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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31 , 2023

or

o **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 001-40502

Lyell Immunopharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**83-1300510**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
201 Haskins Way	
South San Francisco , California	**94080**
(Address of Principal Executive Offices)	(Zip Code)

(650) 695-0677

Registrant's telephone number, including area code

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	LYEL	The Nasdaq Global Select Market

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

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

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

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 x No o

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 x No o

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

Large accelerated filer	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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. o

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. x

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. o

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). o

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

The aggregate market value of the common stock held by non-affiliates of the registrant on June 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $ 654 million based on the closing price reported for such date on the Nasdaq Global Select Market.

The registrant had 254,096,311 shares of common stock outstanding as of February 22, 2024.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2024 Annual Meeting of Stockholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023.

Lyell Immunopharma, Inc.
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. 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, product candidates, planned nonclinical studies and clinical trials, results of nonclinical studies and clinical trials, research and development costs, planned regulatory submissions, regulatory approvals and the timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential” or “continue,” or the negative of these terms or other similar expressions. Forward-looking statements contained in this Annual Report on Form 10-K include, but are not limited to, statements about:

- the sufficiency of our existing cash to fund our future operating expenses and capital expenditure requirements;
- the accuracy and timing of our estimates regarding expenses, revenue opportunities, capital requirements and needs for additional financing;
- the scope, progress, results and costs of developing LYL797, LYL845, LYL119 or any other product candidates we may develop, and conducting nonclinical studies and clinical trials, including for LYL797, LYL845 and LYL119;
- the timing and costs involved in obtaining and maintaining regulatory approvals of LYL797, LYL845, LYL119 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including any expectations regarding seeking special designations for our product candidates for various diseases;
- our plans relating to the commercialization of LYL797, LYL845, LYL119 or any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales force;
- the size of the market opportunities for LYL797, LYL845, LYL119 or any other product candidates we may develop in each of the diseases we may target;
- our reliance on third parties to conduct research activities for LYL797, LYL845, LYL119 or any other product candidates we may develop;
- the characteristics, safety, efficacy and therapeutic effects of LYL797, LYL845, LYL119 or any other product candidates we may develop;
- our estimates of the number of patients in the United States who suffer from the diseases we target and the number of subjects that may enroll in our clinical trials;
- the benefits associated with the U.S. Food and Drug Administration’s (FDA) Orphan Drug designation (ODD), including potential tax credits for qualified clinical trials, prescription drug user-fee exemptions and potential seven-year marketing exclusivity upon FDA approval and comparable benefits associated with foreign ODDs in other countries;
- the progress and focus of our current and planned clinical trials of our product candidates, and the reporting of data from those trials, including the timing thereof;
- the ability of our clinical trials to sufficiently demonstrate the safety and efficacy of LYL797, LYL845, LYL119 or any other product candidates we may develop, and other clinical trial results;
- the success of competing therapies that are, or may become, available;
- developments relating to our competitors and our industry, including any existing or future competing product candidates or therapies;
- our plans relating to the further development and manufacturing of LYL797, LYL845, LYL119 or any other product candidates we may develop, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;

- our potential and ability to successfully manufacture and supply or our ability to contract with third parties to manufacture and supply LYL797, LYL845, LYL119 or any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance, as well as the pricing and reimbursement, of LYL797, LYL845, LYL119 or any other product candidates we may develop, if approved;
- our continued reliance on third parties to assist us in conducting additional clinical trials of LYL797, LYL845, LYL119 or any other product candidates we may develop;
- the scope of protection we are able to establish and maintain for intellectual property rights, including covering our product candidates and technology platforms;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the impact of inflation, macroeconomic conditions and geopolitical conflicts on our business and operations, including on our manufacturing suppliers, collaborators, contract research organizations (CROs) and employees;
- our anticipated use of our existing cash, cash equivalents and marketable securities; and
- our expectations related to the costs, anticipated benefits and financial impact of our reduction in workforce commenced, and substantially completed, in the fourth quarter of 2023.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements speak only as of the date of this Annual Report on Form 10-K and are subject to a number of risks, uncertainties and assumptions described under “Risk Factors” in Part I, Item 1A, and elsewhere in this Annual Report on Form 10-K. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in these forward-looking statements. Except as required by applicable law, we undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement the reasons that actual results could differ materially from those projected in these forward-looking statements, even if new information becomes available in the future.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

SUMMARY OF RISK FACTORS

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 and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. This summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should carefully consider the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K as part of your evaluation of an investment in our common stock.

- We are an early clinical stage biopharmaceutical company and have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing net losses for the foreseeable future.
- We operate in a rapidly evolving field and have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We currently have no products approved for sale and have never generated revenue from product sales. We may never generate revenue from product sales or achieve profitability.
- We will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Our success payment obligations in our success payment agreements may result in dilution to our stockholders or may be a drain on our cash resources to satisfy the payment obligations.
- We are early in our research and clinical development efforts for our product candidates. If we are unable to successfully develop, manufacture and commercialize product candidates or experience significant delays in doing so, our business may be harmed.
- Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use and expand our technology platforms to develop any product candidate.
- We currently have no marketing, sales or distribution infrastructure, and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us.
- We currently manufacture drug products for our clinical trials ourselves. Delays in further qualifying or in receiving regulatory approvals for any manufacturing facility or product candidates, or in expanding our manufacturing capacity or finding suitable third-party manufacturing partners, could delay our development plans and thereby limit our ability to generate product revenues.
- The manufacturing of cellular therapies is very complex. We are subject to a multitude of manufacturing risks, including risks associated with supply chain complexity related to patient materials, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates.
- If our sole clinical or commercial manufacturing facility or any of our potential contract manufacturing organizations are damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.
- We may rely on third parties to manufacture our product candidates, which subjects us to risks and could delay or prevent our development and/or commercialization, if approved, of our product candidates.
- Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.
- We rely on third parties to conduct, supervise and monitor a significant portion of our research and nonclinical studies and clinical trials for our product candidates, and, if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.
- We have in the past, and we may in the future, form or seek collaborations or strategic alliances or enter into additional licensing arrangements, and we may not realize the benefits of such alliances or licensing arrangements.

- We depend on the enrollment and retention of patients in our current and planned clinical trials for our product candidates. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our cellular therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approvals, commercialization or payor coverage of our product candidates.
- The results of research, nonclinical studies or earlier clinical trials are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- Clinical development involves a lengthy and expensive process with an uncertain outcome.
- Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.
- We have in-licensed a portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could potentially lose the ability to continue the development and potential commercialization of one or more of our product candidates.

PART I

Item 1. Business.

Overview

We are a clinical-stage cell therapy company advancing a pipeline of product candidates for patients with solid tumors utilizing our proprietary ex vivo genetic and epigenetic T-cell reprogramming technologies. Our investigational therapies use the patient's own cells as the starting point to generate highly tumor-reactive, longer-lasting functional T cells with enhanced ability to defeat solid tumors. Our innovative reprogramming technologies address what we believe are the primary barriers that limit consistent and long-lasting responses to T-cell therapy in solid tumors: T-cell exhaustion and lack of durable stemness. Our technologies are designed to generate T cells with the ability to persist and self-renew while driving durable tumor cytotoxicity, even in the setting of an immunosuppressive tumor microenvironment. We apply our technologies with the aim of developing T-cell therapies with improved and durable antitumor responses for patients with solid tumors. Our technologies can be applied in a target agnostic manner to multiple T-cell modalities, including chimeric antigen receptor (CAR), tumor-infiltrating lymphocytes (TIL) and T-cell receptor (TCR) therapies.

