAR T-cell therapies through partnerships with world-class organizations in cell therapy manufacturing, including Elevate. 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. Our first product candidate utilizing the Ingenui-T process is KYV-102.

KYV-102, an Autologous CD19 CAR T-cell Product Candidate with Whole Blood Rapid Manufacturing

KYV-102 leverages the same fully human, clinically validated CD19 CAR-T construct as KYV-101. It incorporates the Ingenui-T process, a proprietary, next-generation process that utilizes whole blood with a rapid manufacturing approach. We intend to broaden CAR T patient access with KYV-102 by eliminating the need for apheresis starting material and reducing the manufacturing turnaround time from conventionally manufactured CAR T-cell products. We expect to file an investigational new drug application for KYV-102 in the second half of 2025.

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

Over the longer term, we believe that some patients may 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.

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. Under our Development and Manufacturing Services Agreement with Elevate, dated July 2023, or the Elevate Agreement, we engaged Elevate in November 2024 to provide us with 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 provides 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 the Elevate Agreement, Elevate is undertaking process development services for the development of a rapid whole blood manufacturing process for our CAR T-cell products, including KYV-102.

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, 2025, 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, KYV-102, 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, South Korea, Mexico, New Zealand, Saudi Arabia, and Singapore, and pending patent applications in Australia, Canada, the European Patent Organization, Hong Kong, Israel, India, Japan, South Korea, Mexico, 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 U.S. utility patent application, and a pending patent application in Europe and Taiwan. The second patent family includes a pending international PCT patent application and a pending U.S. utility 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 various autoimmune diseases using T cells expressing a CD19 CAR. The first patent family includes a pending international PCT patent application and a pending U.S. utility patent application, directed to methods of treating myasthenia gravis and stiff person syndrome. The second and third patent families each include a pending international PCT patent application, directed to methods of treating systemic sclerosis and multiple sclerosis, respectively. Patent applications in these patent families, or patent applications claiming priority to them, 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 a pending international PCT patent application. Patent applications claiming priority to this 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, shortened manufacturing processes that may use whole blood as a starting material and may improve cell product quality. Both patent families include pending PCT International non-provisional patent applications. Non-provisional patent applications entering national and/or regional stages claiming priority to these PCT International 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, 2025, we owned two registered trademarks in the United States and 17 registered trademarks in foreign jurisdictions comprising or incorporating the term "KYVERNA." As of March 1, 2025, we owned two registered trademarks in the United States and eight 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 or for products that have received orphan drug designation by FDA.

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 announced and 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 health care professionals, 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, restitution or other penalties, injunctions, recall or seizure of products, total or partial suspension of production or distribution, denial or withdrawal of product approvals or license suspension, refusals of government contracts, or other civil investigations or penalties. 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. For example, in 2023, the Centers for Medicare and Medicaid Services initiated the Cell and Gene Therapy, or CGT, Access Model. This voluntary payment model is designed to test whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies would improve Medicaid beneficiaries' access to innovative treatment. The new Trump Administration revoked the Executive Order under which this voluntary model is being conducted. If CMS proceeds with implementing the CGT model, states may begin to participate in the model in 2025. The possible impact of the CGT model is uncertain. In addition, at the U.S. state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or provider reimbursement constraints, patient out-of-pocket cost caps for certain classes of therapy, discounts, restrictions on certain product access, marketing cost disclosure and other transparency measures, and, in some cases, measures designed to encourage importation from other countries and bulk purchasing.

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. 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. 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.

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. 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 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. 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. 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, and the potential for exclusion from participation in federal healthcare programs. 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. Our future sales and marketing activities, including price reporting activities for our products, if approved, 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. Requirements for compliance under HIPAA are also subject to change, as the U.S Department of Health and Human Services Office of Civil Rights issued a proposed rule that would amend certain security compliance requirements for covered entities and business associates.

The FTC also sets expectations for failing to take appropriate steps to keep consumers' personal information secure or failing to provide a level of security commensurate to promises made to an individual about the security of their personal information (such as in a privacy notice); such failures may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act.

In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Further, the federal Physician Payments Sunshine Act, or the Sunshine Act 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 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. 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. The Trump administration and Congress have indicated that they will continue to seek new 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. HHS has generally won the substantive disputes in these cases. Certain of these cases are now on appeal. 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 as other states have submitted importation program proposals. 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.

Other General Data Protection Laws and Regulation

In the ordinary course of our business, we and the third parties with whom we work process personal and sensitive data. Accordingly, we are, and may in the future become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. For example, 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 EU 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.

Additionally, numerous US states have passed comprehensive data protection laws and all fifty states have in place breach notification laws that may be applicable to our activities. For example, the California Consumer Privacy Act, or CCPA, establishes rights for California residents to their personal data and specific provisions for sensitive personal data and sets certain notice, privacy and security requirements for entities subject to the CCPA. The CCPA or fines and allows private litigants affected by certain data breaches to recover significant statutory damages.

Human Capital Resources

As of March 1, 2025, we had 112 employees, all of whom were full-time. Of those, 84 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, recruiting high caliber talent, retaining, incentivizing and motivating our existing and prospective employees. We aim to ensure a culture of high performance, innovation and accountability. 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.

To that end, in 2024 and 2025 we strengthened our management team with the addition of Warner Biddle, Chief Executive Officer; Naji Gehchan, MD, MSc, MBA, Chief Medical and Development Officer; Dan Maziasz, Chief Business Officer; Cara Bauer PhD, Chief Human Resources Officer; and Tracy Rossin, Senior Vice President of Corporate Affairs, Communications and Investor Relations. Additionally, we appointed Christi Shaw and Mert Aktar to the Board of Directors, bringing decades of industry leadership in corporate strategy and manufacturing expertise, including gene and cell therapy.

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.

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, some 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, or become 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. In April 2024, the FDA issued a public safety statement announcing its initiation of the class labeling changes and noting that patients and clinical trial participants receiving treatment with these products should be monitored life-long for secondary malignancies. 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, 2024. For the years ended December 31, 2024 and 2023, we reported a net loss of $127.5 million and $60.4 million, respectively. As of December 31, 2024, we had an accumulated deficit of $263.5 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, expand, 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;
- consider international expansion; 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 any of our product candidates is approved for marketing by applicable regulatory authorities, our ability to generate revenue from such product 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 products 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 products through our own marketing and sales activities, and any other arrangements to promote these products that we may otherwise establish;
- effectively commercialize any of our products that receive regulatory approval;
- seek and obtain reimbursement and collections for any of our products that receive regulatory approval as part of the commercialization process;
- 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
- ensure that our products 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.

As discussed in Part II, Item 9A of our Annual report on Form 10-K for the year ended December 31, 2023, we previously identified material weaknesses 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.

During the year ended December 31, 2024, our management, with the oversight of the Audit Committee of our board of directors, took substantial measures toward remediating the control deficiencies contributing to the material weaknesses. Specifically, we completed an initial risk assessment process and continue to focus on the principles of the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, framework related to risk assessment; we have engaged a third-party consulting firm to advise and assist in documenting the design and implementation of internal controls over the financial reporting process, including general controls over information systems; and we have hired additional accounting and IT personnel, including but not limited to a Vice President of Accounting/Corporate Controller, a Head of Information Technology, and an Assistant Controller. Our management is committed to maintaining a strong internal control environment and to continuing to implement a strong system of controls and believe that our ongoing remediation efforts, particularly in the improvement of our control environment, will result in significant improvements to our system of controls. However, 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 will continue to implement new procedures and controls and take efforts to address each of the identified weaknesses. These remediation measures will be time consuming and require financial and operational resources.

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. Refer to the section titled "Controls and Procedures" in Part II, Item 9A of this Annual Report on Form 10-K.

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 and cost 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 and/or logistical ease 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 activities, 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, 2025, we had 112 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 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. Given the scarcity of professionals with the scientific knowledge that we require and the competition for qualified personnel among biotechnology businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations. 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, 2024, we had federal NOL carryforwards of $79.2 million and state NOL carryforwards of $205.2 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 have performed a Section 382 study as of December 31, 2023, and 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. As of December 31, 2024, the Section 382 study was updated and we concluded that there were no ownership changes during 2024. Furthermore, there may be additional ownership changes in the future, including 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. Additionally, new income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Trump administration has proposed various U.S. federal tax law changes that, if enacted, could have a material impact on our business, cash flows, financial condition or results of operations. It is also uncertain if and to what extent various states will conform to federal tax laws. 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. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future tax expense.

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 and, as described more fully below, are currently named as a defendant in a recently filed securities class action complaint. 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. As noted above, in December 2024, a shareholder class action complaint, or the Complaint, was filed in the United States District Court for the Northern District of California against our company, certain of our current and former officers and directors, and the underwriters of our initial public offering. The Complaint alleges that the registration statement on Form S-1 filed in connection with our initial public offering and the prospectus contained therein contained material misstatements or omissions in violation of federal securities laws. We believe we have good and substantial defenses to the claims in the complaint, but there is no guarantee that we will be successful in these efforts. We are unable to determine whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by us in our financial statements for the year ended December 31, 2024.

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.

Additionally, we believe, through our interactions with the FDA under our Regenerative Medicine Advanced Therapy, or RMAT, designation, that our phase 2 trial in SPS, which we refer to as a pivotal trial, will be sufficient for use as a registration-enabling study, However, the FDA or other regulatory agencies may conclude that the trial is not sufficient to be registration-enabling to support a Biologic License Application, or BLA, or similar submission in other jurisdictions. 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 Germany, and the independent investigators of such trials file INDs for the treatment of multiple or individual patients with KYV-101. We have also supplied 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 codified German regulatory path. "Individueller Heilversuch" is a form of compassionate use treatment for an individual patient in Germany, where a procedure or treatment that has not received marketing authorization may be used for the expected benefit of a patient who has exhausted all available treatment options, under the discretion of the treating physician. The provision of KYV-101 on a named patient basis and in investigator-initiated trials are not a substitute for, or intended to replace, our clinical trials. The primary goal of these compassionate use treatments is not to assess the effectiveness, but rather to provide a treatment option to patients who have exhausted all other options. 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. Similarly, named patient treatments are carried out by independent physicians in a manner that the physician determines in his or her discretion 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, there can be no assurances 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 without advance notice 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 of, or publication or other use of the observational 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 company-sponsored clinical trials 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. In addition, the FDA or other regulatory authority may require information beyond what we plan to provide in or expect to be required for a marketing application, including additional chemistry, manufacturing and control information, or additional preclinical or clinical data to support approval. These requirements may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. 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, the conflict between Israel and Iran 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, some 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, some 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, investigator initiated trials or named patient activities, 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, in 2024 the FDA initiated class safety labeling changes for BCMA- or CD19-directed genetically modified autologous CAR T cell immunotherapies after it concluded that changes to the boxed warning were warranted to highlight the serious risk of T cell malignancies. In addition to labeling changes, if we were to identify delayed side effects with any of our product candidates, 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 with cell manufacturing, release and testing services for our KYV-101 product candidate. Under our Development and Manufacturing Services Agreement, or the Elevate Agreement, with ElevateBio Base Camp, Inc., or Elevate, we engaged Elevate in November 2024 to provide us with 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 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.

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, some 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. We are aware of third-party U.S. and European patents related to CAR T cells for use in treating autoimmune diseases, which may be relevant to our product candidates. If these patent rights were enforced against us, we believe that we have defenses against any such action, including that these patents are not valid. There could be additional 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 no valid third-party patents and other intellectual property rights can be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof. If we are sued for infringing intellectual property rights of third parties, such litigation 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 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 and we may in the future be subject to claims that former employees, consultants, or other third parties have an interest in our patents or other intellectual property as an inventor, co-inventor, or owner of trade secrets. Although it is our policy to require our employees and consultants who may be involved in the conception or development of

intellectual property to execute agreements assigning that intellectual property to us, we may be unsuccessful in executing such an agreement with each party who conceives or develops intellectual property that we regard as our own or such party may breach the assignment agreement, or 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 obtain 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. 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. In April 2024, the FDA issued a public safety statement announcing its initiation of the class labeling changes and noting that patients and clinical trial participants receiving treatment with these products should be monitored life-long for secondary malignancies. Because all currently approved CAR T-cell immunotherapies are in oncology indications, however, 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 U.S. congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In addition, the IRA,

among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions took effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. On January 17, 2025, CMS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. While there had been some questions about the Trump Administration's position on this program, CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program. In response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. It is unclear whether or how much such rights may be exercised.

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. For example, on January 5, 2024, the FDA approved Florida's Section 804 Importation Program, or SIP, proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA.

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 continued to increase 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. The FDA has issued draft guidance that proposes criteria it will evaluate to determine if a trial is underway, including whether enrollment in the trial has been initiated. 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 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, or MG, in December 2023 and for KYV-101 for the treatment of patients with multiple sclerosis in January 2024 and RMAT designation for KYV-101 for the treatment of SPS in July 2024 and for the treatment of MG in August 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.

We may not be able to obtain orphan drug designation or orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may 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 neither shortens the development time or regulatory review time of a product candidate, nor gives the product candidate any advantage in the regulatory review or approval process. We received orphan drug designation from the FDA for KYV-101 for the treatment of MG in April 2024, for the treatment of SPS in August 2024, and for the treatment of SSc in September 2024, but we may not be granted orphan drug designations for our product candidates in other indications in the U.S. or in other jurisdictions.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain orphan drug exclusivity for that product candidate. 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. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

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

We have received Regenerative Medicine Advanced Therapy, or RMAT, designation for KYV-101 for the treatment of stiff-person syndrome, or SPS, and for the treatment of myasthenia gravis, or MG. This designation may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.

We received Regenerative Medicine Advanced Therapy designation for KYV-101 for the treatment of SPS in July 2024 and for the treatment of MG in August 2024.

A company may request RMAT designation of its product candidate, which designation may be granted if the product meets the following criteria: (i) it is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements

through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

RMAT designation does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

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, former 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 any healthcare reform measures of the Trump 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, 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 took effect 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.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the Loper decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rule-making process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

Our ability to effectively monitor and respond to the rapid and evolving developments and expectations relating to sustainability, including the environmental, social and governance matters, may impose unexpected costs or results in reputational or other harm that could have a material adverse effect on our business.

There is an increasing focus from certain investors, employees, regulators, listing exchanges and other stakeholders concerning corporate responsibility and sustainability matters, including with regard to environmental, social and governance factors. Some investors and investor groups may use these factors—either positively or negatively—to guide their investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies or practices relating to corporate responsibility and sustainability do not align with their expectations. Currently, a number of third-party providers of corporate responsibility and sustainability ratings measure the performance of companies on such topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers, and some major institutional investors have publicly emphasized the importance of these measures to their investment decisions. Topics taken into account in such assessments include, among others, companies' efforts and impacts on climate change, human rights, business ethics and compliance, and the role of companies' board of directors in overseeing various sustainability-related issues. In light of investors' increased focus on these matters, if we are, for example, perceived as lagging in taking steps with respect to these initiatives, certain investors may seek to engage with us on improving our corporate responsibility and sustainability disclosures or performance. They may also make voting decisions or take other actions to hold us and our board of directors accountable.

In addition, there are rapidly evolving developments and changing expectations relating to sustainability matters. As a result, the criteria by which our corporate responsibility and sustainability practices are assessed may change, which could cause us to undertake costly initiatives or actions to satisfy new demands. If we elect not to or are unable to adequately recognize and respond to such developments and changing governmental, societal, investor and/or consumer expectations relating to sustainability matters, we may miss corporate opportunities, become subject to additional scrutiny or incur unexpected costs. We may face risk of litigation or reputational damage in the event that our sustainability policies or practices do not meet the standards set by various constituencies.

We may also face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable sustainability rating from third-party rating services. A low sustainability rating by a third-party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competitors instead. Ongoing focus on corporate responsibility and sustainability matters by investors and other stakeholders as described above may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, financial condition or results of operations, including the sustainability of our business over time, and could cause the market value of our common stock to decline.

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.