Our growing pipeline of promising cell product candidates targets solid tumor indications with large unmet needs that are collectively responsible for approximately 180,000 deaths in the United States annually. Each of our programs provide opportunities to expand into additional indications beyond the patient populations we are initially targeting. Our lead product candidates are summarized in Table 1 below:

Table 1: Lyell's Pipeline

Product	Target	Reprogramming				Target Indications	Preclinical	Phase 1	Phase 2/ Pivotal	Next Milestone
		Genetic		Epigenetic						
		c-Jun	NR4A3	Epi-R™	Stim-R™					
LYL797 CAR T cell	ROR1	✓		✓		TNBC, NSCLC, other ROR1+ solid tumors				Initial data on 20+ patients in 1H24
LYL119 CAR T cell	ROR1	✓	✓	✓	✓	ROR1+ solid tumors				Submit IND 1H24
LYL845 TIL	Multiple antigens			✓		Melanoma (Orphan Drug Designation), CRC, NSCLC				Initial data 2H24
2nd Gen TIL	Multiple antigens	Genetic and Epigenetic Reprogramming				Solid tumors				

Abbreviations: CAR, chimeric antigen receptor; CRC, colorectal cancer; IND, investigational new drug; NSCLC, non-small cell lung cancer; ROR1, receptor tyrosine kinase-like orphan receptor 1; TIL, tumor-infiltrating lymphocytes; TNBC, triple-negative breast cancer.

We were incorporated in June 2018. Our primary activities to date have included clinical development of T-cell therapies, conducting research and development, acquiring technology, entering into strategic collaboration and license agreements, enabling and executing manufacturing activities in support of our product candidate development efforts, organizing and staffing our company, business planning, establishing our intellectual property portfolio, making regulatory submissions, executing clinical trials, raising capital and providing general and administrative support for these activities. We are early in our research and development efforts and are in Phase 1 clinical development of LYL797, our ROR1-targeted CAR T-cell product candidate, and LYL845, our TIL product candidate. Two additional product candidates that each include novel genetic and epigenetic reprogramming technologies are in preclinical development: LYL119, a ROR1-targeted CAR T-cell product candidate and a second generation TIL product candidate. We do not have any products approved for sale.

Our Strategy

Our goal is to realize the potential of cell therapy for solid tumors by developing innovative therapies enhanced with our proprietary T-cell reprogramming technologies, which in nonclinical studies have been shown to generate potent,

tumor-reactive, long-lasting and functional T cells to drive durable tumor cytotoxicity. Lyell was founded by leaders in the fields of oncology and cell therapy who have interrogated and elucidated the mechanisms of T-cell biology and its interactions with cancer for decades. We believe T-cell exhaustion and lack of durable stemness, defined as the ability of T cells to self-renew and persist to drive durable tumor cytotoxicity, are primary barriers to effective cell therapy for solid tumors. Emerging clinical data from the literature has continued to strengthen the rationale for our scientific approach.

Key components of our business strategy to achieve this goal include:

- ***Efficiently advance our diverse pipeline of product candidates*** — We believe our autologous T-cell therapies have the potential to deliver improved, durable clinical outcomes for patients with solid tumors. We have two wholly-owned product candidates in two distinct T-cell modalities, CAR T cell and TIL, currently in Phase 1 development targeting indications with unmet medical needs in large commercial opportunities. We anticipate having initial clinical data for both programs in 2024 and filing an Investigational New Drug (IND) application for a third wholly-owned product candidate in the first half of 2024.
- ***Leverage our proprietary, cell reprogramming technology platforms to create highly tumor-reactive, longer-lasting functional T cells with enhanced ability to defeat solid tumors*** — We seek to develop T-cell therapies to defeat solid tumors by addressing the major barriers to effective cell therapy in solid tumors, including overcoming exhaustion of T cells and creating populations of T cells with properties of durable stemness. Our pipeline of therapeutic candidates includes programs designed to outlast and eradicate solid tumors utilizing our proprietary, stackable and complementary genetic and epigenetic T-cell reprogramming technologies: c-Jun overexpression, NR4A3 knockout, Epi-R™ and Stim-R™.
- ***Continually innovate to develop and advance novel, breakthrough technologies for cell therapy*** — We are committed to continuing to discover, develop and advance disruptive technologies that may have the potential to revolutionize cell therapy and its promise to improve the lives of patients with solid tumors. For example, we are advancing a second generation TIL product candidate enhanced with both genetic and epigenetic reprogramming technologies. In addition, we are advancing our Rejuvenation technology, which is designed to "turn back the clock" to generate more stem-like T cells with reduced epigenetic age and enhanced proliferation ability. These novel technologies are being advanced with the goal of creating products with even greater benefit to patients with cancer.
- ***Maintain state-of-the-art infrastructure and expert capabilities to control and innovate cell product manufacturing*** — We have built and operate a wholly-owned manufacturing facility, LyFE Manufacturing Center™, a multi-product manufacturing center that is producing cell product for our clinical trials. We have, and will continue to, invest in infrastructure that enables real-time monitoring of our manufacturing process and the ability to incorporate insights into our research, manufacturing and clinical development efforts. Our manufacturing strategy includes seeking new ways to efficiently, rapidly and cost-effectively scale manufacturing capacity for our cell product candidates for future clinical trials and potential commercialization. Our proof-of-concept technology transfer collaboration for the manufacture of LYL797 using the Cellares Cell Shuttle™ is an example of this. We are also advancing our Epi-R P2 manufacturing process, which is designed to shorten TIL manufacturing time without impacting cell number and phenotype.
- ***Generate, secure and defend intellectual property on our differentiated technology platforms and product candidates*** — We have developed and secured intellectual property, including know-how, through our internal research efforts, licensing agreements and collaborations. We rigorously analyze, file and protect our intellectual property in an ongoing manner.
- ***Opportunistically pursue strategic partnerships and collaborations to maximize the potential of our technologies and products*** – We consider a variety of ways to collaborate with external partners. Our technologies can be applied in a target and modality agnostic manner to CAR, TIL and TCR therapies to improve the functionality of T cells. In addition to applying our technologies to advance product candidates in our proprietary pipeline, we also assess opportunities to combine our technologies with targets that other companies are pursuing. Our product candidates are designed to address large patient populations, and we will evaluate options for partnering programs, indications or geographies with pharmaceutical or biotechnology companies for development and/or commercialization. We also consider opportunities to acquire or license rights or invest in differentiated product candidates or technologies to complement our pipeline.

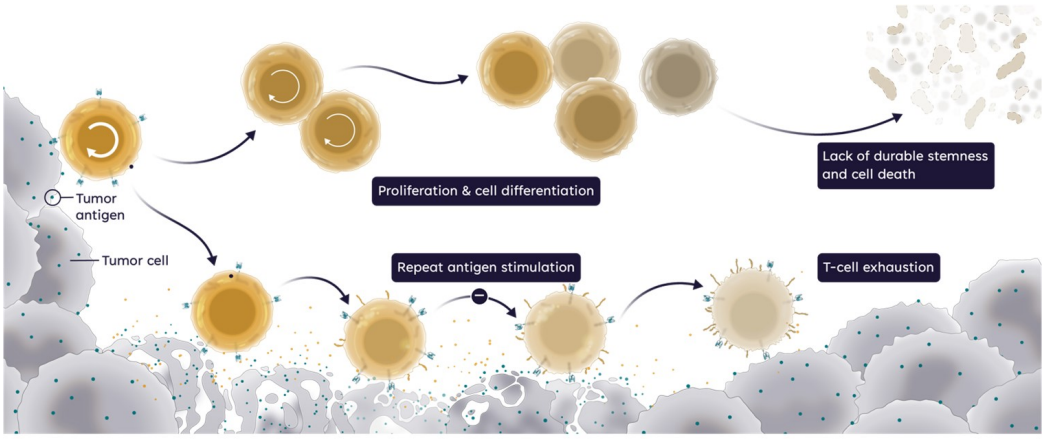
Our Reprogramming Technologies

Cell therapy has demonstrated profound results in some patients suffering from hematologic malignancies, but solid tumors are more complex and have evolved multiple mechanisms to evade and ultimately resist clearance by the

immune system. This has limited the use of cell therapy in solid tumors, which account for 90% of cancer deaths. Based on clinical data and other scientific evidence, we believe **T-cell exhaustion** and **lack of durable stemness**, which include the ability of T cells to persist and self-renew to drive durable tumor cytotoxicity, are two primary barriers limiting the efficacy of cell therapy in solid tumors.

As illustrated in Figure 1, the highly immunosuppressive solid tumor microenvironment drives T cells down a path of exhaustion as a result of chronic and repeated antigen stimulation in solid tumors, which renders the T cells dysfunctional. In addition, standard manufacturing processes often generate T-cell products that are composed of mostly differentiated effector cells – cells that lack the stem-like qualities necessary to enable them to self-renew and sustain therapeutic activity over time.

Figure 1: Cell therapies for solid tumors must overcome two primary barriers: T-cell exhaustion and lack of durable stemness.



T-cell exhaustion describes a dysfunctional cellular state characterized by increased expression of cell surface markers such as PD-1, TIM-3 and LAG-3, and, importantly, the functional inability to respond to antigens and eliminate target cells. A clinical study, previously conducted at the Fred Hutchinson Cancer Center, illustrated the different fates of CAR T cells in solid tumors versus hematologic malignancies and identified T-cell exhaustion as a key barrier to effective cell therapy in the solid tumor microenvironment. In this study (Riddell et al, Keystone, 2020), autologous ROR1-targeted CAR T cells infused into patients with chronic lymphocytic leukemia underwent rapid expansion and retained T-cell effector function, leading to tumor cell clearance and clinical responses. However, when CAR T cells generated with the same method are infused into patients with solid tumors, such as triple-negative breast cancer (TNBC) or non-small cell lung cancer (NSCLC), these T cells often failed to expand adequately, rapidly developed cell surface markers of T-cell exhaustion and adopted a dysfunctional state. The outcome of these studies clearly demonstrated that T-cell exhaustion is a major barrier to effective cell therapy in solid tumors.

Durable stemness describes the quality of a population of T cells to persist through self-renewal, as well as generate differentiated effector cell progenies to provide durable tumor cytotoxicity. Emerging research has shown that effective immunotherapy requires T-cell populations with stem-like characteristics to produce clinical responses, where the presence of stem-like T cells correlates with solid tumor responses to cancer immunotherapy in the setting of solid tumors, including TIL and immune checkpoint blockade therapy (Sade-Feldman et al., *Cell*, Nov. 2018; Krishna et al., *Science*, Dec. 2020)

We have developed proprietary, stackable and complementary genetic and epigenetic reprogramming technologies designed to address these two major barriers. Our reprogramming technologies are designed to generate potent T cells with durable cytotoxic function, irrespective of target and irrespective of whether they are delivered as CAR, TIL or TCR therapies. We have generated T cells that have demonstrated in nonclinical studies the ability to sustain cancer cell killing in murine models of solid tumors and an increased ability to maintain stemness to drive more durable tumor cytotoxicity.

Genetic reprogramming technologies*:* Our two proprietary ex vivo genetic reprogramming technologies are c-Jun overexpression and NR4A3 gene knockout. c-Jun and NR4A3 are involved in the regulation of the activator protein 1 (AP-1) transcription factor pathway, which plays a key role in T-cell effector function. These complementary

reprogramming technologies function within this critical biological pathway to endow T cells with the ability to resist exhaustion.

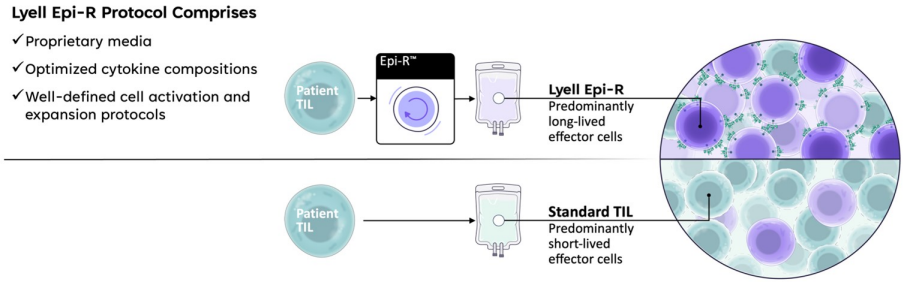
Overexpression of c-Jun is based on the work of Lyell co-founder, Crystal Mackall, M.D., the Ernest and Amelia Gallo Family Professor of Pediatrics and Medicine at Stanford University and Founding Director of the Stanford Center for Cancer Cell Therapy. Dr. Mackall discovered that exhausted T cells have an imbalance in the AP-1 family of transcription factors, and that correcting for this imbalance by overexpression of c-Jun enables T cells to resist exhaustion, infiltrate solid tumors and maintain their functionality and potency. This work was fully described in a *Nature* publication in 2019 (Lynn et al., *Nature*, Dec. 2019).

Our second genetic reprogramming technology, NR4A3 gene knockout, builds on the approach of reprogramming of the AP-1 transcription factor pathway to delay exhaustion and improve antitumor function. We and others have previously observed that the NR4A family of transcription factors is upregulated in exhausted T cells and may contribute to T-cell exhaustion in part by restricting the activity of AP-1. We hypothesize that disruption of NR4A3 expression, along with c-Jun overexpression, may further unleash the potential for maximal c-Jun activity and endow greater functional resistance to exhaustion. Our nonclinical data suggest the combination of these two technologies, NR4A3 gene knockout and c-Jun overexpression, can act in a complementary fashion and may have the potential to further improve the potency and durability of our CAR therapy.

Epigenetic reprogramming technologies: Our two proprietary ex vivo epigenetic reprogramming technologies are Epi-R and Stim-R. These novel manufacturing technologies generate product candidates with more stem-like cells and with greater potency during ex vivo T-cell expansion.

Epi-R is our proprietary ex vivo manufacturing protocol that is designed to generate populations of stem-like T cells with reduced exhaustion and improved proliferation and antitumor activity. T cells with properties of durable stemness have an increased ability to self-renew and persist to drive durable tumor cytotoxicity. This technology is built upon the groundbreaking science conducted at the National Cancer Institute (NCI), where it was demonstrated that products with more stem-like and functional T cells can be achieved by altering the metabolic state of the cells during expansion (Vodnala et al., *Science*, Mar. 2019). Key NCI scientists conducting this research subsequently joined Lyell where they created the Epi-R manufacturing protocol, which intentionally produces T-cell populations with desirable stem-like properties that can be measured both phenotypically and functionally. Our novel Epi-R protocol includes proprietary media, well-defined cell activation and expansion processes, as well as customized cytokine combinations. Epi-R enables manufacturing of T-cell therapy product candidates that are highly potent against cancer cells but also retain characteristics of stemness, which have been clinically associated with effective antitumor immunotherapies (Figure 2). Furthermore, relating specifically to TIL, the application of Epi-R has generated T-cell populations that exhibit a high degree of polyclonality, *i.e*., the retention of a broad repertoire of TCR clonotypes that may react to a broader set of tumor antigens, thus improving the potential of our TIL therapy to counteract the heterogeneous nature of solid tumors. Additionally, we are able to reliably and reproducibly manufacture our TIL products from a variety of solid tumors, including those that have been traditionally hard to manufacture such as from checkpoint refractory malignant melanoma, NSCLC and colorectal cancer (CRC).