Disruptions at the FDA, the SEC and other government agencies, including from government shutdowns, or funding changes, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels, reductions in workforce, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In the past, average review times at the agency have fluctuated, and this may continue in the future. In addition, government funding of other agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. In addition, government shutdowns, if prolonged, could significantly impact the ability of government agencies upon which rely (such as the FDA and SEC) to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Disruptions at the FDA and other agencies may slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the past decade, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

Finally, with the change in presidential administrations in 2025, there is substantial uncertainty as to how, if at all, the new administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates. The impending uncertainty could present new challenges or potential opportunities as we navigate the clinical development and approval process for our product candidates. If we or our collaborators experience delays in obtaining approval or if we or they fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

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. Additionally, in 2024, the FTC finalized updates to the Health Breach Notification Rule that, among other things, clarified its applicability to health apps and other similar technologies and expanded the information the breach notification requirements for entities subject to the rule which may add additional complexity to compliance obligations going forward.

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, amended 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, Montana, Oregon, Texas, Virginia and Utah in 2023 and 2024. Additionally, Delaware, Florida, Indiana, Iowa Kentucky, Maryland, Minnesota, Nebraska, New Hampshire, New Jersey, Rhode Island, Tennessee and others have adopted privacy laws, which took or will take effect from January 1, 2025 through 2026. Some state laws also minimize what data can be collected from consumers and how businesses may use and disclose it. These state privacy laws also require businesses to make disclosures to consumers about data collection, use and sharing practices. In addition, some of these laws (including the CPRA), along with other standalone health privacy laws, subject health related information to additional safeguards and disclosures and some specifically regulate consumer health data, such as the Washington My Health My Data Act, which became effective in 2024, Nevada's Consumer Health Data Privacy Law, which became effective in 2024, and Connecticut's amendments to its privacy law to address health data, which became effective 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 and access to certain data such as the European Health Data Space Regulation. 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 a bill to amend the existing UK framework has been reintroduced (in a different form) by the new UK Government and was announced as a bill which has been introduced into Parliament at the King's speech on July 17, 2024. At this time, there is no specific clarify on the provisions of the bill, or to the extent to which it will amend the UK framework, beyond general descriptions on its intended purpose. This bill, if passed, 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.

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

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

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, or become 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; under the Elevate Agreement we engaged Elevate in November 2024 to provide us with cell manufacturing, release and testing-services for our KYV-101 product candidate; and pursuant to the Oxford Agreement, we 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.

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, 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, criminal and administrative 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. For example, the new Trump administration has substantially altered prior U.S. government international trade policy and has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the new Trump administration has initiated, and is considering imposing additional, tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. It remains unclear what the new Trump administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers and increase the cost of materials purchased to manufacture our product candidates.

We depend on 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 limited source suppliers for certain drug substances, drug products, raw materials, samples, components, and other materials used in our product candidates. For example, WuXi and Elevate are currently our only providers 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, produce insufficient quantities of our supplies or otherwise fail to meet contractual requirements, experience financial difficulties, cease operations, face business disruptions or be acquired by, or enter into

exclusive arrangements with, our competitors. In addition, geopolitical tensions may impact our CMOs. In January 2024, the U.S. House of Representatives introduced the BIOSECURE ACT (H.R. 7085), which was subsequently amended on May 15, 2024 and passed by the U.S. House of Representatives on September 9, 2024, and the Senate advanced a substantially similar bill (S. 3558), both of which would prohibit U.S. federal executive agencies from contracting with any entity where the biotechnology equipment or services of a "biotechnology company of concern" would be used in the performance of that contract. Generally, a "biotechnology company of concern" is a biotechnology company that is subject to the jurisdiction, direction, control, or operates on behalf of a foreign adversary's government and poses a risk to the national security of the U.S. WuXi AppTec was listed as a "biotechnology company of concern." The final language, pathway and timing for the provisions of either of these bills to become law remain uncertain. Although the bill was passed in the House on September 9, 2024, the Senate did not pass the bill before the end of the 118th Congress' term. Nonetheless, if these bills are re-introduced in the House and Senate and become law, or similar laws are passed, they would have the potential to severely restrict our ability to purchase services or products from, or otherwise collaborate with, certain Chinese "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive reimbursement from, the U.S. government. Passage of legislation similar to the BIOSECURE ACT could potentially lead the way for further legislation, sanctions, or restrictions that could potentially impact our relationship with WuXi and the WuXi Agreement due to those entities affiliations with WuXi, which could delay or impact clinical trials and consequently delay or obstruct regulatory approval of our product candidates.

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 that may impact the operation of our business, 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. See the risk factor under the heading "We or our directors or officers may be subject to securities litigation, which is expensive and could divert management attention" above for a discussion of a recently filed securities class action complaint in which we are currently named as a defendant.

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. As of December 31, 2024, we had 2,491,968 shares of common stock available for future issuance under our 2024 Plan. 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. Additionally, pursuant to our 2024 Inducement Equity Incentive Plan, or our Inducement Plan, our management is authorized to grant equity-based awards in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares solely to our prospective employees provided that certain criteria are met. As of December 31, 2024, we had 1,070,741 shares of common stock available for future issuance under our Inducement Plan. Unless our board of directors or a committee thereof elects not to increase the number of shares available for future grant each year under the 2024 Plan or Inducement Plan, 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.

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, 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 of 1933, as amended, or 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.

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 December 31, 2024, our executive officers, directors and holders of 5% or more of our capital stock beneficially owned approximately 52.1% 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 our Annual Reports 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 our initial public offering, 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 our Annual Reports 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 Effects 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. In December 2024, a shareholder class action complaint, or the Complaint, was filed in the United States District Court for the Northern District of California against our Company, certain of our current and former officers and directors, and the underwriters of our initial public offering. The Complaint alleges that the registration statement on Form S-1 filed in connection with our initial public offering and the prospectus contained therein contained material misstatements or omissions in violation of federal securities laws. We believe we have good and substantial defenses to the claims in the Complaint, but there is no guarantee that we will be successful in these efforts. We are unable to determine whether any loss ultimately will occur or to estimate the range of such loss; therefore, no amount of loss has been accrued by us in our financial statements for the year ended December 31, 2024. 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, 2025, there were approximately 28 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

None.

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 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 clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases. Our goal is to liberate patients from autoimmune diseases through the curative potential of cell therapy. Our approach is supported by our breadth of experience treating patients with our lead product candidate, KYV-101, across more than 15 autoimmune disease indications. This has been documented through the scientific publication of multiple autoimmune case studies, our proprietary dataset of patients treated through named patient forms of compassionate use, our experience in ongoing investigator-initiated trials at leading academic institutions, as well as early clinical data from our ongoing company-sponsored trials illustrating the potential of these therapies to deeply deplete B cells with the aim of achieving durable treatment-free remission. This validation provides us with a clear path to continue advancing KYV-101 through late-stage clinical development and commercialization across two broad areas of autoimmune disease: neuroinflammation and rheumatology.

Our lead program, KYV-101, is an autologous, fully human CD19 CAR T-cell product candidate incorporating highly potent CD28 co-stimulation. KYV-101 is made from an underlying chimeric antigen receptor, or CAR, licensed from the National Institutes of Health, or the NIH. We believe that this uniquely designed CAR in KYV-101 has the potential to deliver a differentiated therapeutic profile in autoimmune disease. In addition to a fully human scFv domain, the CAR in KYV-101 was also designed with a human CD8α hinge and transmembrane domain, a human CD28 costimulatory domain, and a human CD3ζ activation domain. This same 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 similar rates of durable antitumor responses while delivering improved tolerability in the clinic among adult oncology patients, as compared to the CAR used to create Yescarta®. We believe that these differentiated properties of the CAR in KYV-101 are critical for the potential success of CAR T cells as autoimmune disease therapies.

Our focused clinical development pipeline includes a pivotal Phase 2 trial of KYV-101 in stiff person syndrome, or SPS, a Phase 2 trial of KYV-101 in myasthenia gravis, or MG, and two multi-center Phase 1/2 trials for patients with lupus nephritis, or LN. We are also harnessing investigator-initiated trials and other Kyverna-sponsored clinical trials, or KYSA trials, including in multiple sclerosis and systemic sclerosis, to inform the next priority indications to advance into late-stage development. Additionally, our pipeline includes next-generation CAR T-cell therapies in both autologous and allogeneic formats, including efficiently expanding into broader autoimmune indications and increasing patient reach with KYV-102 using our proprietary whole blood rapid manufacturing process. We believe our cell therapy approach to autoimmune disease may present a significant advantage over current standard-of-care therapies by aiming for deep B cell depletion, an immune reset and long-term remission in autoimmune diseases.

KYV-101 is currently being evaluated in company-sponsored KYSA trials and investigator-initiated trials in numerous B-cell mediated autoimmune diseases with a prioritized focus in SPS, MG and LN. We have aligned with the FDA on a registrational Phase 2 trial design in SPS, KYSA-8. This KYSA-8 pivotal Phase 2 trial in SPS has enrolled 70% of study participants, with completion of enrollment expected in mid-2025. We also continue to progress our chemistry, manufacturing and controls, or CMC, readiness efforts in a capital-efficient manner in support of an anticipated biologics license application, or BLA, filing with the FDA in 2026. We expect to report topline data from our pivotal Phase 2 trial in SPS in the first half of 2026 and anticipate filing our first BLA with the FDA in 2026.

Our Phase 2 trial in MG, KYSA-6, has completed enrollment of patients in an initial six-patient cohort and we plan to report interim data from this cohort in the second half of 2025. We received Regenerative Medicine Advanced Therapy, or RMAT, designations and Orphan Drug Designations from the FDA for both SPS and MG as well as Orphan Drug Designation from the European Medicines Association in MG. We continue to engage in positive dialogue with the FDA and expect to provide an update on the registrational path for KYV-101 in MG in the first half of 2025.

We are also currently advancing two Phase 1/2 trials in LN, KYSA-1 and KYSA-3. We have completed the dose-escalation cohort of KYSA-1 and are now treating patients at the target dose. We expect to report Phase 1 data from both of these trials in the second half of 2025. In November 2024, we presented clinical data at ACR Convergence 2024 that demonstrated positive sustained efficacy and durability at >6-month follow-up observed in patients with severe LN treated with KYV-101 at the therapeutic dose.

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, and from the sale of shares of our common stock in our initial public offering in February 2024, or the IPO. Our net losses were $127.5 million and $60.4 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of $263.5 million. Management has determined that our cash and cash equivalents and available-for-sale marketable securities of $286.0 million as of December 31, 2024 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 equity or 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;
- explore additional indications for our existing product candidates;
- procure manufacturing of clinical supply and manufacturing operations 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. Under our Development and Manufacturing Services Agreement, dated July 2023, or the Elevate Agreement, with ElevateBio Base Camp, Inc., or Elevate, we engaged Elevate in November 2024 to provide us with 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 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.

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 the Elevate Agreement, Elevate is undertaking process development services for the development of a rapid whole blood manufacturing process for our CAR T-cell products, including KYV-102.

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.

Initial Public Offering

On February 8, 2024, our common stock began trading on the Nasdaq Global Select Market under the symbol "KYTX". On February 12, 2024, we closed the IPO and issued 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 gross proceeds of $366.9 million. Net proceeds were $336.2 million, after deducting underwriting discounts and commissions and other offering costs. Immediately prior to the IPO closing, all of the outstanding shares of our redeemable convertible preferred stock converted into shares of our common stock on a 1-for-4.5511 basis.

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 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. As of December 31, 2024, we recognized $0.6 million related to benchmark royalties for regulatory approvals and patients' dosing in clinical trials as research and development expenses in the statement of operations and comprehensive loss. As of December 31, 2024, $0.6 million were recorded as accounts payable in the balance sheet. No other benchmark royalties were probable or payable as of December 31, 2024 and 2023. We recognized $0.2 million as research and development expense related to minimum annual royalty payments in each of the years ended December 31, 2024 and 2023.

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 each of December 31, 2024 and 2023.

As of December 31, 2024 and 2023, Intellia owned less than 5% of our outstanding equity

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, the conflict between Israel and Iran, tensions in United States-China relations, disruptions in the banking industry and inflationary trends, and the imposition, or threatened imposition, of tariffs and potential retaliatory trade restrictions. The fiscal years 2024 and 2023 were marked by significant market uncertainty and increasing inflationary pressures. These market dynamics continue into 2025, 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.

Components of Operating Results

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.

Our general and administrative expenses have increased, and are expected to continue to 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.

Interest Income

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

Interest Expense

Interest expense consists primarily of interest expense related to our laboratory 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, 2024 and 2023

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

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands, except percentages)			
Operating expenses				
Research and development	$ 112,473	$ 49,923	62,550	125%
General and administrative	30,131	12,483	17,648	141%
Total operating expenses	142,604	62,406	80,198	129%
Loss from operations	(142,604)	(62,406)	(80,198)	129%
Interest income	15,359	2,282	13,077	573%
Interest expense	(142)	(187)	45	(24)%
Other expense, net	(90)	(55)	(35)	64%
Total other income, net	15,127	2,040	13,087	642%
Net loss	(127,477)	(60,366)	(67,111)	111%

Research and Development Expenses

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

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands, except percentages)			
External costs:				
License fees, milestone payments and annual maintenance fees related to acquired technologies	$ 912	$ 248	$ 664	268%
CRO, CMO, professional consulting and other third-party preclinical studies and clinical trials costs	67,678	21,468	46,210	215%
Other research and development costs, including laboratory materials and supplies	2,318	5,288	(2,970)	(56)%
Internal costs:				
Personnel-related	30,272	16,800	13,472	80%
Facilities and overhead	11,293	6,119	5,174	85%
Total research and development expenses	$ 112,473	$ 49,923	$ 62,550	125%

Research and development expenses increased by $62.6 million, or 125%, from $49.9 million for the year ended December 31, 2023 to $112.5 million for the year ended December 31, 2024. CRO, CMO, professional consulting and other third-party preclinical studies and clinical trial costs increased by $46.2 million for the year ended December 31, 2024 compared to 2023, as we continued advancing our lead product candidate, KYV-101, through clinical development. Other research and development costs, including laboratory materials and supplies,

decreased by $3.0 million for the year ended December 31, 2024 compared to 2023, mainly due to a reduction in procurement of materials for our research and development activities. License fees, milestone payments and annual maintenance fees related to acquired technologies for the year ended December 31, 2024 mainly included expenses related to the minimum annual royalties and milestone fees of $0.9 million payable to the NIH.

In 2024, personnel-related research and development costs increased by $13.5 million as a result of hiring personnel in our research and development organization during the year. This increase included an increase of $1.7 million in stock-based compensation expense, as we granted more options. Facilities and overhead costs increased by $5.2 million for 2024, mainly due to a $1.3 million increase in allocated overhead expenses, a $1.0 million increase in depreciation expense, a $1.1 million increase in software licenses expense, and an increase in conferences, recruitment and other expenses.

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

	Year Ended December 31,		Change	
	2024	2023	$	%
	(in thousands, except percentages)			
KYV-101	$ 61,884	$ 18,267	$ 43,617	239%
KYV-201	3,947	4,509	(562)	(12)%
Other research and development activities	5,077	4,228	849	20%
Total external research and development expenses	$ 70,908	$ 27,004	$ 43,904	163%

In 2024, KYV-101 program expenses increased by $43.6 million, primarily attributable to a $39.0 million increase in CRO, CMO and other clinical trials costs as we continued to advance KYV-101 through clinical development. KYV-101 program CRO, CMC and other clinical trial costs in 2024 also include $4.0 million compared to $1.6 million in 2023 of external expense related to the development of our Ingenui-T manufacturing process. The Ingenui-T manufacturing process is also used to develop a new program, KYV-102, announced in January 2025. Professional consulting expenses related to KYV-101 increased by $4.1 million and license maintenance expenses increased by $0.5 million for the year ended December 31, 2024 compared to the year ended December 31, 2023.

KYV-201 expenses decreased by $0.6 million for the year ended December 31, 2024 compared to the year ended December 31, 2023. CRO, CMO and consulting expenses increased by $0.7 million. This increase was off-set by a $1.2 million decrease in other research and development costs, such as reagents, laboratory materials and supplies expenses.

Other research and development activities increased by $0.8 million for the year ended December 31, 2024 compared to the year ended December 31, 2023 and include expenses related to reagents, lab supplies, outsourced research and development and professional consulting services.