Figure 2: As shown below, Lyell's proprietary Epi-R manufacturing protocol produces T-cell populations with long-lived stem-like characteristics. This protocol is used in our LYL797 CAR T-cell product candidate and in our LYL845 TIL product candidate, which are both in Phase 1 clinical trials, as well as our LYL119 CAR T-cell product candidate in preclinical development.



Our second epigenetic reprogramming technology, Stim-R, is a proprietary synthetic-cell mimetic composed of lipid-coated silica micro-rods that mimic the physiological cell-like presentation of signals to control T-cell activation in the manufacturing process. Current manufacturing platforms typically utilize antibody-conjugated beads that were

developed decades ago for expanding T cells. This standard approach does not provide precise control over the strength or duration of the signaling that drives T-cell expansion ex vivo. Our Stim-R platform optimizes signaling parameters during T-cell activation using degradable lipid-coated silica rods that can be functionalized to regulate cell activation more closely mimicking natural T-cell stimulation. This technology allows for greater control over the duration, intensity and type of signals delivered during cell expansion and manufacturing, resulting in the generation of more potent T-cell products with desirable phenotypic and functional properties.

T-cell rejuvenation technologies: We and others have documented the impact of aging on T-cell function, which begins to decline after puberty, and at an increasingly accelerated rate after age 65. Morbidity and mortality from cancer also increase with age. Thus, we are working to advance another novel reprogramming technology that focuses on rejuvenation of antitumor T cells. We are developing a method designed to maintain T-cell identity while reducing the epigenetic age of the cells. This technology is currently in the research stage. We have generated data illustrating the ability to "turn back" the epigenetic clock in a process called cellular rejuvenation, without changing the T-cell's identity as would occur in the setting of induced pluripotent stem cell-derived T cells.

Our Clinical Programs

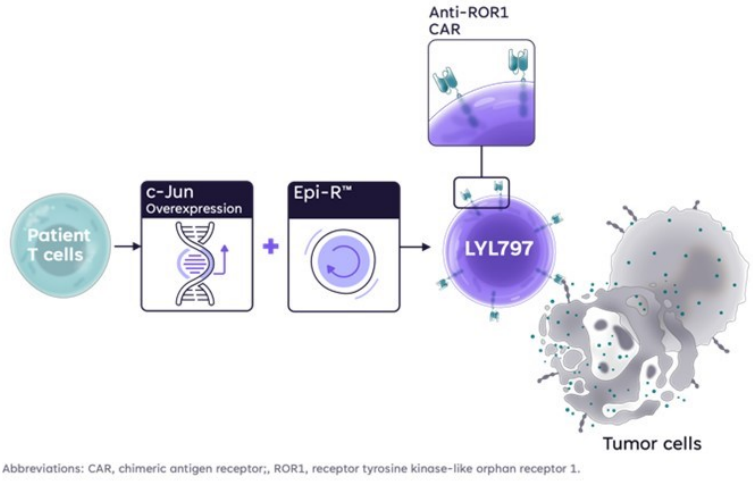
We are advancing a diverse pipeline of four wholly-owned product candidates, including two product candidates in Phase 1 clinical development, LYL797 and LYL845. Two additional product candidates, LYL119 and a second generation TIL product candidate, are in preclinical development. Each of our programs currently target cancers with large unmet need and provide opportunity to expand into additional indications. We have deployed our technologies in our pipeline in the following manner to provide rapid clinical proof-of-concept (see Table 1):

- LYL797 incorporates our c-Jun and Epi-R technologies and is undergoing evaluation in a Phase 1 clinical trial enrolling patients with relapsed/refractory TNBC or NSCLC.
- LYL119 incorporates our c-Jun, NR4A3, Epi-R and Stim-R technologies and is currently in preclinical development.
- LYL845 incorporates our Epi-R technology and is undergoing evaluation in a Phase 1 clinical trial including patients with advanced melanoma, relapsed/refractory NSCLC or CRC.

LYL797: A genetically and epigenetically reprogrammed ROR1 CAR T-cell product candidate designed for differentiated potency and durability targeting multiple solid tumor indications.

We are applying our c-Jun and Epi-R technologies to our lead CAR T-cell product candidate, LYL797, which is expected to be an intravenously-administered CAR T-cell product targeting the receptor tyrosine kinase-like orphan receptor 1 (ROR1) protein. ROR1 is a fetal protein expressed during embryogenesis and is believed to be important in cell migration, polarity and survival. It is expressed in several cancer types, including TNBC, NSCLC, ovarian cancer and chronic lymphocytic leukemia, and is generally associated with a poor prognosis. LYL797 (Figure 3) contains a CAR with a 4-1BB/CD3ζ intracellular domain, a transmembrane domain, an optimized spacer domain and a single-chain variable fragment (scFv) derived from an R12 rabbit monoclonal antibody that recognizes and binds with high specificity to human ROR1. LYL797 also incorporates c-Jun and a proprietary optimized truncated version of human EGFR ($EGFR_{opt}$) used for tracking the CAR T cells in the peripheral blood post treatment and can also be used as a safety measure with the administration of cetuximab, if needed. LYL797 is manufactured utilizing our proprietary Epi-R technology.

Figure 3: LYL797: ROR1 CAR T cell + c-Jun + Epi-R.



Phase 1 Clinical Trial

Our Phase 1 clinical trial (NCT05274451) is designed to evaluate the safety and antitumor activity of LYL797 in patients with ROR1-positive TNBC or NSCLC.

The trial is designed as an open label, dose escalation and expansion trial in patients with relapsed/refractory TNBC who have failed at least two lines of therapy and patients with relapsed/refractory NSCLC who have failed at least one line of therapy. Per protocol, dose expansion at the recommended dose identified during dose escalation is expected to occur in at least 15 patients with TNBC and 15 patients with NSCLC. The primary outcome measure assesses the safety and tolerability of LYL797. Patients will be monitored for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome, as well as tissue-specific toxicities in ROR1-expressing organs. Secondary outcome measures include clinical activity based on the evaluation of antitumor activity as evaluated by Response Evaluation Criteria in Solid Tumors (RECIST) criteria and characterization of the pharmacokinetic profile of LYL797. Exploratory biomarkers of T-cell function – exhaustion and stemness – will also be assessed.

In the first half of 2024, we plan to share initial clinical and translational data from the trial from at least 20 patients, which we anticipate will provide an early indication of clinical effect.

Target Indications

We are initially developing LYL797 for the treatment of ROR1-positive TNBC and NSCLC. Significant subsets of patients with common cancers express ROR1, including TNBC and NSCLC, two of the highest ROR1-expressing solid tumor indications. Results from our own ROR1 screening program are consistent with what is reported in the literature. Using our immunohistochemistry assay in the screening for our Phase 1 trial, as of September 2023, we have found that approximately 50% of patients with TNBC and approximately 33% of patients with NSCLC have tumors that express ROR1. If successful, we may expand into other ROR1-positive cancers, including potentially ovarian and other solid tumors.

Breast cancer is the second most common cancer in American women. Currently, the average risk for a woman in the United States to develop breast cancer is approximately 13%. Breast cancers that demonstrate the absence of estrogen receptor and progesterone receptor and no overexpression of HER2 are referred to as TNBC. Approximately 10-15% of patients with breast cancer have TNBC and triple negative status tends to be more common in women younger than age 40, who are African American or who have a BRCA1 mutation. TNBCs have a high tendency to metastasize, and patients are at a higher risk to relapse compared to other molecular types. TNBCs differ from other types of invasive breast cancer in that TNBC tumors grow and spread faster, have limited treatment options and have a worse prognosis. In the United States, there are approximately 40,000 new cases of TNBC annually and approximately 22% of breast cancer deaths are from TNBC. Once TNBC has spread to distant parts of the body, the 5-year survival rate is only 11.5% despite currently available treatment options. For non-metastatic disease, available treatments include surgery, combined with neoadjuvant and adjuvant chemotherapy. Chemotherapy is usually anthracycline, alkylator or taxane-based. PARP inhibitors, such as

olaparib, may be used in the adjuvant setting. For metastatic disease, options include combination chemotherapy and pembrolizumab. At recurrence, patients with tumors that are low HER2 expressing are candidates for Fam-trastuzumab deruxtecan. Otherwise, the antibody-drug conjugate sacituzumab govitecan-hziy is a treatment option.

Lung cancer is the leading cause of cancer mortality worldwide, accounting for about 2.2 million new cases and 1.8 million deaths worldwide in 2020. Globally, lung cancer is the leading cause of cancer death for men. For women, it is the second leading cause of cancer death, following only breast cancer. In the United States, it is expected to account for approximately 12% of all new cancer cases. It is estimated that 125,000 deaths from this cancer will occur in the United States in 2024.

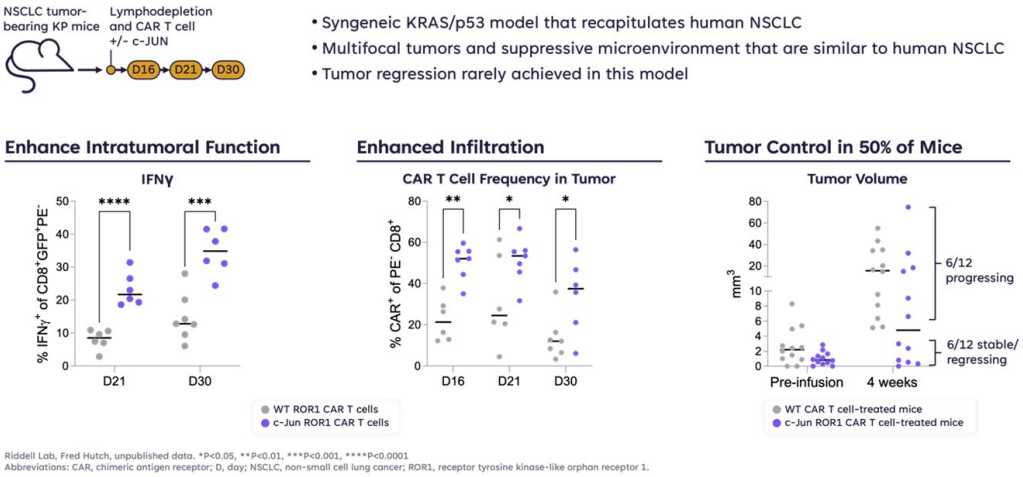
NSCLC is more prevalent than small cell lung cancer, constituting approximately 85% of all lung cancer diagnoses. The 5-year survival rates depend upon the stage of the disease. NSCLC that is diagnosed at an early stage, typically when the cancer is confined to the lung, has a 5-year survival rate of approximately 65%. Regional NSCLC, or disease that has spread to nearby lymph nodes or tissues but has not yet metastasized to distant organs, has a 5-year survival rate of approximately 40%. Metastatic NSCLC is the most advanced stage of NSCLC where the cancer has spread to distant organs. The 5-year survival rate for metastatic NSCLC is generally much lower, often less than 10%. Although there are multiple treatments, including surgery, radiation and approved therapies including chemotherapy, immunotherapy and targeted drug therapy, we believe there remains a tremendous need for better therapies to improve survival.

Nonclinical Data

We have conducted extensive nonclinical in vitro and in vivo studies supporting development of LYL797. Nonclinical studies of ROR1 CAR T cells that overexpress c-Jun have demonstrated tumor reduction, enhanced cytokine production and tumor infiltration in an aggressive NSCLC syngeneic animal model (Figure 4). CAR T cells generated with our Epi-R manufacturing protocol exhibit enhanced durability and cytotoxicity (Figure 5). Additionally, in a nonclinical xenograft tumor model, LYL797, combining c-Jun overexpression and Epi-R, demonstrated prolonged survival in a xenograft NSCLC animal model (Figure 6).

Our scientific co-founder, Stanley Riddell, M.D., first tested the hypothesis that overexpression of c-Jun could improve T-cell function in a rigorous solid tumor model of NSCLC (Figure 4). Dr. Riddell and colleagues utilized a transgenic mouse model with inducible oncogenic driver mutations KRASG12D and p53 deletion. Once triggered, these mice developed tumors *de novo* that recapitulate an immunosuppressive tumor microenvironment, akin to human NSCLC. Previous studies have shown that this aggressive tumor model does not respond to chemotherapy or PD-L1 immunotherapy. In our study, we observed that this aggressive tumor model is also resistant to treatment with ROR1 CAR T cells, just as was observed in treating human NSCLC with ROR1 CAR T cells. In contrast, tumor-bearing mice treated with ROR1 CAR T cells that overexpressed c-Jun demonstrated greater infiltration by the T cells into the tumor, enhanced function of those T cells and tumor regression or stabilization in 50% of the mice versus the 100% tumor progression observed in mice treated with ROR1 CAR without overexpression of c-Jun.

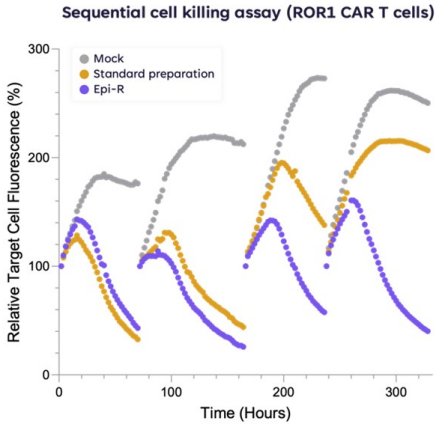
Figure 4: Nonclinical efficacy demonstrated with c-Jun overexpressing ROR1 CAR T cells in aggressive NSCLC model.



Riddell Lab, Fred Hutch, unpublished data. *P<0.05, **P<0.01, ***P<0.001, ****P<0.0001
Abbreviations: CAR, chimeric antigen receptor; D, day; NSCLC, non-small cell lung cancer; ROR1, receptor tyrosine kinase-like orphan receptor 1.

We have also demonstrated that CAR T cells generated with Epi-R are able to kill tumor cells over time in an experiment where the CAR T cells are repeatedly challenged to kill tumor cells over multiple rounds (Figure 5). In this experiment, CAR T cells are co-cultured with ROR1-positive tumor cells, and tumor cell killing can be assessed and quantified by measurement of decreasing fluorescence. CAR T cells were repeatedly challenged with tumor cells over multiple rounds to assess the durability of tumor cell killing. Cells generated through standard expansion protocols gradually lose their functionality by the third round and are significantly less effective in killing tumor cells by the fourth round of tumor cell killing. In contrast, cells generated with the Epi-R protocol continue to kill tumor cells. Importantly, the Epi-R cells are no longer in the Epi-R protocol, suggesting that the stem-like attribute derived from the epigenetic reprogramming is sustained after the manufacturing protocol and for the duration of the experiment.