General and Administrative Expenses

General and administrative expenses increased $17.6 million, or 141%, to $30.1 million for the year ended December 31, 2024 from $12.5 million for the year ended December 31, 2023. The increase in general and administrative expenses was primarily attributable to a $10.7 million increase in salaries and benefits, an increase of $4.7 million in professional services costs related to legal, accounting and consulting services, and a $2.2 million increase in facilities and overhead costs. The increase in salaries and benefits expenses include a $4.5 million increase in stock-based compensation expense, which includes $2.8 million of expenses recognized in connection with the note forgiveness and stock modification expense related to the former chief executive officer.

Interest Income

Interest income increased $13.1 million, from $2.3 million for the year ended December 31, 2023 to $15.4 million for the year ended December 31, 2024. The increase primarily relates to increased amounts invested in available-for-sale marketable securities and cash equivalents following the IPO in February 2024.

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, 2024, 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, an upfront payment of $17.5 million under the Gilead Agreement and net proceeds from the IPO of $336.2 million. As of December 31, 2024, we had $286.0 million in cash, cash equivalents and available-for-sale marketable securities.

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, 2024, we had an accumulated deficit of $263.5 million. Based on the current cash forecast, management has determined that our cash and cash equivalents and available-for-sale marketable securities of $286.0 million as of December 31, 2024 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. Our operating cash burn can vary from quarter to quarter; for example, we made certain one-time investments in our CMC readiness in the second half of 2024, which we expect to continue through the first half of 2025 for an anticipated BLA in 2026. We have also accelerated enrollment in certain of our clinical trials, with completion of enrollment in our pivotal Phase 2 trial in SPS expected in mid-2025. For these reasons, we currently expect our operating cash burn in the first half of 2025 to be higher than our operating cash burn in the second half of 2025. 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;
- litigation expenses we incur to defend against any claims, including 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,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (114,250)	$ (52,410)
Net cash used in investing activities	(160,902)	(8,785)
Net cash provided by financing activities	337,113	58,118
Net increase (decrease) in cash and cash equivalents	$ 61,961	$ (3,077)

Operating Activities

Net cash used in operating activities was $114.3 million and $52.4 million for the years ended December 31, 2024 and 2023, respectively.

Cash used in operating activities for the year ended December 31, 2024, was primarily due to our net loss of $127.5 million, decreased by other non-cash charges of $5.4 million and decreased by a net reduction of $7.9 million in our net operating assets and liabilities. Non-cash changes primarily consisted of $8.4 million stock-based compensation expense, $2.1 million depreciation and amortization expense and a $2.5 million non-cash lease expense, partially offset by $7.7 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 other accrued expenses and current liabilities of $10.9 million, primarily due to an increase in accrued CRO and CMO research and development expenses, an increase in accrued compensation of $2.1 million, and an increase in accounts payable of $0.7 million, partially offset by a decrease in operating lease liabilities of $2.4 million, an increase in other non-current assets of $2.0 million, and an increase in prepaid expenses and other current assets of $1.5 million.

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 of stock-based compensation expense, $1.7 million of 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.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2024, was $160.9 million, which consisted of $490.0 million of purchases of available-for-sale marketable securities and $2.2 million of purchases of property and equipment, offset by $331.3 million in proceeds from maturities of available-for-sale marketable securities.

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.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2024, was $337.1 million, which consisted of $341.2 million cash proceeds from the issuance of shares of our common stock in the IPO, net of underwriting discount and $0.3 million of proceeds from exercises of stock options, partially offset by a payment of $3.4 million related to offering costs and a payment of $1.0 million related to finance lease obligations.

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.

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 our other agreements to be terminated and did not have any other non-cancellable obligations under these agreements as of December 31, 2024 and 2023.

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, 2024 and 2023.

As of December 31, 2024, we leased approximately 68,000 square feet of office and laboratory space in Emeryville, California under operating leases which have terms through February 2027. We also have multiple leases for laboratory equipment with 36-month terms that are accounted for as finance leases. As of December 31, 2024, our non-cancellable lease obligations were $8.1 million and $1.1 million under operating and finance leases, respectively, of which $3.6 million and $0.9 million related to operating and finance leases, respectively, 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 option 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 — Prior to the IPO, the fair market value of our common stock was determined by our board of directors with assistance from management and external valuation experts. Our approach to estimating the fair market value of our common stock was consistent with the methods outlined in the American Institute of Certified Public Accountants' Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. Following our IPO, the fair market value of our common stock is based on its closing price on Nasdaq as reported on the date of the stock option grant.

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.

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 Rate 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, 2024. 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. Based on their evaluation, the CEO and the CFO have concluded that our disclosure controls and procedures were not effective as of December 31, 2024 because of the material weaknesses in our internal control over financial reporting described below.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act. Our management, including the CEO and the CFO, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the 2013 framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO. Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2024, due to the material weaknesses in internal control over financial reporting, described below. However, after giving full consideration to these material weaknesses, and the additional analyses and other procedures we performed to ensure that our financial statements included in this Annual Report on Form 10-K were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, our management has concluded that our financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with GAAP.

Material Weaknesses in Internal Controls Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As previously disclosed in Part II, Item 9A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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 continue to exist as of December 31, 2024.

As previously disclosed in Part II, Item 9A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, 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 continue to exist as of December 31, 2024.

Ongoing Remediation of Material Weaknesses

During the year ended December 31, 2024, our management, with the oversight of the Audit Committee of our board of directors, has taken substantial measures toward remediating the control deficiencies contributing to the material weaknesses identified above. These remediation efforts include the following:

- We have hired additional accounting and IT personnel, including but not limited to the hiring of a Vice President of Accounting/Corporate Controller, a Head of Information Technology, and an Assistant Controller;
- We have engaged a third-party consulting firm to advise and assist in documenting the design and implementation of internal controls over the financial reporting process, including general controls over information systems;
- We have completed an initial risk assessment and continue to focus on the principles of the COSO framework related to risk assessment;
- We have begun to design and implement and will continue to enhance our entity level controls across each of the COSO components necessary for effective internal control;
- We have formalized process documentation of all key processes and systems, including the mapping of controls to relevant financial reporting and IT risks;
- We have designed and implemented general controls over information systems across the majority of our relevant financial systems;
- We have engaged a third-party technical accounting firm to help management with accounting, presentation and disclosures of complex and judgmental transactions and created an internal cross-functional disclosure committee that includes senior members of the organization;
- We have begun to design and implement the necessary management review controls across all financial statement areas; and
- We performed manual procedures to validate the completeness and accuracy of certain reports generated from various financial systems that are relevant to the preparation of the financial statements.

Our management is committed to maintaining a strong internal control environment. We are committed to continuing to implement a strong system of controls and believe that our ongoing remediation efforts, particularly in the improvement of our control environment, will result in significant improvements to our system of controls. However, material weaknesses are not considered remediated until the new controls have been operational for a sufficient period of time, and management concludes, through testing, that these controls are operating effectively. We will continue to take efforts to address each of the identified weaknesses during fiscal year 2025. This remediation process may require additional resources and will require time to implement. We will continue to

monitor the effectiveness of these remediation measures, and we will make any changes to the design of our remediation plans and take such other actions that we deem appropriate given the circumstances.

Attestation of Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

Changes in Internal Control over Financial Reporting

Other than the material weakness remediation measures described above, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures, management recognizes that because of the inherent limitations in all control systems, any controls and procedures, no matter how well designed and operated, can provide only reasonable not absolute, assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and the benefits of controls and procedures must be considered relative to their costs.

Item 9B. Other Information.

10b5-1 Trading Plan Activity

During the fiscal quarter ended December 31, 2024, 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.

Restated Non-Employee Director Compensation Program

Effective March 25, 2025, the compensation committee of our board of directors implemented a Restated Non-Employee Director Compensation Program, or the Restated Director Compensation Program, which amends and restates the Company's non-employee director compensation program that was adopted in connection with the IPO, or the Prior Director Compensation Program. The Restated Director Compensation Program provides that each non-employee director initially elected or appointed to our board of directors after March 25, 2025 will automatically be granted (A) an option under the 2024 Plan to purchase that number of shares of our common stock equal to $262,500 divided by the per share grant date fair value of the option award, which 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, and (B) restricted stock units under the 2024 Plan or any other applicable Company equity incentive plan then maintained by us covering a number of shares of common stock equal to $87,500 divided by the per share grant date fair market value as of the date of the grant, rounded down to the nearest whole share, which will vest as to 1/3rd of the shares subject thereto on each one-year anniversary over three years, subject to continued service through the applicable vesting date.

In addition, pursuant to the Restated Director Compensation Program, on the date of each annual meeting of our stockholders, commencing with our 2025 annual meeting of shareholders, 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 (A) an option, or the Annual Option Grant, under the 2024 Plan to purchase that number of shares of our common stock equal to (a) $131,250, divided by (b) the per share grant date fair value of the option award, or (B) restricted stock units, or the Annual RSU Grant, under the 2024 Plan or any other applicable Company equity incentive plan then maintained by us covering a number of shares of common stock equal to $43,750 divided by the per share grant date fair market value as of the date of the grant, rounded down to the nearest whole share. Each of the Annual Option Grant and the Annual RSU Grant will be automatically granted on the date of each applicable annual meeting of shareholders and will vest in full on the earlier of (i) the 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 Restated Director Compensation Program, upon a change-in-control transaction, all outstanding equity awards held by our non-employee directors will vest in full. The cash compensation under the Restated Director Compensation Program remains the same as what was provided for in the Prior Director Compensation Program. See Part III, Item 11 of this Annual Report on Form 10-K for additional details regarding our non-employee director compensation.

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 27, 2025, our board of directors consists of eight members. In accordance with our amended and restated certificate of incorporation, 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, Christi Shaw 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 Warner Biddle, Mert Aktar 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 27, 2025:

Name	Age	Position(s)	Director Since
Class I Directors whose terms expire at the 2025 Annual Meeting of Stockholders			
Beth Seidenberg, M.D.(1)(2)(3)	68	Director	2018
Fred E. Cohen, M.D., D.Phil.(1)(3)	68	Director	2018
Class II Directors whose terms expire at the 2026 Annual Meeting of Stockholders			
Ian Clark(2)	64	Director	2021
Christi Shaw.(1)(2)	58	Director	2024
Steve Liapis, Ph.D.(3)(4)	37	Director	2022
Class III Directors whose terms expire at the 2027 Annual Meeting of Stockholders			
Warner Biddle	58	Chief Executive Officer and Director	2024
Mert Aktar.(3)(4)	46	Director	2024
Daniel K. Spiegelman(4)	66	Director	2021

(1) Member of the Compensation Committee.
(2) Member of the Nominating and Corporate Governance Committee.
(3) Member of the Science and Technology Committee.
(4) Member of the Audit Committee.

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 BioPartners, a life science 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., Atara Biotherapeutics, Inc. (Nasdaq: ATRA), and Progyny, Inc. (Nasdaq: PGNY), from June 2011 to January 2019, December 2012 to June 2018, August 2012 to June 2023 and May 2010 to November 2024, respectively. Dr. Seidenberg serves on the boards of directors of Vera Therapeutics, Inc. (Nasdaq: VERA), Acelyrin, Inc. (Nasdaq: SLRN), Sagimet Biosciences, Inc. (Nasdaq: SGMT) 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.

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 M.D. 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 boards of directors of several biotechnology and pharmaceutical organizations, including CareDx, Inc. (Nasdaq: CDNA), Progyny, Inc. (Nasdaq: PGNY) and Intellia Therapeutics, Inc. (Nasdaq: NTLA). He is a past member of the boards of UroGen Pharma Ltd. (Nasdaq: URGN), 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 Bioscience, Inc. (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.

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 Head of Global Product Strategy 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 Executive Vice President, Commercial Operations and Senior Vice President, General Manager of BioOncology. 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 U.S.A, United Kingdom, Canada, Eastern Europe and France. Currently, Mr. Clark is on the board of directors of several public biopharmaceutical and biotechnology companies, including Takeda Pharmaceutical Company Limited (NYSE: TAK), Corvus Pharmaceuticals, Inc. (Nasdaq: CRVS), Guardant Health, Inc. (Nasdaq: GH), Olema Pharmaceuticals, Inc. (Nasdaq: OLMA) and GoodRx Holdings, Inc. (Nasdaq: GDRX). Mr. Clark previously served on the boards of and Avrobio, Inc. (Nasdaq: AVRO), 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. Mr. Clark serves as an advisor to KKR & Co., Inc., and was previously 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.

Christi Shaw has served as a member of our board of directors since September 2024. Ms. Shaw is a seasoned healthcare executive with over 30 years of experience in the biopharmaceutical industry. Most recently, she served as Chief Executive Officer of Kite Pharma, Inc., a Gilead company specializing in the development of cancer immunotherapies, from August 2019 to March 2023. Ms. Shaw has served on the board of directors of Beam Therapeutics Inc. (Nasdaq: BEAM) since December 2023, and on the board of directors for ReAlta Life Sciences, Inc. since January 2024. Ms. Shaw also served as a director of Avantor, Inc. (NYSE: AVTR) from November 2018 through May 2024. From April 2017 to August 2019, she served as Senior Vice President of Eli Lilly & Co. (NYSE: LLY), a global healthcare company, and President of Lilly Bio-Medicines, the business within Eli Lilly Company that comprised its neuroscience and immunology divisions. From 2014 to 2016, Ms. Shaw served as U.S. country head and President of Novartis Pharmaceutical Corporation, a global healthcare company, and from 2010 to 2014, as North American region head of Novartis Oncology. Prior to 2010, Ms. Shaw held several leadership positions at Johnson & Johnson, Inc. (NYSE: JNJ). Previously, she served as an executive committee member of the Biotechnology Innovation Organization. Ms. Shaw is also the co-founder of the More Moments More Memories Foundation, which assists people with cancer and their caregivers. Ms. Shaw is also an advisor for Family Reach's Clinical Trial Access Program which she co-founded with her sister (More Moments More Memories) to assist people with cancer access clinical trials. Ms. Shaw holds a B.B.A. in Marketing from Iowa State University and an M.B.A. from the University of Wisconsin.

We believe that Ms. Shaw is qualified to serve on our board of directors because of her extensive experience in executive positions with several biopharmaceutical companies and her experience serving on the boards of several life science companies.

Steve Liapis, Ph.D. has served as a member of our board of directors since November 2022. Dr. Liapis is a Managing Director 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, Inc., Incendia Therapeutics, Inc., Totus Medicines, Inc., Opna Bio LLC, Aro Biotherapeutics Company, and Weaver Biosciences, Inc. 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.

Warner Biddle has served as our Chief Executive Officer and a member of our board of directors since September 2024. Mr. Biddle previously worked at Kite Pharma, Inc. from August 2020 to September 2024, where he served as Senior Vice President and Global Head of Commercial. Prior to that, Mr. Biddle served as Vice President and Franchise Head for the Breast/Gynecologic and Skin Cancer Franchises at Genentech from January 2018 to August 2020. During his prolific tenure, he led the cross-functional strategy and launches for several key commercial and pipeline products while driving significant portfolio growth. Prior to his oncology roles, Mr. Biddle served as Vice President, Sales and Marketing for Ophthalmology at Genentech from November 2013 to December 2015, and also held various global leadership roles in Europe and Canada across multiple therapeutic disease areas at Novartis and GlaxoSmithKline. Mr. Biddle earned a Bachelor's Degree in Commerce with Honors from the University of Saskatchewan.

We believe that Mr. Biddle is qualified to serve as a member of our Board due to his extensive experience as an executive in the biopharmaceutical industry across numerous therapeutic areas.