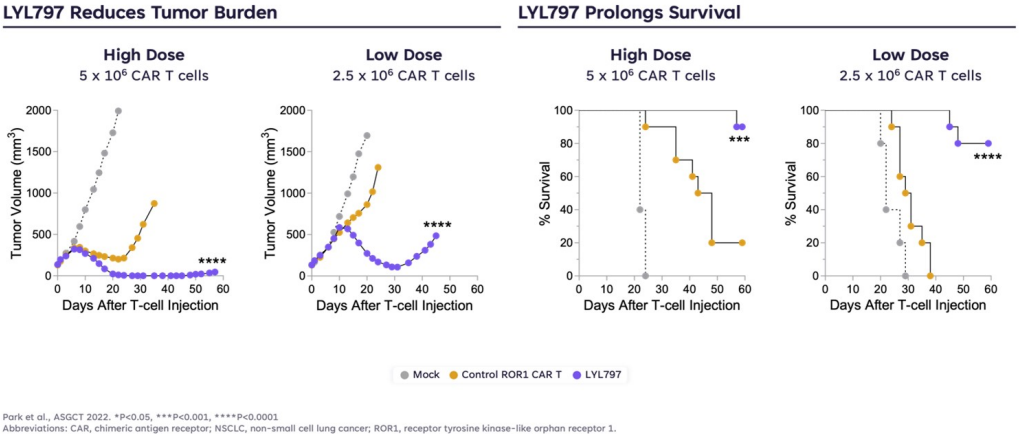
Figure 5: The Epi-R protocol produces populations of T cells with durable cytotoxicity.



In May 2022, at the American Society of Gene and Cell Therapy Annual Meeting, we presented a study that assessed in vivo functional activity of LYL797 (ROR1 CAR T cells with c-Jun and Epi-R) compared to conventional ROR1 CAR T cells in an established human ROR1-positive H1975 mouse xenograft model. In this study, LYL797 demonstrated improved expansion in the peripheral blood of tumor-bearing animals and control of tumor growth, which led to prolonged survival (Figure 6).

Taken together, these nonclinical data characterize LYL797 and demonstrate that ROR1-targeted CAR T cells reprogrammed with c-Jun and Epi-R can overcome barriers of T-cell exhaustion and lack of durable stemness.

Figure 6: LYL797 reduces tumor burden and prolongs survival in NSCLC (H1975) xenograft model.



Park et al., ASGCT 2022. *P<0.05, ***P<0.001, ****P<0.0001
Abbreviations: CAR, chimeric antigen receptor; NSCLC, non-small cell lung cancer; ROR1, receptor tyrosine kinase-like orphan receptor 1.

LYL845: A novel epigenetically reprogrammed TIL product candidate designed for differentiated potency and durability targeting multiple solid tumor indications.

We are applying our epigenetic reprogramming technology, Epi-R, to develop LYL845, which is expected to be an intravenously-administered autologous TIL therapy for multiple solid tumors. Our Epi-R manufacturing protocol comprises proprietary media, optimized cytokine compositions and well-defined cell activation and expansion protocols used during our manufacturing process.

TIL have previously shown clinical benefit in patients with advanced melanoma and other solid tumors with high mutational burden. Published data from third-party TIL trials show that treating metastatic melanoma patients with TIL can result in complete and durable responses. Response rates to TIL therapy in patients with other advanced solid tumors such as lung, colorectal and breast have been much lower than those observed in advanced melanoma. Broad TIL efficacy has been limited by poor enrichment of tumor-reactive T cells and the poor quality and limited growth potential of expanded T cells. Failure to maintain polyclonality of TIL during production may also limit their ability to eradicate cancer cells given the inherent heterogeneous nature of solid tumors. LYL845 incorporates our Epi-R technology that has shown promising improvements in enhancing T-cell potency, antitumor activity and increased polyclonality of TIL in nonclinical experiments. We recently received ODD for LYL845 as a potential novel treatment for patients with advanced melanoma.

Phase 1 Clinical Trial

Our Phase 1 clinical trial (NCT05573035) is designed to evaluate the safety and antitumor activity of LYL845 in patients with advanced melanoma, NSCLC and CRC. If successful, we expect to expand into additional indications.

The trial is designed as an open label, dose escalation and expansion trial in patients with relapsed and/or refractory metastatic or locally advanced solid tumors. Per protocol, dose expansion at the recommended dose identified during dose escalation is expected to occur in at least 15 patients with advanced melanoma, 15 patients with NSCLC and 15 patients with CRC. The primary outcome measure assesses the safety and tolerability of LYL845. Secondary outcome measures include clinical activity based on the evaluation of antitumor activity as evaluated by RECIST criteria and characterization of the pharmacokinetic profile of LYL845. Evaluation of T-cell expansion, phenotype, clonal diversity and persistence will also be assessed. Patients will be monitored for CRS.

We plan to share initial clinical and translation data from the trial in the second half of 2024, when we expect to have a meaningful number of patients that can provide an early indication of clinical effect.

Target Indications

We are initially developing LYL845 for advanced melanoma, NSCLC and CRC. Based on our success with those indications, we plan to include patients with other solid tumors, potentially including head and neck, cervical, breast and pancreatic cancer. Although patients with these cancers may benefit initially from radiation therapy, chemotherapy,

surgery, and more advanced alternatives such as checkpoint therapies, immunotherapies or targeted therapies, most patients with these types of cancers eventually relapse. After becoming resistant to initial lines of therapy, patients are limited to palliative care, experimental therapies in clinical trials or chemotherapy regimens that are often highly toxic and largely ineffective. Overall, despite recent advances in therapeutic development, for most patients diagnosed with advanced solid tumors, long-term survival rates remain low.

Melanoma of the skin is among the most common cancers in the United States behind breast, prostate, lung and CRC. It is one of the most common cancers in young adults and especially in young women. It is estimated there are over 100,000 new cases of melanoma diagnosed in the United States per year. Melanoma arises due to genetic mutations in melanocytes, the pigment producing cells, which can be found in the skin, eye, inner ear and leptomeninges, and represents the most aggressive and the deadliest form of skin cancer. Although melanoma accounts for only ~1% of all dermatologic cancers, it is responsible for ~80% of deaths from skin cancer. Only ~16% of patients with advanced melanoma survive for five years. Available treatment options include surgery, radiation therapy, immunotherapy (PD-1 inhibitors), chemotherapy and targeted therapies (MEK and BRAF inhibitors).

A description of NSCLC can be found above in the section describing the Phase 1 clinical trial for LYL797.