Mert Aktar has served as a member of our board of directors since October 2024. Mr. Aktar is an accomplished life sciences industry executive with over twenty years of multinational experience in bridging science and business in pharmaceuticals and biotechnology. He has served as Chief Executive Officer of Receptive Bio, Inc., a privately held biotechnology company based in Southern California, since February 2024. Prior to joining Receptive Bio, Inc., Mr. Aktar was the Senior Vice President and Global Head of Corporate Development & Strategy at Kite Pharma, Inc., from April 2020 to September 2023, where he played a key leadership role in shaping the future direction of Kite and establishing it as a global leader in cell therapy. Mr. Aktar led numerous deals strengthening Kite's R&D portfolio, including expansion in Asia, facilitating regulatory approval and commercial launch of the first autologous cell therapy product in China, and transfer of commercial rights from Daiichi Sankyo and regulatory approval and commercial launch of Yescarta in Japan. Prior to joining Kite, Mr. Aktar served as Vice President and Head of Business Development and Corporate Development at Unum Therapeutics Inc. from May 2019 to March 2020. Prior to that, Mr. Aktar held a number of senior leadership positions at Shire plc (now Takeda Pharmaceutical Company Limited) from April 2011 to May 2019, most recently serving as the Global Head of Hematology and Immunology Business Development from November 2017 to May 2019. While at Shire, Mr. Aktar facilitated the company's acquisitions of Baxalta Inc. and Dyax Corp., and orchestrated Shire's inaugural SEC-registered debt offering. Mr. Aktar held senior leadership positions at large biotech and pharma organizations across diverse modalities (cell therapy, gene therapy, nucleotide-based therapies, antibody therapeutics and small molecules) and therapeutic areas (oncology, hematology, immunology, rare genetic diseases and neuroscience). Mr. Aktar has served on the board of directors of ReAlta Life Sciences, Inc. since January 2024. Mr. Aktar holds an MBA from MIT Sloan School of Management, a B.S. in Chemical Engineering from Worcester Polytechnic Institute, and an M.S. in Engineering Management from Tufts University.

We believe that Mr. Aktar is qualified to serve as a member of our board of directors due to his education and extensive experience as an executive officer in the biopharmaceutical and biotechnology industries.

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 to $2.0B in revenues with sales in 70 countries and from $4B to $15B market cap. 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. (Nasdaq: GILD). 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 Spruce Biosciences, Inc. (Nasdaq: SPRB), Maze Therapeutics Inc. (Nasdaq: MAZE) and vTv Therapeutics Inc. (Nasdaq: VTVT), and serves on the boards of directors of several private biotechnology companies, including Tizona Therapeutics, Inc. and Bluejay Therapeutics, Inc. From 2020 to 2024, he served as a member of the board of directors of Myriad Genetics, Inc. (Nasdaq: MYGN), and from 2020 to 2024, he served as a member of the board of directors of Opthea Limited (Nasdaq: OPT). 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, 2025:

Name	Age	Position(s)
Warner Biddle.	58	Chief Executive Officer and Director
Ryan Jones	38	Chief Financial Officer
Karen Walker	64	Chief Technology Officer
Naji H. Gehchan, M.D.	43	Chief Medical and Development Officer

Warner Biddle Biographical information regarding Warner Biddle 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, Inc. (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.

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 Company (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.

Naji H. Gehchan, M.D. has served as our Chief Medical Officer since January 2025. Dr. Gehchan is an accomplished biopharmaceutical physician-executive with extensive experience in drug development, commercialization and general management. Most recently, Dr. Gehchan served as Head of Clinical Development Oncology for imlunestrant at Eli Lilly & Co. (NYSE: LLY), from April 2021 to January 2025. In this role, he built and led high-performing teams to advance with agility and speed Eli Lilly's next-generation oral SERD from Phase

1 to global submission. Dr. Gehchan joined Eli Lilly in October 2008, holding various leadership roles across geographies and functions. From September 2019 to April 2021, he served as Associate Vice President of Sales on the U.S. Diabetes Leadership Team. Previously, he served as Chief Marketing Officer and Business Unit Head, BioMedicines, from August 2015 to September 2019, leading the launches of Eli Lilly's immunology portfolio across France and other European countries. Prior to joining Eli Lilly, he worked at Johnson & Johnson as a Medical Advisor, Internal Medicine & Health Economics from April 2008 to October 2008. Dr. Gehchan also served as an Attending Physician and Resident in internal medicine at Hotel-Dieu de France and CHU Montpellier from June 2005 to June 2007. In addition to his professional career, Dr. Gehchan has been a Faculty Mentor and Guest Lecturer at MIT Sloan since 2023, and a Lecturer in Leadership and Management at ESCP Business School since 2019. Dr. Gehchan earned his Doctor of Medicine in 2006, and Masters in Biological Sciences (Genetics and Immunology) in 2004 from Saint Joseph University of Beirut, a Specialized Masters in Healthcare Management from ESCP Business School in 2009, and an Executive Master of Business Administration from the Massachusetts Institute of Technology Sloan in 2022.

Family Relationships

There are no family relationships between or among any of our executive officers or directors.

Legal Proceedings with Directors or Executive Officers

Refer to the disclosure in Part I Item 3 under the heading "Legal Proceedings" in this Annual Report on Form 10-K regarding a shareholder class action complaint that was filed against certain of our current and former officers and directors, including Mr. Jones, Ms. Walker, Mr. Clark, Dr. Cohen, Mr. Liapis, Dr. Seidenberg and Mr. Spiegelman, in December 2024.

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://ir.kyvernatx.com/corporate-governance/governance-overview. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our Company consistent with the highest standards of business ethics and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose: (1) the nature of any substantive amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions; and (2) the nature of any waiver, including an implicit waiver, from a provision of our Code of Business Conduct and Ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future 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, Mert Aktar 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 our 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.

SEC regulations require us to identify in this Annual Report on Form 10-K anyone who failed to file a timely required report during the most recent fiscal year. Based solely upon our review of forms we received, or written representations from reporting persons stating that they were not required to file these forms, we believe that during our fiscal year ended December 31, 2024, all Section 16(a) filing requirements were satisfied on a timely basis, except for: (a) the Form 3 for Dr. Liapis that was due on February 7, 2024, the date the registration statement for our IPO was declared effective by the SEC, which was inadvertently filed one day late on February 8, 2024, due to an unexpected delay by the financial printer that we used to file the Section 16(a) forms in connection with our IPO; and (b) the Form 4 filed to report the initial option award granted to Mr. Aktar in connection with his appointment to our board of directors on October 21, 2024, which was inadvertently filed one day late on October 24, 2024.

11. Executive Compensation.

Executive Compensation

Our named executive officers, or NEOs, for the year ended December 31, 2024, are:

- Warner Biddle, our current Chief Executive Officer;
- Peter Maag, Ph.D., our former Chief Executive Officer;
- Dominic Borie, M.D., Ph.D., our former President, Research and Development and current Strategic Advisor to the Chief Executive Officer and Board;
- Karen Walker, our current Chief Technology Officer; and
- James Chung, M.D., Ph.D. our former Chief Medical Officer.

Mr. Biddle commenced service with us as our Chief Executive Officer in September 2024. Dr. Borie transitioned to his role as our Strategic Advisor to the Chief Executive Officer and Board effective January 2025.

Summary Compensation Table

The following table sets forth certain information with respect to the compensation paid to our named executive officers for the fiscal years ended December 31, 2024 and 2023:

Name and principal position	Year	Salary ($)	Bonus ($)	Option awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)	Total ($)
Warner Biddle	2024	182,292	650,000 [3]	13,760,605	375,000	25,000 [4]	14,992,896
Chief Executive Officer							
Peter Maag, Ph.D.	2024	786,466	-	-	-	694,764 [5]	1,481,230
Former Chief Executive Officer[6]	2023	438,875	247,500	1,554,197	-	23,617 [7]	2,264,189
Dominic Borie, M.D., Ph.D.	2024	440,000	-	-	147,840	-	587,840
Former President, Research and Development[8]							
Karen Walker	2024	440,000	-	-	151,360	-	591,360
Chief Technology Officer	2023	387,899	150,150	520,502	-	23,593 [7]	1,082,144
James Chung, M.D., Ph.D.	2024	404,576	-	-	-	220,000 [10]	624,576
Former Chief Medical Officer[9]	2023	401,995	152,982	520,502	-	90,643 [7]	1,166,122

(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 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) The amounts in this column for 2024 relate to amounts earned by our named executive officers pursuant to our bonus program described below under "—Narrative to Summary Compensation Table—2024 Bonuses".
(3) Represents a one-time sign-on bonus. See "—Narrative to Summary Compensation Table—2024 Bonuses—Biddle Sign-On Bonus" below for additional details.
(4) Amount represents a reimbursement of legal fees incurred by Mr. Biddle in connection with entering into his employment offer letter. See "Employment Arrangements – Warner Biddle" below for additional details.
(5) Amount represents (a) a severance payment of $550,000 paid to Dr. Maag pursuant to a Separation and General Release Agreement entered into with Dr. Maag in connection with his resignation in September 2024, (b) consulting fees in an aggregate amount of $137,499.99 (or a monthly payment of $45,833.33 for three months of consulting services), and (c) COBRA payments in an aggregate amount of $7,263.60, payable to Dr. Maag pursuant to a Separation and General Release Agreement entered into with Dr. Maag. See "Employment Arrangements – Peter Maag, Ph.D." below for additional details.
(6) Dr. Maag resigned effective September 13, 2024.
(7) Comprised solely of insurance benefits paid by us on behalf of the NEO.
(8) In accordance with SEC guidance, compensation information for Dr. Borie for fiscal year 2023 has not been included in this table because Dr. Borie was not a named executive officer for fiscal year 2023. Dr. Borie transitioned from his role as our President, Research and Development to Strategic Advisor to our Chief Executive Officer and our board of directors effective January 2025.
(9) Dr. Chung resigned effective November 22, 2024.
(10) Amount represents a severance payment agreed to be paid to Dr. Chung pursuant to a Letter Agreement entered into with Dr. Chung in connection with his resignation in November 2024. See "Employment Arrangements – James Chung, M.D., Ph.D." below for additional details.

Narrative to Summary Compensation Table

2024 Salaries

Our NEOs each receive a base salary to compensate them for services rendered to our Company. The base salary payable to each NEO is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities.

For 2024, Mr. Biddle had an annual base salary of $625,000, which was established in connection with his appointment as our Chief Executive Officer in September 2024 and prorated for 2024 based on his start date.

For 2024, Dr. Maag, our former Chief Executive Officer, had an annual base salary of $550,000 until he resigned from our Company in September 2024.

For 2024, Dr. Borie, who served as our President, Research and Development during all of 2024, had an annual base salary of $440,000.

For 2024, Ms. Walker had an annual base salary of $440,000.

For 2024, Dr. Chung, our former Chief Medical Officer, had an annual base salary of $440,000 until he resigned from our Company in November 2024.

Our board of directors and Compensation Committee may adjust base salaries from time to time in their discretion.

2024 Bonuses

Each of our NEOs, other than Dr. Maag and Dr. Chung, was eligible to receive a bonus for 2024. Each NEO's target bonus is expressed as a percentage of their annual base salary, which can be achieved by meeting company and individual goals. The 2024 annual bonus for each of Mr. Biddle, Dr. Borie and Ms. Walker was targeted at 60%, 40% and 40% of the NEO's base salary, respectively. Per our offer letter with Mr. Biddle, Mr. Biddle's target bonus was not pro-rated for 2024.

In January 2025, our Compensation Committee determined achievement under our 2024 annual bonus program. Our board of directors, upon recommendation of the Compensation Committee, awarded a bonus to Mr. Biddle based on corporate and individual performance in an amount of $375,000. The Compensation Committee awarded bonuses to Dr. Borie and Ms. Walker based on corporate and individual performance in the amount of $147,840 and $151,360, respectively.

Our board of directors and Compensation Committee may adjust annual bonuses or award discretionary bonuses from time to time.

Biddle Sign-On Bonus

In connection with Mr. Biddle's appointment as our Chief Executive Officer in September 2024, we agreed to pay Mr. Biddle a one-time bonus of $650,000, less applicable withholdings, or the Sign-On Bonus, within thirty days after Mr. Biddle's start date. We paid the Sign-On Bonus to Mr. Biddle in October 2024.

Equity-Based Compensation

In September 2024, in connection with Mr. Biddle's appointment as our Chief Executive Officer, Mr. Biddle was granted a stock option to purchase 2,579,259 shares of our common stock, which vests over four years, with 25% of the total number of shares subject to the option vesting on September 16, 2025, and 1/48th of the total number of shares subject to the option vesting monthly thereafter, subject to Mr. Biddle's continued services to us on each applicable vesting date. The option has an exercise price of $6.89 per share, which our Compensation Committee determined equaled fair market value of our common stock on the date of grant.

Employment Arrangements

We have entered into offer letters and employee confidential information and inventions assignment agreements with each of our named executive officers. Each offer letter sets forth the title, base salary, target bonus opportunity and initial equity awards for the executive. 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.

Warner Biddle

On September 14, 2024, we entered into an offer letter with Mr. Biddle, or the Biddle Offer Letter. Pursuant to the Biddle Offer Letter, Mr. Biddle's initial annualized salary is $625,000, and he was paid a one-time Sign-On Bonus of $650,000, less applicable withholdings, in October 2024. In the event of Mr. Biddle's termination of employment by us for Cause (as defined in the Biddle Offer Letter), or if Mr. Biddle resigns without Good Reason (as defined in the Biddle Offer Letter), in either case prior to September 16, 2025, Mr. Biddle agreed to repay the Sign-On Bonus to us within thirty days after such termination or resignation. Additionally, Mr. Biddle will be eligible to receive an annual performance bonus of up to 60% of his base salary (which will not be pro-rated for 2024). Mr. Biddle is also entitled to be reimbursed for up to $150,000 of relocation/moving expenses. Mr. Biddle's employment with us is on an "at-will" basis.

In connection with his appointment, and as provided in the Biddle Offer Letter, on September 16, 2024, we granted Mr. Biddle an option pursuant to the 2024 Inducement Equity Incentive Plan to purchase 2,579,259 shares of our common stock, or the Biddle Option, which Biddle Option will vest over four years, with 25% of the total number of shares subject to the Biddle Option vesting on September 16, 2025, and 1/48th of the total number of shares subject to the Biddle Option vesting monthly thereafter, subject to Mr. Biddle's continued services to us on each applicable vesting date.

In connection with his employment, Mr. Biddle also entered into our standard Employee Confidential Information and Inventions Assignment Agreement, which includes confidentiality provisions, an invention assignment and non-compete covenants during his employment and non-solicit covenants during his employment and for one year thereafter.

Peter Maag, Ph.D.

In October 2022, we entered into an offer letter with Dr. Maag, or the Maag Offer Letter, our former Chief Executive Officer, which provided 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. Effective January 1, 2024, Dr. Maag's base salary was increased to $550,000 and his target bonus was increased to 55% of his annual base salary. In accordance with the Maag Offer Letter, on November 22, 2022, we granted Dr. Maag an option to purchase an aggregate of 1,397,285 shares of our common stock pursuant to the 2019 Plan (as defined below) with an exercise price of $3.15 per share, or the Initial Maag Option, with the following vesting schedule: 25% of the shares subject to the Initial Maag 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 our 2019 Plan) as of each vesting date. The Initial Maag 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 Maag 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 provided that Dr. Maag may pay up to 50% of the aggregate exercise price of the Initial Maag 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 Maag 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.

The Maag Offer Letter provided that if we terminated Dr. Maag's employment for Cause (as defined in the Maag Offer Letter) at any time, if he resigned without Good Reason (as defined in the Maag Offer Letter) or if his employment terminated as a result of his death or disability, he would receive his base salary accrued through his last day of employment but would not be entitled to any other form of compensation from the Company, including severance benefits. If we terminated Dr. Maag's employment without Cause or he resigned for Good Reason and other than as a result of his death or disability, and provided such termination constituted 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 would have been 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 became 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 Maag Option (including for this purpose any unvested shares of our common stock issued upon exercise of the Initial Maag 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.

On September 13, 2024, we and Dr. Maag entered into a Separation and General Release Agreement, or the Separation Agreement, pursuant to which Dr. Maag resigned as our Chief Executive Officer, and also as a director, effective September 13, 2024, or the Separation Date, which contains a release of claims against us and the following severance benefits to be paid to Dr. Maag; provided, that he does not revoke the release of claims: full monthly COBRA premiums for Dr. Maag to continue healthcare insurance coverage under COBRA until the earliest of: (a) the close of the 12-month period following the end of the Contractor Period (as defined below); (b) the date Dr. Maag is no longer eligible to receive COBRA continuation coverage; or (c) the date on which Dr. Maag becomes eligible to receive similar healthcare insurance coverage from another employer or another source.