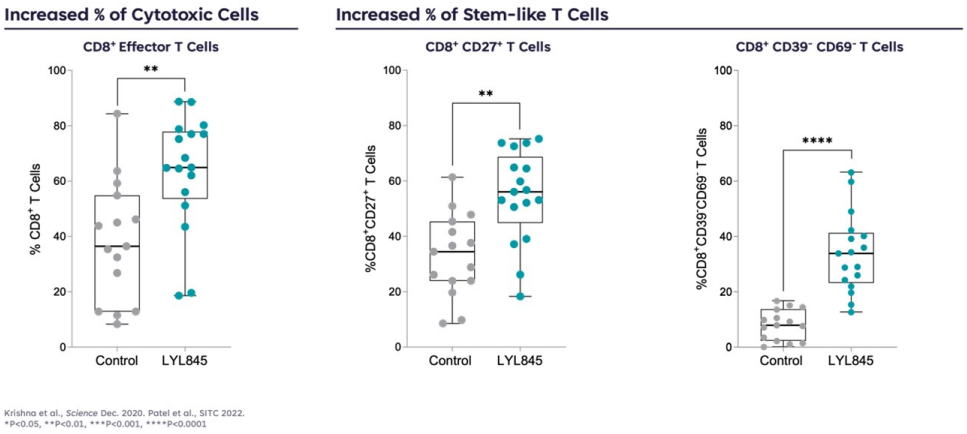
CRC is the second leading cause of cancer-related deaths in the United States. Most colorectal cancers are a type of tumor called adenocarcinoma, which is cancer of the cells that line the inside tissue of the colon and rectum. In 2023, an estimated 150,000 people were diagnosed with CRC and approximately 53,000 will die from the disease. For patients diagnosed with metastatic disease, the 5-year survival rate is approximately 14%. Approximately 25% of patients have metastatic disease at diagnosis, and about 50% of patients with colorectal cancer will eventually develop metastases. Over 35% of the patients with a new diagnosis of CRC will die within five years. Currently available treatments include surgery, radiation therapy, chemotherapy, immunotherapy and targeted therapy (vascular endothelial growth factor, epidermal growth factor receptor, BRAF, NTRK, HER2 and kinase inhibitors) or the antibody-drug conjugate fam-trastuzumab deruxtecan.

Nonclinical Data

We have conducted nonclinical studies supporting the development of LYL845. These studies have demonstrated that TIL generated with our Epi-R technology have phenotypes (stemness markers and cytotoxic T cells) associated with clinical responses in published literature and preserved polyclonal tumor reactive cells. In addition, manufacturing with Epi-R allows us to expand TIL from not only immunologically hot tumors such as melanoma, but also immunologically colder tumors such as NSCLC and CRC.

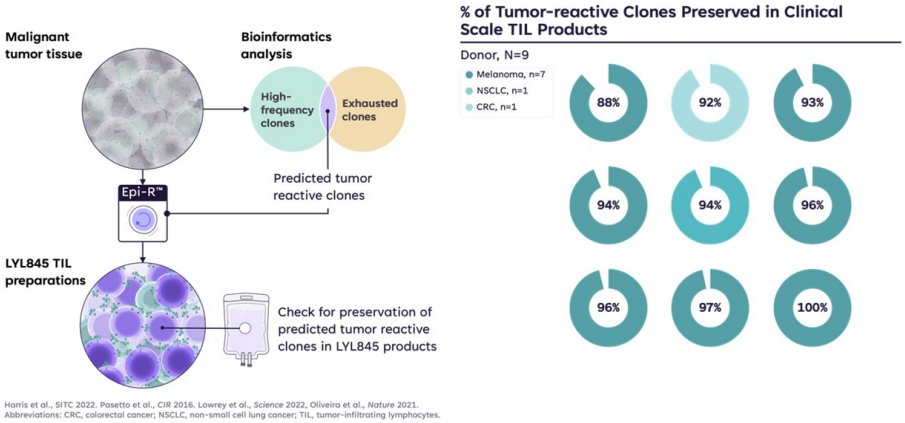
In November 2022, at the Annual Meeting of the Society for Immunotherapy of Cancer (SITC), we presented data that demonstrated the ability of our Epi-R technology to yield a product (LYL845) with qualities that have been linked with antitumor functionality and improved outcomes in previous TIL clinical trials, including a greater proportion of CD8+ cytotoxic T cells and enrichment of T cells with stem-like profiles (Figure 7), and better metabolic fitness compared to control TIL.

Figure 7: LYL845 is enriched for cells with characteristics associated with improved clinical outcomes (Krishna et al., *Science,* Dec. 2020).



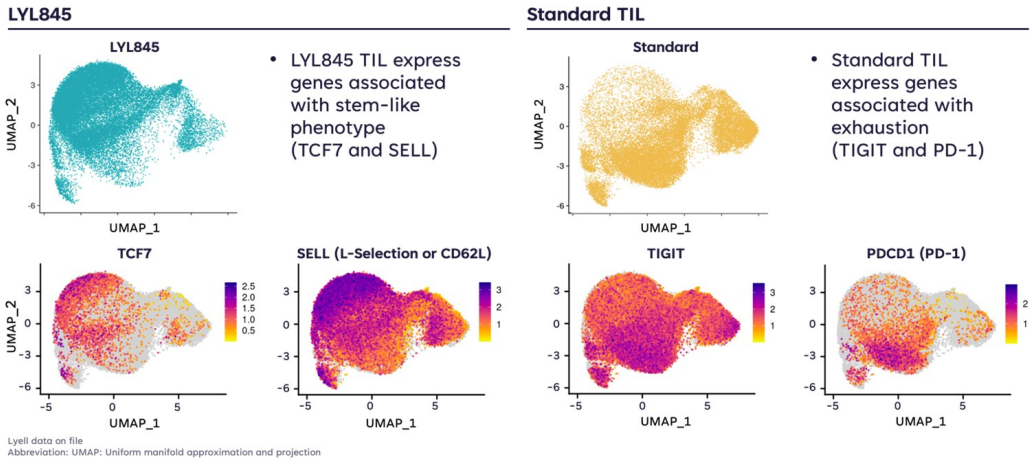
We also presented at the 2022 meeting of SITC comprehensive analyses of transcriptomic profiles, polyclonality and prediction of tumor reactive T cell clones in our LYL845 product candidate. In particular, our bioinformatic analyses demonstrated that LYL845 products expanded using Epi-R manufacturing protocol at clinical scale were highly polyclonal and preserved approximately 94% of the predicted tumor reactive clones (Figure 8). Further, preserved putative tumor reactive clones in LYL845 products have increased stemness and reduced exhaustion-associated genes compared to TIL products derived from the standard process. The tumor-specific reactivity of LYL845 was confirmed by demonstrating dose-dependent antitumor cytolytic activity and cytokine secretion in tumor cell specific co-culture assays.

Figure 8: LYL845 TIL preserve ~94% of predicted tumor reactive clones to enable targeting of heterogeneous solid tumors.



We have also shown in nonclinical studies with TIL products generated from tissue from five donors using either the LYL845 process or standard process that TIL products generated with our LYL845 Epi-R manufacturing protocol express more genes associated with stem-like phenotypes such as TCF-7 and SELL versus TIL products generated with the standard process which express more genes associated with exhaustion such as TIGIT and PD-1 (Figure 9).

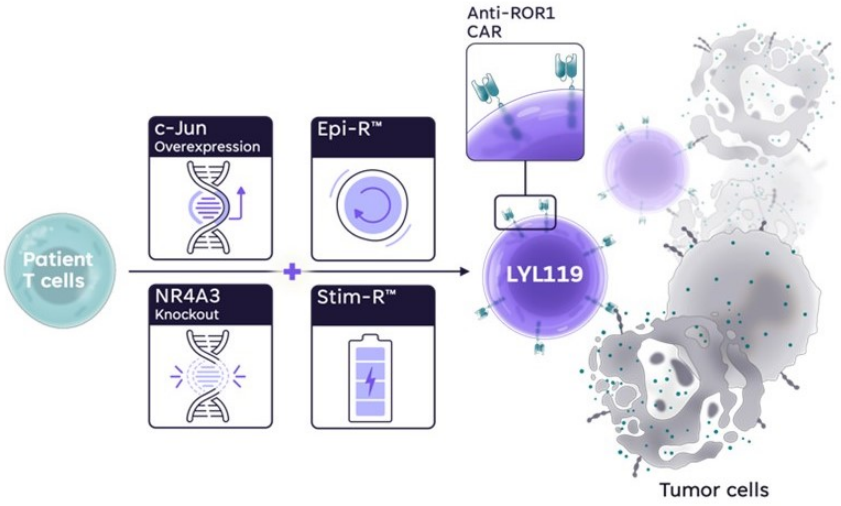
Figure 9: Transcriptomic data of TIL products generated from five donor tissues using either standard or LYL845 Epi-R manufacturing protocol (four melanoma and one NSCLC) demonstrate that LYL845 generated with Epi-R are enriched for T cells with stem-like quality.