Additionally, the Separation Agreement further provides that, commencing on the Separation Date for a period of up to six months, or the Contractor Period, Dr. Maag shall provide certain contractor services, including providing such assistance to our Chief Executive Officer primarily relating to the transition of his prior responsibilities and knowledge transfer activities. As compensation for such contractor services, and subject to Dr. Maag providing such contractor services in good faith, we will provide Dr. Maag with a monthly payment of $45,833.33 (payable no later than the last day of the subsequent month for services performed for the prior month and prorated for any partial months) and Dr. Maag's equity compensation outstanding as of September 13, 2024, will continue to vest in accordance with the terms of the applicable award agreement(s) and plan(s), which such

awards shall continue to be subject to such terms, including, without limitation, with respect to expiration. Further, if, within 60 days of the termination of the Contractor Period, Dr. Maag re-executes the Separation Agreement and allows it to become effective and irrevocable as a result of such re-execution, and, so long as Dr. Maag provided the requested services during the Contractor Period in good faith and the Contractor Period either terminated naturally at the end of such Contractor Period or was terminated earlier by Dr. Maag, then (i) we will pay Dr. Maag $550,000, less all applicable withholdings and deductions, during the 12-month period commencing 6-months following the Separation Date, payable in accordance with our normal payroll practices, and (ii) solely for purposes of stock option vesting and expiration, but subject to Dr. Maag continuing to comply with his obligations to us, Dr. Maag shall be deemed to remain a continuous service provider through, and terminating on, June 13, 2025.

Dominic Borie, M.D., Ph.D.

In December 2019, we entered into an offer letter with Dr. Borie, or the Borie Offer Letter, which provided for at-will employment as our Chief Executive Officer, with an initial base salary of $395,000, an annual target bonus equal to 40% of his annual base salary, and a one-time sign-on bonus of $130,000 granted on the condition that Dr. Borie remain employed by us through the one-year anniversary of his start date.

In May 2022, we entered into an Amendment to the Borie Offer Letter, or the Amended Borie Offer Letter, which provided for Dr. Borie's transition to the position of President, Research and Development. Pursuant to the Amended Borie Offer Letter, Dr. Borie's salary continued to be paid at the then-current rate of $420,844, while being eligible for the same benefits, bonus target percentage and severance benefits as set forth in the Borie Offer Letter. We also agreed to grant Dr. Borie an option to purchase 149,545 shares of our common stock, with an exercise price of $4.42, subject to the following vesting schedule: 25% of the shares subject to the option vested on May 6, 2023 and the balance would vest in equal monthly installments over the following 36 months of his Continuous Service (as defined in the 2019 Plan).

Effective January 1, 2024, Dr. Borie'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.

In January 2025, Dr. Borie transitioned to the role of Strategic Advisor to our Chief Executive Officer and our board of directors.

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.

James Chung, M.D., Ph.D.

In March 2021, we entered into an offer letter with Dr. Chung, or the Chung Offer Letter, which provided 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 was subject to the following vesting schedule: 25% of the shares subject to the option vested on April 12, 2022 and the balance would 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 provided 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 remained 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.

On November 8, 2024, Dr. Chung resigned from the Company, effective as of November 22, 2024. On November 20, 2024, we entered into a letter agreement, or the Chung Letter Agreement, which contains, among other things, a release of claims against the Company and the following severance benefits to be paid to Dr. Chung provided that he does not revoke the release of claims against the Company: (a) $220,000 (equal to six months of his base salary in effect at the time of his resignation from the Company), less all applicable withholdings and deductions, payable in accordance with the Company's regular payroll practices, and (b) full monthly COBRA premiums for Dr. Chung to continue healthcare insurance coverage under COBRA until the earliest of: (1) the close of the six-month period following November 22, 2024; (2) the date on which Dr. Chung becomes eligible for substantially equivalent health insurance coverage in connection with new employment, or (3) the date Dr. Chung ceases to be eligible for COBRA coverage for any reason.

Potential Payments Upon Termination or Change in Control

Warner Biddle

Pursuant to the Biddle Offer Letter, if we terminate Mr. Biddle's employment without Cause (as defined in the Biddle Offer Letter), or Mr. Biddle resigns for Good Reason (as defined in the Biddle Offer Letter), Mr. Biddle will be entitled to (a) a lump sum payment equal to eighteen months of Mr. Biddle's then-current annual base salary, (b) a lump-sum payment equal to Mr. Biddle's then-current target bonus, less all applicable withholdings and deductions, paid on the 60th day following Mr. Biddle's separation from service, (c) reimbursement of COBRA premiums for Mr. Biddle and his eligible dependents for eighteen months; provided, that such reimbursement will cease on the date that Mr. Biddle becomes covered under a similar plan, and (d) acceleration of vesting with respect to any unvested service-based equity awards for an additional eighteen months; provided, that if the separation from service occurs within twelve months following a "Change in Control" (as defined in the Biddle Offer Letter), Mr. Biddle shall be entitled to full acceleration of vesting with respect to 100% of all unvested equity awards (with any performance-based vesting requirements being deemed satisfied at target). Payment of the foregoing under the Biddle Offer Letter is conditioned upon Mr. Biddle's execution of a separation agreement and release of claims in our favor.

Karen Walker

The Walker Offer Letter provides that if, at any time, we terminate 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 us, including severance benefits. If, outside of a CIC Period (as defined in the Walker Offer Letter), we terminate 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, we terminate 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, including medical, dental, vision, disability, life insurance and 401(k) plans. We did not provide any perquisites or personal benefits to any of our named executive officers during 2024. However, our Compensation Committee or board of directors may from time to time approve perquisites in the future when our Compensation Committee or board of directors determines that they are necessary or advisable to fairly compensate or incentivize our employees. Our Compensation Committee or board of directors may also 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 2024

The following table presents certain information concerning outstanding equity awards held by each of our named executive officers at December 31, 2024:

			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
Warner Biddle	9/16/2024 [2][3]	9/16/2024[1]	—	2,579,259	$ 6.89	9/16/2034
Peter Maag, Ph.D.	11/22/2022 [2][3]	10/13/2022	349,324	640,420	$ 3.15	11/21/2032
	7/13/2023 [4]	7/1/2023	309	708	$ 4.33	7/12/2033
	11/6/2023 [4]	1/1/2024	—	329,590	$ 4.83	11/5/2033
Dominic Borie, M.D., Ph.D.	7/13/2023 [4]	7/1/2023	390	708	$ 4.33	7/12/2033
	11/6/2023 [4]	1/1/2024	—	21,972	$ 4.83	11/5/2033
	5/19/2022 [4]	5/6/2022	37,396	52,955	$ 4.42	5/18/2032
James Chung, M.D., Ph.D.	4/27/2021 [4]	4/12/2021	22,622	—	$ 3.37	4/26/2031
	7/13/2023 [4]	7/1/2023	367	—	$ 4.33	7/12/2033
Karen Walker	11/18/2021 [4]	9/13/2021	65,350	17,298	$ 4.42	11/17/2031
	7/13/2023 [4]	7/1/2023	388	709	$ 4.33	7/12/2033
	11/6/2023 [4]	1/1/2024	—	109,863	$ 4.83	11/5/2033

(1) Option vests and becomes exercisable as to 25% of the total number of shares subject to the option on the first anniversary of the vesting commencement date and as to 1/48th of the total number of shares subject to the option on each monthly anniversary of the vesting commencement date thereafter, subject to any accelerated vesting set forth in the NEO's offer letter.

(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, 2024.

(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. Pursuant to the terms of the Separation Agreement with Dr. Maag, solely for purposes of stock option vesting and expiration, but subject to Dr. Maag continuing to comply with his obligations to us, Dr. Maag shall be deemed to remain a continuous service provider through, and terminating on, June 13, 2025.

(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 directors 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.

2024 Inducement Equity Incentive Plan

On September 14, 2024, the Compensation Committee adopted the Kyverna Therapeutics, Inc. 2024 Inducement Equity Incentive Plan, or the Inducement Plan. The Inducement Plan will serve to advance our interests by providing a material inducement for the best available individuals to join the Company as employees by affording such individuals an opportunity to acquire a proprietary interest in the Company.

The Inducement Plan provides for the grant of equity-based awards in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares solely to our prospective employees or an affiliate of the Company provided that certain criteria are met. Awards under the Inducement Plan may only be granted to an individual, as a material inducement to such individual to enter into employment with the Company or an affiliate of the Company, who (i) has not previously been an employee or director of the Company or (ii) is rehired following a bona fide period of non-employment with the Company. The Inducement Plan is administered by the Compensation Committee and expires ten years from the date of effectiveness.

The Inducement Plan has not been and will not be approved by our stockholders. Awards under the Inducement Plan will be made pursuant to the exemption from Nasdaq stockholder approval requirements for equity compensation provided by Nasdaq Listing Rule 5635(c)(4), which permits Nasdaq-listed companies to make inducement equity awards to new employees without first obtaining stockholder approval of the award.

Equity Award Timing Procedures

In accordance with Item 402(x) of Regulation S-K under the Securities Act, we are providing information regarding our procedures related to the grant of certain equity awards close in time to the release of material non-public information, or MNPI. Although we do not have a formal policy, program or plan that requires us to award equity or equity-based compensation on specific dates, we generally expect to issue equity awards to our executive officers annually in the first fiscal quarter of each year, and such awards are approved by our Compensation Committee in the first fiscal quarter of each year. Additionally, our Insider Trading Policy prohibits directors, officers and employees from trading in our common stock while in possession of or on the basis of MNPI about us.

We have not timed, and do not plan to time, the disclosure of MNPI for the purpose of affecting the value of executive compensation.

In the year ended December 31, 2024, no options were granted to our NEOs within four business days prior to, or one business day following, the filing or furnishing of a periodic or current report by us that disclosed MNPI, other than a Current Report on Form 8-K disclosing the grant of an option award to Mr. Biddle in connection with his appointment as our Chief Executive Officer and a member of our board of directors.

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.

Non-Employee Director Compensation

Prior to our IPO, we did not have a formalized non-employee director compensation program, but we provided compensation to our non-employee directors who are not affiliated with our investors in accordance with their individual agreements.

We entered into an offer letter, dated September 14, 2021, with Mr. Clark to serve as the Chairperson of our board of directors. Pursuant to Mr. Clark's offer letter, we agreed to pay Mr. Clark an annual cash retainer and issue Mr. Clark an option to purchase shares of our common stock. Similarly, pursuant to our offer letter with Brian Kotzin, M.D., a former member of our board of directors, dated January 8, 2020, we agreed to pay Dr. Kotzin an annual cash payment 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. In addition, 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. The advisor agreement with Mr. Spiegelman terminated on February 7, 2024. In addition, we 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.

In connection with our IPO, effective February 12, 2024, we implemented a non-employee director compensation program, or the Director Compensation Program. Pursuant to the Director Compensation Program, our non-employee directors received cash compensation, paid quarterly in arrears, as follows commencing February 12, 2024, which amounts were pro-rated for 2024:

- Each non-employee director receives a cash retainer in the amount of $40,000 per year.
- The independent Chairperson of the Board receives an additional cash retainer of $35,000 per year.
- The Chairperson of the Audit Committee receives 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 receives 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 receives 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 receives 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 receives 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 receives 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 receives 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 receives 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 our 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.

Prior to March 25, 2025, our Director Compensation Program provided that each non-employee director initially elected or appointed to our board of directors after February 12, 2024, would 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 $350,000 divided by the per share grant date fair value of the option award. The Initial Grant would 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, our Director Compensation Program provided that on the date of each annual meeting of our stockholders following the completion of the IPO and prior to March 25, 2025, each non-employee director who (i) had been serving on our board of directors for at least four months and (ii) would continue to serve as a non-employee director immediately following such annual meeting would 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 would 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.

Effective March 25, 2025, the compensation committee of our board of directors implemented a Restated Non-Employee Director Compensation Program, or the Restated Director Compensation Program, which amended and restated the Director Compensation Program. The Restated Director Compensation Program provides that each non-employee director initially elected or appointed to our board of directors after March 25, 2025 will automatically be granted (A) an option under the 2024 Plan to purchase that number of shares of our common stock equal to $262,500 divided by the per share grant date fair value of the option award, which 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, and (B) restricted stock units under the 2024 Plan or any other applicable Company equity incentive plan then maintained by us covering a number of shares of common stock equal to $87,500 divided by the per share grant date fair market value as of the date of the grant, rounded down to the nearest whole share, which will vest as to 1/3rd of the shares subject thereto on each one-year anniversary over three years, subject to continued service through the applicable vesting date.

In addition, pursuant to the Restated Director Compensation Program, on the date of each annual meeting of our stockholders, commencing with our 2025 annual meeting of shareholders, 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 (A) an option, or the Annual Option Grant, under the 2024 Plan to purchase that number of shares of our common stock equal to (a) $131,250, divided by (b) the per share grant date fair value of the option award, or (B) restricted stock units, or the Annual RSU Grant, under the 2024 Plan or any other applicable Company equity incentive plan then maintained by us covering a number of shares of common stock equal to $43,750 divided by the per share grant date fair market value as of the date of the grant, rounded down to the nearest whole share. Each of the Annual Option Grant and the Annual RSU Grant will be automatically granted on the date of each applicable annual meeting of shareholders and will vest in full on the earlier of (i) the 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 Restated Director Compensation Program, upon a change-in-control transaction, all outstanding equity awards held by our non-employee directors will vest in full. The cash compensation under the Restated Director Compensation Program remains the same as what was provided for in the Director Compensation Program.

Director Compensation Table

The following table sets forth information for 2024 regarding the compensation awarded to, earned by or paid to our non-employee directors. Directors who are also our employees receive no additional compensation for their service as directors.

Name[1]	Fees Earned or Paid in Cash ($)	Option Awards ($)[1][2]	All Other Compensation ($)	Total ($)
Mert Aktar[3]	11,284	349,841	—	361,125
Ian Clark	88,750	—	—	88,750
Fred E. Cohen, M.D., D.Phil.	48,942	—	—	48,942
Brian Kotzin, M.D.[4]	49,719	—	—	49,719
Steve Liapis, Ph.D.[5]	—	—	—	—
Beth Seidenberg, M.D.	54,952	—	—	54,952
Christi Shaw[6]	15,840	349,894	—	365,734
Daniel K. Spiegelman	58,846	—	12,414[7]	71,260

(1) The amounts reported represent the grant date fair value of option awards granted to our non-employee directors during the year ended December 31, 2024, as computed in accordance with FASB ASC 718, rather than amounts paid to or realized by the individual. See Note 10 of the financial statements included in this Annual Report on Form 10-K for the assumptions used in calculating this amount.
(2) As of December 31, 2024, our non-employee directors held the following option awards and did not hold any stock awards:

Name	Shares Underlying Option Awards
Mert Aktar	87,741
Ian Clark	364,398
Fred E. Cohen, M.D., D.Phil.	32,959
Steve Liapis, Ph.D.	—
Beth Seidenberg, M.D.	32,959
Christi Shaw	66,592
Daniel K. Spiegelman	50,537

(3) Mr. Aktar was appointed to our board of directors effective October 20, 2024.
(4) Dr. Kotzin resigned from our board of directors effective September 13, 2024.
(5) Dr. Liapis has opted not to accept compensation for his service on our board of directors.
(6) Ms. Shaw was appointed to our board of directors effective September 14, 2024.
(7) The amount reported represents consulting fees paid to Mr. Spiegelman for services provided to the Company from January 1, 2024 through February 7, 2024.

Compensation Committee Interlocks and Insider Participation

During 2024, our Compensation Committee consisted of Beth Seidenberg, M.D., Fred E. Cohen, M.D., D.Phil. and Steve Liapis, Ph.D. through October 19, 2024, and Dr. Seidenberg, Dr. Cohen and Christi Shaw commencing on October 20, 2024. None of the members of our Compensation Committee during 2024, nor any of the current members of our Compensation Committee, has at any time been one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers on our board of directors or Compensation Committee.

Clawback Policy

Our board of directors has adopted the Company's Clawback Policy, or the Clawback Policy, effective as of February 7, 2024, applicable to our current and former executive officers, as defined in Exchange Act Rule 10D-1(d), in accordance with SEC rules and the applicable Nasdaq listing standards. This Clawback Policy applies to incentive-based compensation that is granted, earned or vested wholly or in part upon the attainment of one or more financial reporting measures (each, a "Financial Reporting Measure") that is received by an executive officer (a) after beginning service as an executive officer, (b) who served as an executive officer at any time during the performance period for that compensation, (c) while we have a class of its securities listed on a national securities exchange or association and (d) during the three completed fiscal years immediately preceding the date on which we conclude, or reasonably should have concluded, that we are required to prepare a restatement with respect to any such Financial Reporting Measure. The Clawback Policy provides that, in the event of a restatement of our financial statements due to material noncompliance with financial reporting requirements, the administrator of the Clawback Policy will recover (subject to limited exceptions) the amount (as determined on a pre-tax basis) of incentive-based compensation erroneously received by an executive officer (i.e., in the event that the amount of such compensation was calculated based on the achievement of certain financial results that were subsequently revised due to the restatement, and the amount of the incentive-based compensation that would have been earned by such executive officer had the financial results been properly reported would have been lower than the amount actually paid).

Insider Trading Policy

We have adopted an Insider Trading Policy, or the Insider Trading Policy, which provides guidelines to our employees, directors, officers and consultants with respect to transactions in our securities, including the purchase, sale and/or other disposition of our securities. We adopted the Insider Trading Policy and the procedures set forth therein to help avoid inadvertent instances of improper insider trading. We believe the Insider Trading Policy is reasonably designed to promote compliance with insider trading laws, rules and regulations and listing standards applicable to Kyverna.

Prohibition on Hedging, Pledging and Similar Transactions

Our Insider Trading Policy also prohibits covered individuals, including our NEOs, from (i) making short sales of our securities, (ii) engaging in transactions in puts, calls or other derivative instruments related to our securities, (iii) engaging in any hedging or similar transaction designed to decrease the risks associated with holding our securities and (iv) purchasing our securities on margin or pledging our securities as collateral.

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 December 31, 2024, by:

- 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;
- each of our named executive officers as set forth in the summary compensation table above;
- each of our directors; and
- all of our current executive officers and directors as a group.

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 December 31, 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 43,214,918 shares of our common stock outstanding as of December 31, 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 December 31, 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	9.5%
Entities affiliated with Northpond Ventures III, LP(3)	3,255,426	7.5%
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%
JPMORGAN CHASE & CO.(6)	2,380,021	5.5%

Named Executive Officers and Directors:		
Warner Biddle	—	—
Peter Maag, Ph.D.(7)	911,677	2.1%
Dominic Borie, M.D., Ph.D. (8)	499,706	1.2%
Karen Walker(9)	111,332	*
James Chung, M.D., Ph.D.(10)	88,947	*
Ian Clark(11)	270,767	*
Fred E. Cohen, M.D.(12)	4,533,538	10.5%
Christi Shaw(11)	9,248	*
Mert Aktar(11)	9,749	*
Steve Liapis, Ph.D.	—	—
Daniel K. Spiegelman(11)	26,460	*
Beth Seidenberg, M.D.(13)	4,533,538	10.5%
All executive officers and directors as a group (11 persons)(14)	9,584,269	21.9%

* 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 Schedule 13D filed by Vida Ventures, LLC ("Vida I"), VV Manager LLC ("Vida I GP"), Vida Ventures III, L.P. ("Vida III"), Vida Ventures III-A, L.P. ("Vida III-A"), Vida Ventures GP III, L.L.C. ("Vida III GP") and Fred E. Cohen, M.D., D.Phil. on May 3, 2024. Consists of: (i) 4,523,924 shares of common stock held by Vida I, (ii) 252,553 shares held by Vida III, and (iii) 583 shares held by Vida III-A. Vida I GP is the general partner of Vida I and may be deemed to have voting, investment and dispositive power with respect to these securities. Vida III GP is the general partner of each of Vida III and Vida III-A and may be deemed to have voting, investment, and dispositive power with respect to these securities. Arie Belldegrun, Leonard Potter and Dr. Cohen (a member of our board of directors) are the members of the investment committee of Vida I GP (the "Vida I Investment Committee"). Each of the Vida I Investment Committee and the members thereof may be deemed to share voting, investment and dispositive power with respect to these securities held by Vida I. Arie Belldegrun, Helen Kim, Arjun Goyal, Rajul Jain and Stefan Vitorovic are the members of the investment committee of Vida III GP (the "Vida III Investment Committee"). Each of the Vida III Investment Committee and the members thereof may be deemed to share voting, investment and dispositive power with respect to these securities held by each of Vida III and Vida III-A. The address of Vida, Vida I GP, 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 September 30, 2024, as reported in a Schedule 13G filed by Westlake BioPartners Fund I, L.P. ("Westlake Fund I"), Westlake BioPartners GP I, LLC ("Westlake GP I"), Westlake BioPartners Opportunity Fund I, L.P. ("Westlake Opportunity Fund I"), Westlake BioPartners Opportunity GP I, LLC ("Westlake Opportunity GP I"), Beth Seidenberg, M.D., a member of our board of directors, and Dr. Sean E. Harper on November 12, 2024. Consists of: (i) 3,787,940 shares of common stock held by Westlake Fund I, and (ii) 735,984 shares of common stock held by Westlake Opportunity Fund I. Westlake GP I and Westlake Opportunity GP I, the general partners of Westlake Fund I and Westlake Opportunity Fund I, respectively, may be deemed to have sole dispositive power over such shares, and Dr. Seidenberg and Dr. Harper, the managing directors of Westlake GP I and Westlake Opportunity GP I, may be deemed to have shared power to dispose of the shares held by Westlake Fund I and Westlake Opportunity Fund I. The address for Westlake Fund I and Westlake Opportunity Fund I is 3075 Townsgate Rd., Suite 140, Westlake Village, CA 91361.
(6) JPMORGAN CHASE & CO. filed a Schedule 13G with the SEC on October 10, 2024, reporting that, as of September 30, 2024, it had sole voting power with respect to 2,037,226 shares of common stock and sole dispositive power with respect to 2,380,021 shares of common stock in its capacity as a parent holding company in accordance with Rule 13d-1(b)(1)(ii)(G) under the Exchange Act. The principal business address of JPMORGAN CHASE & CO. is 383 Madison Avenue, New York, NY 10179.
(7) Consists of (i) 407,541 shares of our common stock currently held and (ii) 504,136 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024.
(8) Consists of (i) 449,210 shares of our common stock currently held by a family trust of which Dr. Borie is the trustee and (ii) 50,496 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024.
(9) Consists of (i) 9,636 shares of our common stock currently held and (ii) 101,696 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024.
(10) Consists of (i) 65,918 shares of our common stock currently held and (ii) 23,029 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024.
(11) Consists solely of shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024.
(12) Consists of (i) 4,523,924 shares of common stock held by Vida I listed in footnote (4) above, and (ii) 9,614 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024. Dr. Cohen, a member of our board of directors, is a member of the Vida I Investment Committee, and may be deemed to share voting and dispositive power over the shares held by Vida I.
(13) Consists of (i) the 4,523,924 shares listed in footnote (5) above as held by Westlake Fund I and Westlake Opportunity Fund I and (ii) 9,614 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024. Dr. Seidenberg, a member of our Board, is a managing director of Westlake GP I and Westlake Opportunity GP I, and may be deemed to have shared power to dispose of the shares held by Westlake Fund I and Westlake Opportunity Fund I.
(14) Consists of (i) 9,101,434 shares of common stock beneficially owned by our current executive officers and directors (which includes an aggregate of 43,950 beneficially owned by one additional executive officer), and (ii) 482,835 shares of our common stock subject to options that are exercisable within 60 days of December 31, 2024 (which includes an aggregate of 45,687 shares of common stock subject to options held by one additional executive officer).

Equity Compensation Plan Information

The following table sets forth additional information as of December 31, 2024 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, 2024. The information includes the number of shares covered by, and the weighted average exercise price of, outstanding options, the number of shares subject to restricted stock unit awards 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 Stockholders[1][2]	5,215,664	$ 4.75[3]	2,491,968[4]
Equity Compensation Plans Not Approved by Stockholders[5]	2,929,259	6.65	1,070,741
Total	8,144,923	$ 5.44	3,562,709

(1) Includes the Kyverna Therapeutics, Inc. 2019 Stock Plan, or the 2019 Plan, the 2024 Plan and the ESPP. Only stock options were outstanding under the 2019 Plan and stock options and restricted stock unit awards were outstanding under the 2024 Plan as of December 31, 2024. No new awards may be made under the 2019 Plan.
(2) The 2024 Plan and the ESPP contain "evergreen" provisions, pursuant to which (i) the number of shares of common stock reserved for issuance pursuant to awards under the 2024 Plan shall be increased on the first day of each year beginning in 2025 and ending in 2034, equal to the lesser of: (A) five percent (5.0%) of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, and (B) such smaller number of shares of common stock as determined by our board of directors; and (ii) the number of shares of common stock which will be authorized for sale under the ESPP shall be increased on the first day of each year beginning in 2025 and ending in 2034, equal to the lesser of: (A) one percent (1.0%) of the shares of stock outstanding on the last day of the immediately preceding fiscal year, (B) 422,000 shares of our common stock (subject to adjustment for recapitalizations, stock splits and similar transactions), and (C) such smaller number of shares of stock as determined by our board of directors. On January 1, 2025, an additional 2,160,745 shares of our common stock were reserved for issuance pursuant to awards under the 2024 Plan pursuant to the "evergreen" provision, and an additional 422,000 shares of our common stock were reserved for issuance under the ESPP pursuant to the "evergreen" provisions.
(3) The weighted-average exercise price does not take into account 549,001 shares of common stock subject to outstanding unvested restricted stock unit awards granted pursuant to the 2024 Plan.
(4) Excludes 422,000 shares that were available for future issuance under the ESPP as of December 31, 2024.
(5) Comprised of the Kyverna Therapeutics, Inc. 2024 Inducement Equity Incentive Plan.

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 at year-end for the last two completed years, 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 an affiliate or immediate family members thereof, 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.

Closing Under Series B Convertible Preferred Stock Financing

In closings held on June 29, 2023, July 7, 2023, and July 31, 2023, we issued and sold an aggregate of 32,052,994 shares of our Series B convertible preferred stock at a purchase price of $1.8719 per share for an aggregate purchase price of $59,999,999.55.

The following table summarizes the Series B convertible preferred stock purchased by holders of more than 5% of our capital stock in the closings of the Series B convertible preferred stock financing held on June 29, 2023, July 7, 2023 and July 31, 2023, 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 automatically converted into shares of our common stock at a ratio of one-for-4.5511 immediately prior to the closing of our IPO completed on February 12, 2024.

Name[1]	Series B Convertible Preferred Stock Purchased (Shares)	Aggregate Purchase Price ($)
Northpond Ventures III, LP[2]	2,083,445	$3,900,000.70
Westlake BioPartners Fund I, L.P.[3]	3,349,538	$6,270,000.19
Vida Ventures, LLC[4]	3,349,538	$6,270,000.19
Gilead Sciences, Inc.	4,006,624	$7,499,999.47
Entities affiliated with RTW Investments LP[5]	1,041,722	$1,949,999.43
jVen Capital, LLC[6]	96,159	$180,000.04
Bain Capital Life Sciences Opportunities III, LP	12,351,087	$23,119,999.76

(1) For details regarding certain of these stockholders and their equity holdings, see "Security Ownership of Certain Beneficial Owners and Management".
(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) Dr. Seidenberg is a member of our Board 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) 471,759 shares of Series B convertible preferred stock issued to RTW Master Fund, Ltd., (ii) 391,759 shares of Series B convertible preferred stock issued to RTW Innovation Master Fund, Ltd., and (iii) 178,204 shares of Series B convertible 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 as of the date of the Rights Agreement: 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 granted certain rights to the holders of our outstanding convertible preferred stock, including registration rights with respect to the registrable securities held by them. We are obligated to pay the registration expenses, other than the underwriting discounts and selling commissions, of the shares registered pursuant to any such registrations. In addition, the Rights Agreement imposed certain affirmative obligations on us, including, among other things, our obligation to grant certain holders of 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 our IPO, and granted certain information and inspection rights to such holders. Excluding the registration rights, each of these obligations terminated in connection with the closing 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.

Director and Officer Indemnification and Insurance

We have entered into indemnification agreements with each of our directors and executive officers. These agreements, among other things, require us to indemnify each director and executive officer to the fullest extent permitted by Delaware law, including indemnification of expenses such as attorneys' fees, judgments, penalties, fines and settlement amounts incurred by the director or executive officer in any action or proceeding, including any action or proceeding by or in right of us, arising out of the person's services as a director or executive officer. We have obtained an insurance policy that insures our directors and officers against certain liabilities, including liabilities arising under applicable securities laws. For more information regarding these agreements, see Part III, Item 11 of this Annual Report on Form 10-K.

Promissory Note with Former Chief Executive Officer

In December 2022, our former chief executive officer, a related party, early exercised options for 349,321 shares of our common stock in exchange for a partial recourse promissory note receivable with the principal amount of $1.1 million. The note bore interest of 4.27% per annum and was due in December 2027. On January 12, 2024, we forgave the promissory note in full, which included 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

Certain holders of more than 5% of our capital stock and their affiliated entities purchased shares of our common stock in the IPO from the underwriters for payment in excess of $120,000 as summarized in the following table. The underwriters received the same underwriting discount from the sale of the shares of our common stock to these holders as they did from the sale of other shares of our common stock sold to the public in the IPO:

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

Our board of directors has 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. 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. Our Audit Committee is tasked with the review and oversight of related party transactions as required by Nasdaq and SEC rules (including, without limitation, those defined in Item 404 of Regulation S-K, but excluding any compensation-related matters).

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., Christi Shaw, Mert Aktar, Steve Liapis, Ph.D., Beth Seidenberg, M.D. and Daniel K. Spiegelman are independent directors as defined under the Nasdaq Rules. Mr. Biddle 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, 2024 and 2023:

	Fiscal Year Ended December 31,	
	2024	2023
Audit Fees[1]	$909,285	$ 883,385
Audit-Related Fees	—	—
Tax Fees[2]	—	70,232
All Other Fees	—	—
Total Fees	$ 909,285	$ 953,617

(1) Audit fees consist of 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 years ended December 31, 2024 and 2023 included $411,000 and $582,000, respectively, incurred in connection with the filing of our Registration Statement on Form S-1 in connection with our IPO in February 2024.

(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-K	3/26/2024	4.2
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 September 14, 2024, between Kyverna Therapeutics, Inc. and Warner Biddle.	8-K	9/16/2024	10.1
10.8*	Employment Offer Letter, dated December 30, 2024, between Kyverna Therapeutics, Inc. and Naji H. Gehchan, M.D.			
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
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

Exhibit Number	Description	Registrant's Form	Date Filed with the SEC	Exhibit Number
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.			
10.17#	Separation and General Release Agreement, dated September 13, 2024, between Kyverna Therapeutics, Inc. and Peter Maag, Ph.D.	8-K	9/16/2024	10.2
10.18#	Letter Agreement, dated November 26, 2024, between Kyverna Therapeutics, Inc. and James Chung, M.D., Ph.D.	8-K	11/26/2024	10.1
19.1*	Kyverna Therapeutics, Inc. Insider Trading Policy.			
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.	10-K	3/26/2024	97

* 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 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 27, 2025

By: /s/ Warner Biddle
Warner Biddle
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Warner Biddle 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/ Warner Biddle **Warner Biddle**	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2025
/s/ Ryan Jones **Ryan Jones**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2025
/s/ Ian Clark **Ian Clark**	Director	March 27, 2025
/s/ Fred E. Cohen, M.D., D.Phil. **Fred E. Cohen, M.D., D.Phil.**	Director	March 27, 2025
/s/ Mert Aktar **Mert Aktar**	Director	March 27, 2025
/s/ Steve Liapis, Ph.D. **Steve Liapis, Ph.D.**	Director	March 27, 2025
/s/ Beth Seidenberg, M.D. **Beth Seidenberg, M.D.**	Director	March 27, 2025
/s/ Daniel Spiegelman **Daniel Spiegelman**	Director	March 27, 2025
/s/ Christi Shaw **Christi Shaw**	Director	March 27, 2025

Kyverna Therapeutics, Inc.

INDEX TO FINANCIAL STATEMENTS

Audited Financial Statements as of and for the Years Ended December 31, 2024 and 2023

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, 2024 and 2023, the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (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, 2024 and 2023, 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 2021.

San Diego, California

March 27, 2025

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

	December 31,	
	2024	2023
Assets		
Current assets		
Cash and cash equivalents	$ 96,621	$ 34,647
Available-for-sale marketable securities	189,358	22,896
Prepaid expenses and other current assets	4,622	3,121
Total current assets	290,601	60,664
Restricted cash	552	565
Property and equipment, net	3,347	2,326
Operating lease right-of-use assets	6,468	6,494
Finance lease right-of-use assets	841	1,790
Other non-current assets	2,836	3,356
Total assets	$ 304,645	$ 75,195
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	$ 4,624	$ 4,358
Accrued compensation	4,883	2,812
Accrued license expense – related party	6,250	6,250
Other accrued expenses and current liabilities	14,059	3,519
Operating lease liabilities, short-term portion	3,161	1,964
Finance lease liabilities, short-term portion	779	956
Total current liabilities	33,756	19,859
Operating lease liabilities, net of short-term portion	4,160	5,238
Finance lease liabilities, net of short-term portion	142	921
Total liabilities	38,058	26,018
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock, no par value; no shares authorized, issued and outstanding as of December 31, 2024; $0.00001 par value, 114,556,997 shares authorized as of December 31, 2023; 114,556,997 shares issued and outstanding as of December 31, 2023; liquidation preference of $181,273 as of December 31, 2023	—	180,574
Stockholders' equity (deficit)		
Preferred stock, 10,000,000 shares authorized, $0.00001 par value, no shares issued and outstanding as of December 31, 2024; no shares authorized, issued, and outstanding as of December 31, 2023	—	—
Common stock, $0.00001 par value; 490,000,000 and 140,492,016 shares authorized as of December 31, 2024 and 2023, respectively; 43,214,918 and 1,250,103 shares issued and outstanding as of December 31, 2024 and 2023, respectively	—	—
Additional paid-in capital	530,002	4,642
Accumulated other comprehensive income	105	4
Accumulated deficit	(263,520)	(136,043)
Total stockholders' equity (deficit)	266,587	(131,397)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 304,645	$ 75,195

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,	
	2024	2023
Operating expenses		
Research and development	$ 112,473	$ 49,923
General and administrative	30,131	12,483
Total operating expenses	142,604	62,406
Loss from operations	(142,604)	(62,406)
Interest income	15,359	2,282
Interest expense	(142)	(187)
Other expense, net	(90)	(55)
Total other income, net	15,127	2,040
Net loss	(127,477)	(60,366)
Other comprehensive income		
Unrealized gain on available-for-sale marketable securities, net	101	30
Total other comprehensive income	101	30
Net loss and other comprehensive loss	$ (127,376)	$ (60,336)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.33)	$ (89.61)
Weighted-average shares of common stock outstanding, basic and diluted	38,334,571	673,622

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

Kyverna Therapeutics, Inc.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (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' Equity (Deficit)
	Shares	Amount	Shares	Amount				
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)
Issuance of common stock upon initial public offering, net of underwriting commissions and issuance costs of $30,686	—	—	16,675,000	—	336,164	—	—	336,164
Conversion of redeemable convertible preferred stock into common stock in connection with initial public offering	(114,556,997)	(180,574)	25,171,265	—	180,574	—	—	180,574
Common shares issued upon exercise of options	—	—	118,550	—	259	—	—	259
Stock-based compensation expense	—	—	—	—	8,357	—	—	8,357
Vesting of early exercised options and restricted stock	—	—	—	—	6	—	—	6
Net loss	—	—	—	—	—	(127,477)	—	(127,477)
Unrealized gain on available-for-sale marketable securities, net	—	—	—	—	—	—	101	101
Balance at December 31, 2024	—	$ —	43,214,918	$ —	$ 530,002	$ (263,520)	$ 105	$ 266,587

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

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

	Year Ended December 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (127,477)	$ (60,366)
Adjustments to reconcile net loss to net cash used in operations:		
Stock-based compensation	8,357	2,220
Accretion of discounts on available-for-sale marketable securities	(7,664)	(1,115)
Depreciation and amortization expense	2,133	1,707
Non-cash lease expense	2,544	1,720
Changes in assets and liabilities:		
Prepaid expense and other current assets	(1,501)	(1,192)
Other non-current assets	(1,955)	(1,849)
Accounts payable	736	4,083
Accrued compensation	2,071	1,401
Other accrued expenses and current liabilities	10,905	2,660
Operating lease liability	(2,399)	(1,679)
Net cash used in operating activities	(114,250)	(52,410)
Cash flows from investing activities		
Purchases of available-for-sale marketable securities	(489,997)	(54,847)
Proceeds from maturities of available-for-sale marketable securities	331,300	46,683
Purchases of property and equipment	(2,205)	(621)
Net cash used in investing activities	(160,902)	(8,785)
Cash flows from financing activities		
Proceeds from issuance of common stock upon initial public offering, net of underwriting commissions	341,171	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	59,900
Proceeds from exercise of common stock options	259	645
Principal paid on finance lease liabilities	(956)	(781)
Payments for offering costs	(3,361)	(1,646)
Net cash provided by financing activities	337,113	58,118
Net increase (decrease) in cash and cash equivalents and restricted cash	61,961	(3,077)
Cash, cash equivalents and restricted cash, at beginning of period	35,212	38,289
Cash, cash equivalents and restricted cash, at end of period	$ 97,173	$ 35,212
Reconciliation of cash, cash equivalents and restricted cash to statement of financial position		
Cash and cash equivalents	96,621	34,647
Restricted cash	552	565
Cash, cash equivalents and restricted cash at end of period	$ 97,173	$ 35,212
Supplemental disclosure for non-cash investing and financing activities		
Conversion of 114,556,997 shares of redeemable convertible preferred stock to common stock shares upon the closing of initial public offering	$ 180,574	$ —
Unpaid deferred offering costs included in accounts payable and other current liabilities	$ —	$ 829
Vesting of restricted stock	$ 6	$ 71
Right-of-use asset obtained in exchange for operating and finance lease liability	$ 2,518	$ 975
Supplemental disclosure of cash flow information		
Cash paid for interest	$ 142	$ 187

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 clinical-stage biopharmaceutical company focused on developing cell therapies for patients with autoimmune diseases. The lead product candidate, KYV-101, is advancing through late-stage clinical development across two broad areas of autoimmune disease: neuroinflammation and rheumatology. 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 $336.2 million, after deducting underwriting commissions and other offering costs totaling $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, 2024, the Company has an accumulated deficit of $263.5 million. The Company had net losses of $127.5 million and $60.4 million for the years ended December 31, 2024 and 2023, respectively. The Company had cash used in operations of $114.3 million and $52.4 million for the years ended December 31, 2024 and 2023, respectively.

The Company has historically financed its operations primarily through issuances of redeemable convertible preferred stock and convertible notes, revenue from its collaboration agreement and sale of shares of its common stock in the IPO. As of December 31, 2024, the Company had cash and cash equivalents and available-for-sale marketable securities of $286.0 million. The Company expects to continue to incur operating losses and negative cash flows from operations to support the development of its product candidates, to expand 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 the completion of 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 and available for sale marketable securities balances 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 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.

Cash and Cash Equivalents

Cash and cash equivalents include cash in readily available checking accounts and available-for-sale marketable securities with maturities of less than 90 days from the date of purchase.

Restricted Cash

As of each of December 31, 2024 and 2023, 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, 2024, consist of U.S treasury bills with original maturities of greater than 90 days from the date of purchase. 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. As of December 31, 2024, the Company also had investments in money market funds, corporate debt obligations 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.

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 Offering Costs

Deferred offering costs, consisting of legal, accounting and other third-party fees directly relating to in-process equity financings or offerings, are capitalized. The deferred offering costs are offset against offering proceeds upon the completion of the financing or the offering. The Company had zero and $2.5 million deferred offering costs recorded as other non-current assets as of December 31, 2024 and 2023, 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, 2024 and 2023.

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 was recorded separate from stockholders' deficit because the shares contain deemed liquidation features that were not solely within the Company's control. The holders of the preferred stock controlled 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 did not adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such stock because it was 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. 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.

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. 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.

Basic and diluted net loss attributable to common stockholders per share was 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 did 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 was attributed entirely to common stockholders.

Comprehensive Loss

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (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 asset and 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

As an "emerging growth company," the Jumpstart Our Business Startups Act, allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use the extended transition period for complying with new or revised accounting standards. As a result, the Company's financial statements may not be

comparable to the financial statements of issuers who are required to comply with the effective date for new or revised accounting standards that are applicable to public companies.

Recently Adopted Accounting Pronouncements

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 adopted the new standard for the fiscal year 2024. The impact of adoption resulted in enhanced disclosures in the notes to the financial statements (see Note 14, "Segment Reporting").

New Accounting Pronouncements Not Yet Adopted

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 amendments in this ASU should be applied prospectively; however, retrospective application is also permitted. The Company is currently evaluating the impact from the adoption of this standard on the Company's financial statements.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation (Subtopic 220-40): Disaggregation of Income Statement Expenses*. The amendments in ASU 2024-03 require a public business entity to disclose specific information about certain costs and expenses in the notes to its financial statements for interim and annual reporting periods. The objective of the disclosure requirements is to provide disaggregated information about a public business entity's expenses to help investors (a) better understand the entity's performance, (b) better assess the entity's prospects for future cash flows, and (c) compare an entity's performance over time and with that of other entities. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of 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, 2024, was as follows (in thousands):

	Fair Value Measurements			
As of December 31, 2024	**Total**	**Level 1**	**Level 2**	**Level 3**
Cash equivalents				
Money market funds	$ 36,745	$ 36,745	$ —	$ —
Corporate debt obligations	33,910	—	33,910	—
U.S. Treasury bills	25,426	—	25,426	—
Available-for-sale marketable securities				
U.S. Treasury bills	189,358	—	189,358	—
Total fair value of assets	$ 285,439	$ 36,745	$ 248,694	$ —

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	$ —

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, corporate debt obligations, U.S. Treasury bills and available-for-sale marketable securities consisted of U.S. Treasury 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, 2024, the Company's available-for-sale marketable securities consisted of debt securities issued by the U.S. Treasury and corporate debt obligations with contractual maturities on various dates within the next 12 months.

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, 2024 (in thousands):

As of December 31, 2024	Total Amortized Cost	Total Unrealized Gains	Total Unrealized Losses	Total Estimated Fair Value
Money market funds (included in cash and cash equivalents)	$ 36,745	$ —	$ —	$ 36,745
U.S. Treasury obligations ($25,426 included in cash and cash equivalents)	214,677	107	—	214,784
Corporate debt obligations (included in cash and cash equivalents)	33,912	—	(2)	33,910
Total available for sale marketable securities	$ 285,334	$ 107	$ (2)	$ 285,439

As of December 31, 2024, $96.1 million was included in cash equivalents and $189.4 million was included in available-for-sale marketable securities.

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

As of December 31, 2024 and 2023, 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, 2024 and 2023, the Company did not recognize any impairment losses on its investments.

As of each of December 31, 2024 and 2023, accrued interest receivable was zero. 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 did not write off any accrued interest receivables for the year ended December 31, 2024 and 2023.

5. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net, consists of the following (in thousands):

	December 31,	
	2024	2023
Laboratory equipment	$ 4,130	$ 3,409
Computer equipment and software	1,132	138
Furniture and fixtures	936	622
Leasehold improvements	821	645
Property and equipment, gross	7,019	4,814
Less accumulated depreciation	(3,672)	(2,488)
Total property and equipment, net	$ 3,347	$ 2,326

Depreciation expense related to property and equipment was approximately $1.2 million and $0.9 million for the years ended December 31, 2024 and 2023, respectively.

Other Accrued Expenses and Current Liabilities

Other accrued expenses and current liabilities consist of the following (in thousands):

	December 31,	
	2024	2023
Accrued CRO research and development expenses	$ 5,669	$ 728
Accrued CMO research and development expenses	5,487	1,002
Other accrued expenses	2,903	1,789
Total other accrued expenses and current liabilities	$ 14,059	$ 3,519

6. License and Collaboration Agreements

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. The Company paid $3.3 million for acquired licenses.

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 $5.7 million for the autologous patent license agreement and $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. The Company recognized $0.2 million as research and development expense related to minimum annual royalty payments in each of the years ended December 31, 2024 and 2023. As of December 31, 2024, the Company recognized $0.6 million related to benchmark royalties for regulatory approvals and patients' dosing in clinical trials as research and development expenses in the statement of operations and comprehensive loss. As of December 31, 2024, $0.6 million were recorded as accounts payable in the balance sheet. No other benchmark royalties were probable or payable as of December 31, 2024 and 2023.

Intellia License and Collaboration Agreement

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 shares of its Series B Preferred Stock with the fair value of $7.0 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, 2024 and 2023.

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 redeemable convertible preferred stock, of which 4,042,066 shares were issued as consideration under the Kite Agreement (see below).

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.

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.

On October 24, 2023, Gilead provided the Company with 90 days' written notice to terminate the Gilead Agreement, and such termination became effective as of January 22, 2024. As of and for the years ended December 31, 2024 and 2023, there were no activities and contract balances related to the Gilead Agreement.

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.) (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.

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, 2024 and 2023, the Company had the total sublicensing fee of $6.3 million as current accrued license expense—related party. There are no future milestones payable to offset the sublicensing fee due to the termination of the Gilead Agreement. The Company and Gilead have not yet agreed on the settlement of the sublicensing fee.

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, 2024 and 2023.

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. During the year ended December 31, 2024, the Company recognized $0.6 million related to benchmark royalties under the NIH Agreement as research and development expenses in the statement of operations and comprehensive loss. As of December 31, 2024, $0.6 million were recorded as accounts payable in the balance sheet. No other milestones were achieved or probable as of December 31, 2024 and 2023. 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, 2024 and 2023, and no such royalties were due.

Contractual Obligations and Commitments

The Company enters 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. The Company does not expect any of these agreements to be terminated and does not have any non-cancellable obligations under these agreements as of December 31, 2024 and 2023.

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.

On December 9, 2024, a shareholder class action complaint was filed in the United States District Court for the Northern District of California against the Company, certain of its current and former officers and directors, and the underwriters of the IPO. The complaint alleges that the registration statement on Form S-1 filed in connection with the IPO and the prospectus contained therein contained material misstatements or omissions in violation of federal securities laws. The Company intends to defend the claims in this lawsuit vigorously and believes it has good and substantial defenses to the claims in the complaint, but there is no guarantee that the Company will be successful in these efforts. Given the complexity of the issues in the lawsuit, the fact that the lawsuit was recently filed and is in its early stages, and the inherent uncertainty of litigation, the Company is unable to make any predictions about the ultimate outcome of this matter. As a result, the Company is unable to determine whether any loss ultimately will occur or to estimate the range of such loss. No amount of loss has been accrued in the accompanying financial statements for the year ended December 31, 2024.

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, 2024 and 2023, the Company does not have any material indemnification claims that were probable or reasonably possible.

Leases

As of December 31, 2024, the Company leased office and laboratory space in Emeryville, California under operating leases which have terms through February 2027. The lease includes an option to extend the lease for an additional 36 months. 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, 2024 and 2023.

Components of the lease expense for the years ended December 31, 2024 and 2023, were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Operating lease cost	$ 3,252	$ 2,429
Finance lease cost:		
Amortization of right-of-use assets	949	838
Interest on lease liabilities	142	187
Short-term lease cost	—	1
Variable lease cost	1,072	970
Total lease expense	$ 5,415	$ 4,425

Supplemental cash flow information related to leases was as follows for the years ended December 31, 2024 and 2023 (in thousands):

	Year Ended December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 3,073	$ 2,384
Operating cash flows from finance leases	142	187
Financing cash flows from finance leases	956	781
Right-of-use assets obtained in exchange for lease obligations upon inception of lease (noncash):		
Operating leases	2,518	—
Finance leases	—	975

The following is a schedule by year of future payments of the Company's lease liabilities as of December 31, 2024 (in thousands):

	Operating Leases	Finance Leases
2025	$ 3,563	$ 887
2026	4,046	179
2027	446	—
Thereafter	—	—
Total lease payments	8,055	1,066
Less interest	(734)	(145)
Total lease liability balance	7,321	921
Less: current portion	(3,161)	(779)
Non-current lease liabilities	$ 4,160	$ 142

The weighted-average remaining lease term and discount rate related to the Company's operating lease liabilities as of December 31, 2024, were 2.1 years and 9%, respectively. The weighted-average remaining lease term and discount rate related to the Company's finance lease liabilities as of December 31, 2024, were 1.1 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, 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 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

In June 2023 and July 2023, the Company issued 32,052,994 additional shares of Series B redeemable convertible 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.

On February 12, 2024, in connection with the closing of the IPO, all outstanding shares 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.

9. Common Stock

As of December 31, 2024 and 2023, common stock shares reserved for future issuance were as follows:

	December 31,	
	2024	2023
Redeemable convertible preferred stock, as converted	—	25,171,265
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 as of December 31, 2023 and none as of December 31, 2024)	7,595,922	3,960,713
Unvested restricted stock units awards	549,001	—
Shares available for future options grants	3,562,709	487,673
Shares available for future grants under the Employee Stock Purchase Plan	422,000	—
Total shares reserved for future issuance	**12,129,632**	**29,619,651**

Early Exercise of Options for a Promissory Note

In December 2022, the Company's former chief executive officer (the "Former CEO"), a then-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 bore interest at 4.27% per annum and was to be 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 were considered not substantive. While the issued shares were not considered outstanding for accounting purposes, they were legally issued and had voting and dividend rights. The shares were included in common stock on the statement of redeemable convertible preferred stock and stockholders' deficit as of December 31, 2023, and were not included in the calculation of net loss per share attributable to common stockholders for the year ended December 31, 2023.

On January 12, 2024, the Company and the Former 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. As the shares subject to the options that were early exercised were vested as of the date of the forgiveness of the note, these are included in the calculation of net loss per share attributable to common stockholders from the date of the note's forgiveness. The Company concluded that the note forgiveness was effectively a repricing of options and is a modification. Therefore, the incremental stock-based compensation expense was recognized for the vested shares at the modification date (see Note 10).

10. Equity Incentive Plans

In January 2024, the Company's board of directors adopted, and stockholders approved, the Company's 2024 Equity Incentive Plan (the "2024 Plan"), which became effective on February 6, 2024. The Company initially reserved 4,215,000 shares of common stock for future issuance under the 2024 Plan. In addition, 3,960,713 shares issued and outstanding under the Company's 2019 Equity Incentive Plan, as amended (the "2019 Plan"), may be added to the 2024 Plan as such shares become available from time to time if awards terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. The 2024 Plan also provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2025 and ending on January 1, 2034, by an amount equal to the lesser of (i) 5% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, and (ii) such smaller number of shares of stock as determined by the Company's board of directors. No more than 12,645,000 shares of stock may be issued upon the exercise of incentive stock options under the 2024 Plan.

The Company may grant incentive stock options ("ISOs"), nonstatutory stock options ("NSOs"), restricted stock units ("RSUs"), restricted stock awards ("RSAs"), stock appreciation rights ("SARs"), performance awards and other awards to the Company's officers, employees, directors and consultants. Options under the 2024 Plan may be granted for periods of up to 10 years at exercise prices no less than the fair market value of the common stock on the date of grant and usually vest over four years. The exercise price of an option granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. The grant date fair market value of all awards made under the 2024 Plan and all cash compensation paid by the Company to any non-employee director for services as a director in any fiscal year may not exceed $750,000, increased to $1,000,000 in the fiscal year of their initial service as a non-employee director. The 2024 Plan is the successor to the 2019 Plan and no additional awards may be granted under the 2019 Plan. All outstanding awards granted under the 2019 Plan will remain subject to the terms of the 2019 Plan. The 2019 Plan provided for the grant of incentive stock options, nonstatutory stock options, RSUs and RSAs to the Company's officers, employees, directors and consultants.

As of December 31, 2024, ISOs, NSOs and RSUs had been granted under the 2024 Plan. As of December 31, 2024, 2,491,968 shares of the Company's common stock were available for issuance under the 2024 Plan.

In January 2024, the Company's board of directors and stockholders adopted the Company's 2024 Employee Stock Purchase Plan (the "ESPP"), which became effective on February 6, 2024. The Company initially reserved 422,000 shares of common stock for future issuance under the ESPP. The ESPP permits participants to purchase common stock through payroll deductions of up to 15% of their eligible compensation. Employees purchase shares of common stock at a price per share equal to 85% of the lower of the fair market value at the start of the offering or on the date of purchase. The aggregate number of shares reserved for issuance under the ESPP will automatically increase each January 1, beginning on January 1, 2025 and ending on January 1, 2034, by an amount equal to the lesser of 1% of the Company's total outstanding shares of common stock on the immediately preceding December 31st, and 422,000 shares or a lesser number of shares as may be determined by the Company's board of directors.

In September 2024, the Company adopted the 2024 Inducement Equity Incentive Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of equity-based awards in the form of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units and performance shares solely to prospective employees of the Company or an affiliate of the Company provided that certain criteria are met. Awards under the Inducement Plan may only be granted to an individual, as a material inducement to such individual to enter into employment with the Company or an affiliate of the Company, who (i) has not previously been an employee or director of the Company or (ii) is rehired following a bona fide period of non-employment with the Company. The Company reserved 4,000,000 shares of common stock for future issuance under the Inducement Plan. As of December 31, 2024, 2,929,259 shares were granted and 1,070,741 shares were available for future grant under the Inducement Plan.

Stock Options

Stock options issued under the 2019 Plan, 2024 Plan and the Inducement Plan generally vest over a four-year period and expire ten years from the date of grant. Certain options provide for accelerated vesting if there is a change in control, as defined in the individual award agreements and the Company's severance policies.

A summary of option activity under the 2019 Plan, 2024 Plan and the Inducement 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, 2023 *	4,310,034	$ 4.09	9.09	$ 11,810
Options granted	4,419,225	$ 7.58		
Options exercised	(467,871)	$ 2.90		
Options cancelled and forfeited	(660,665)	$ 8.34		
Options expired	(4,801)	$ 4.04		
Outstanding at December 31, 2024 *	7,595,922	$ 5.83	7.58	$ 760
Exercisable at December 31, 2024 **	1,437,877	$ 3.92	4.60	$ 444
Vested and expected to vest at December 31, 2024	7,595,922	$ 5.83	7.58	$ 760

* Outstanding number of options as of December 31, 2023 excludes 349,321 shares of common stock issued in connection with the early exercised options for a non-recourse promissory note, which were not considered substantive for accounting purposes. These shares are included in the number of options exercised during the year ended December 31, 2024, upon the note forgiveness in January 2024 (see Note 9)

** Includes 303,472 shares of unvested stock options for which the holders have the right to early exercise such options as of December 31, 2024.

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, 2024 and 2023, was $5.89 and $4.39, respectively. The total fair value of options that vested during the years ended December 31, 2024 and 2023 was $2.5 million and $1.9 million, respectively. As of December 31, 2024, total unrecognized stock-based compensation expense was $26.7 million, which is expected to be recognized over a weighted-average period of 3.2 years. The intrinsic value of options exercised during the year ended December 31, 2024 and 2023 was $3.8 million and $1.0 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.

Restricted Stock Units

During the year ended December 31, 2024, the Company granted RSUs for 539,143 shares with a weighted-average price per share of $7.02. RSU shares vest over a four-year period. The fair value of the RSUs equals the fair value of the Company's common stock as of the grant date. The estimated fair value of RSUs granted was $3.8 million. As of December 31, 2024, total unrecognized compensation expense for RSUs was $3.6 million, which is expected to be recognized over weighted-average period of 3.4 years.

During the year ended December 31, 2024, the Company granted performance RSUs for 100,000 shares with a weighted-average price per share of $8.05. Performance RSU shares vest in full upon the Company receiving certain regulatory approvals within 36 months from the grant date. The fair value of the performance RSUs equals the fair value of the Company's common stock as of the grant date. The estimated fair value of performance RSUs granted was $0.8 million. As of December 31, 2024, total unrecognized compensation expense for performance RSUs was $0.8 million. Compensation expense of $0.8 million for performance RSUs is expected to be recognized when it is probable that the performance criteria will be achieved over the remaining vesting term. As of December 31, 2024, the performance criteria was not probable and no expense was recognized.

	Number of RSUs	Weighted-Average Grant Rate Fair Value
Unvested at December 31, 2023	—	$ —
Granted - RSUs	539,143	7.02
Granted - Performance RSUs	100,000	8.05
Vested	—	—
Forfeited - RSUs	(90,142)	7.09
Unvested at December 31, 2024	549,001	$ 7.19

Early Exercise of Employee Options

Certain employees received stock options prior to the IPO 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 were 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 December 31, 2024 and 2023, there was zero and $0.1 million repurchase liability related to the unvested shares, respectively. As of December 31, 2024 and 2023, zero and 8,125 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 stock 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 were not considered substantive for accounting purposes (see Note 9).

Stock-Based Compensation Expense

The Black-Scholes option pricing model, used to estimate fair value of the option awards, requires the use of the following assumptions:

- *Fair value of common stock.* Prior to the IPO, the fair market value of common stock was 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 was 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"). Subsequent to the IPO, the fair value of common stock is the Company's closing price per share on the Nasdaq Global Select Market at the grant date.
- *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 stock options has been determined by calculating the midpoint of the contractual term of the options and the weighted-average vesting period.
- *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 was estimated using the Black-Scholes valuation model using the following assumptions for the years ended December 31, 2024 and 2023, respectively:

	Year ended December 31,	
	2024	2023
Expected volatility	93%-95%	91%-95%
Expected dividend yield	—%	—%
Expected term (in years)	5.8-6.1	5.9-6.2
Risk-free interest rate	3.5%-4.5%	3.6%-4.7%

The following tables presents the classification of stock-based compensation expense related to stock options and RSUs granted (in thousands):

	Year ended December 31,	
	2024	2023
Research and development	$ 2,455	$ 792
General and administrative	5,902	1,428
Total stock-based compensation expense	$ 8,357	$ 2,220

The above stock-based compensation expense was related to the following stock-based awards (in thousands):

	Year ended December 31,	
	2024	2023
Restricted stock units	$ 313	$ —
Stock options	8,044	2,220
Total stock-based compensation expense	$ 8,357	$ 2,220

During 2024, in connection with the Former CEO note forgiveness (see Note 9), the Company recognized stock-based compensation expense of $1.1 million in general and administrative expenses in the statement of operations and comprehensive loss for the year ended December 31, 2024. In addition, during 2024, in connection with the entry into a separation agreement with the Former CEO, the Company recognized stock-based compensation expense of $1.7 million related to modification of certain vesting terms in the Former CEO's stock-based awards, which was recorded in general and administrative expenses in the statement of operations and comprehensive loss for the year ended December 31, 2024.

11. 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,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders	$ (127,477)	$ (60,366)
Denominator:		
Weighted average shares used in computing basic and diluted net loss per share	38,334,571	673,622
Net loss per share attributable to common stockholders, basic and diluted:	$ (3.33)	$ (89.61)

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,	
	2024	2023
Redeemable convertible preferred stock, as converted	—	25,171,265
Options issued and outstanding	7,595,922	3,960,713
Unvested early exercised common stock options	—	8,125
Unvested early exercised common stock options exercised for non-recourse promissory note (Note 9)	—	349,321
Unvested RSUs outstanding	549,001	—
	8,144,923	29,489,424

12. Income Taxes

The Company has recorded no income tax expense for the years ended December 31, 2024 and 2023. 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,	
	2024	2023
Income tax computed at federal statutory rate	21.00%	21.00%
State taxes	7.4%	6.6%
Other permanent differences	(0.2)%	(0.8)%
Research credits	4.8%	1.1%
Stock-based compensation	(0.9)%	(0.6)%
State uncertain tax positions	(5.6)%	(5.9)%
Change in valuation allowance	(26.5)%	(21.4)%
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,	
	2024	2023
Net operating loss carry forwards	$ 17,209	$ 10,807
Capitalized research and development expenditures	30,769	13,327
Reserves and accruals	1,505	816
Lease liabilities	2,123	2,091
Research credits	9,950	1,714
Stock-based compensation	963	216
Accrued license	1,812	1,814
License and upfront fees	3,080	2,936
Other	57	83
Total gross deferred tax assets	67,468	33,804
Less: Valuation allowance	(65,593)	(31,772)
Total deferred tax assets	$ 1,875	$ 2,032
Deferred tax liabilities		
Property and equipment	—	(147)
Lease right-of-use assets	(1,875)	(1,885)
Total gross deferred tax liabilities	(1,875)	(2,032)
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 $33.8 million and $12.9 million during the years ended December 31, 2024 and 2023, respectively.

The Company has net operating loss carryforwards for federal and state income tax purposes of $79.2 million and $205.2 million, respectively, as of December 31, 2024. 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 2044.

As of December 31, 2024, the Company has federal and state research and development credit carryforwards of approximately $9.4 million and $3.1 million, respectively. The federal credits will expire in various amounts 2041 through 2044 and the state credits can be carried forward indefinitely.

Under Section 382 of the Internal Revenue Code of 1986, as amended, the ability to utilize net operating loss carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if the Company has experienced an "ownership change". 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 of California net operating losses to expire unused due to Section 382 limitations. As of December 31, 2024, the Section 382 study was updated and the Company concluded that there were no ownership changes during 2024.

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, 2024 and 2023, is as follows (in thousands):

	2024	2023
Beginning balance	$ 8,395	$ 3,600
Increase in tax positions in prior periods	711	184
Increase in tax positions in the current period	10,357	4,611
Ending balance	$ 19,463	$ 8,395

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, 2024 and 2023, 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.

13. Related Party Transactions

For the year ended December 31, 2024 and 2023, the Company recorded zero and less than $0.1 million, respectively, to deferred offering costs related to an advisory services agreement with one of its board members.

On January 12, 2024, the Company and the Former 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. The promissory note was issued by the Former CEO in December 2022 in connection with early exercised options (see Note 9).

In September 2024, the Company's Former CEO resigned and entered into a consulting agreement for six months that can be extended by both parties for an additional 12 months. The Former CEO is eligible to receive $0.6 million as severance benefits, monthly consulting fees and health benefits for up to 12 months. The Former CEO's outstanding option awards will continue vesting as per the original terms until June 2025, if the consulting agreement continues until then. The Company concluded that the Former CEO does not provide substantive services for accounting purposes after his resignation. In connection with the Former CEO's resignation, the Company recognized $2.6 million as general and administrative expenses as related to severance benefits and stock awards modification for the year ended December 31, 2024. The Company recognized $1.7 million to additional paid in capital related to stock awards modification expense. As of December 31, 2024, the Company recognized $0.4 million in other accrued expenses and current liabilities related to severance payments.

14. Segment Reporting

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 ("CODM"), reviews financial information on an aggregate basis for purposes of allocating resources, assessing performance and monitoring budget versus actuals. The CODM assesses performance based on net loss as reported on the statement of operations and comprehensive loss. The measure of segment assets is reported on the balance sheet as total assets. Further, segment depreciation expense and segment asset additions are consistent with amounts reported within the statement of cash flows given the Company's operations are aggregated within a single reportable segment. All of the Company's long-lived assets are located in the United States. Asset and other balance sheet information is not reported to the CODM.

The following table sets forth the Company's summary of segment loss, including significant segment expenses for the years ended December 31, 2024 and 2023 (in thousands):

	Year ended December 31,	
	2024	2023
Research and development expenses:		
KYV-101	$ 61,884	$ 18,267
Other programs	3,947	4,509
Other research and development expenses[(a)]	46,642	27,147
Total research and development expenses	112,473	49,923
General and administrative expenses:		
General and administrative expenses[(b)]	30,131	12,483
Total general and administrative expenses	30,131	12,483
Total operating expenses	142,604	62,406
Loss from operations	(142,604)	(62,406)
Interest income	15,359	2,282
Interest expense	(142)	(187)
Other income, net	(90)	(55)
Total other income, net	15,127	2,040
Net loss	$ (127,477)	$ (60,366)

[(a)] Primarily includes personnel costs, license fees, R&D consulting services, unallocated CRO and CMO costs and allocated overhead and facilities expenses

[(b)] Primarily includes personnel costs, allocated overhead and facilities expenses, legal, IT, accounting and general and administrative expenses

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