LYL119: An innovative ROR1 CAR T-cell product candidate designed for enhanced cytotoxicity.

A key pillar of our strategy is to continually innovate to develop and advance novel, breakthrough technologies that address key barriers to effective cell therapy for solid tumors. We have advanced a new genetic reprogramming technology, NR4A3 knockout, and a new epigenetic reprogramming technology, Stim-R, that are being applied in our new CAR T-cell product candidate, LYL119 (Figure 10). These technologies are stackable and complementary to c-Jun and Epi-R and are designed to further improve the antitumor potency and durability of T cells.

Figure 10: LYL119: ROR1 CAR T cell + c-Jun + NR4A3 KO + Epi-R + Stim-R.



LYL119 is being advanced with the goal of potentially creating even greater benefit for patients with ROR1-positive solid tumors. An IND application is expected to be submitted for LYL119 in the first half of 2024.

c-Jun is a transcription factor in the activator protein 1 (AP-1) pathway, which plays a key role in driving T-cell function. NR4A family transcription factors contribute to T-cell exhaustion by restraining AP-1 activity. Reducing NR4A

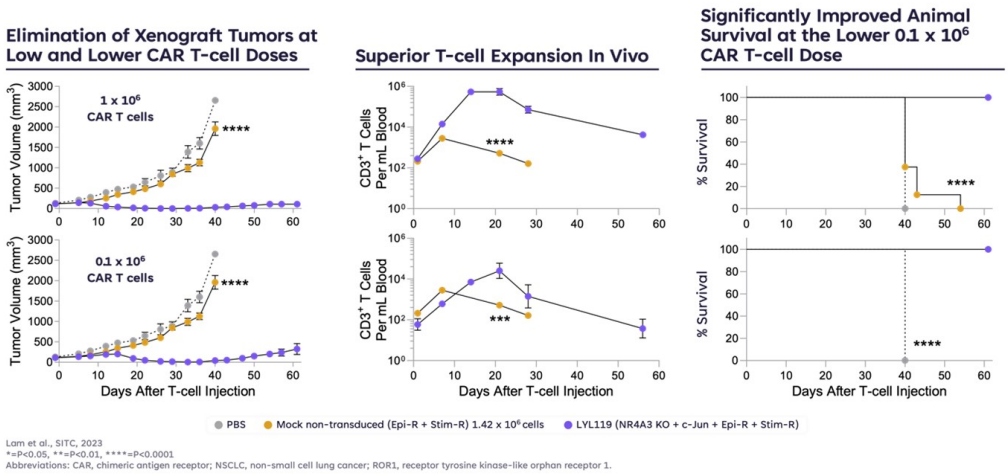
expression enhances T-cell function associated with increased expression of AP-1-regulated genes. Our NR4A3 knockout reprogramming technology furthers the hypothesis that reprogramming of the AP-1 transcription factor pathway in T cells may delay exhaustion and improve anti-tumor function.

Our Stim-R technology is a customizable, degradable, synthetic cell biomimetic composed of lipid-coated silica micro-rods that mimic the physiological cell-like presentation of signals to control T-cell properties. Stim-R allows for rapid tuning of T-cell signal presentation to generate T-cell products with desirable phenotypic and functional properties. We have optimized a Stim-R formulation to control T-cell stimulation and expansion to generate T-cell products with an enhanced activation state, resulting in improved potency compared with conventional T-cell activating reagents. In nonclinical models, we have shown that Stim-R CAR T cells demonstrate prolonged persistence and enhanced cytotoxicity in response to serial antigen stimulation.

Nonclinical Data

In November at the 2023 meeting of SITC, we presented nonclinical data demonstrating that LYL119 enhances survival in vivo in a murine H1975 xenograft tumor model, even at a very low CAR T-cell dose of 100,000 CAR T cells (Figure 11). Additionally, both in vitro and in vivo nonclinical data demonstrated that the combination of all four of our genetic and epigenetic reprogramming technologies resulted in superior cytotoxicity, improved proliferation and sustained cytokine production upon repeated antigen stimulation compared to various controls lacking one or more of the reprogramming technologies.

Figure 11: LYL119 eliminated H1975 (NSCLC) xenograft tumors and improved survival, even at low doses.



Lam et al., SITC, 2023
*=P<0.05, **=P<0.01, ****=P<0.0001
Abbreviations: CAR, chimeric antigen receptor; NSCLC, non-small cell lung cancer; ROR1, receptor tyrosine kinase-like orphan receptor 1.

Our Manufacturing Capabilities

We believe it is critically important to control and continuously monitor all aspects of the cell therapy manufacturing process to mitigate risks, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. As we developed our technologies, we made a strategic decision to invest in building our own manufacturing facility to control our supply chain, maximize efficiencies in cell product production time, optimize cost and quality, protect proprietary aspects of our reprogramming technologies and have the ability to rapidly incorporate advancements and new innovations. We view our manufacturing team and capabilities as a significant competitive advantage.

Our LyFE Manufacturing Center™ located in Bothell, Washington is approximately 73,000 square feet and is comprised of manufacturing suites, laboratories and offices. Our LyFE Manufacturing Center was commissioned and designed to be in compliance with U.S. and European Union current Good Manufacturing Practices (cGMP) standards and has a flexible and modular design enabling CAR T-cell, TIL, TCR T-cell and cGMP viral vector production to control and de-risk the manufacturing sequence and timing of the major components of our supply chain. Owning our own facility has enabled seamless collaboration across research, process development and manufacturing for high-quality reproducibility at manufacturing scale.

We are currently producing clinical supply for our Phase 1 trials at our LyFE Manufacturing Center. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. While we believe this capacity is sufficient to support our pipeline programs into pivotal trials and, if approved, early commercialization, we are also advancing multiple strategic alternatives to innovate and scale manufacturing in the future. We are evaluating third-party manufacturing options, such as the recently initiated CAR T-cell proof-of-concept collaboration with Cellares, as part of an overall CAR T-cell manufacturing strategy to build scale and reduce cost. For TIL, we are advancing our Epi-R P2 manufacturing protocol to shorten delivery time of TIL product to patients. In November 2023 at SITC, we presented nonclinical data demonstrating that our Epi-R P2 TIL manufacturing process reduces the TIL culture duration to less than three weeks (from the standard time of four to six weeks) while maintaining the desired yield, stemness phenotype and retention of tumor reactive clones.

Competition

The pharmaceutical industry is highly competitive and dynamic, owing to rapidly advancing technologies. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, government agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future. In addition, during development, our product candidates may compete against other experimental treatments, whether cell therapy or other modalities, for patients with certain histologies or patients with tumors expressing certain antigen targets of interest.

We are aware of a number of companies using ex vivo cell therapy approaches to treat solid tumors. Some of these companies may have substantially greater financial and other resources than we have, such as larger research and development staff and well-established marketing and sales forces, or may operate in jurisdictions where lower standards of evidence are required to bring products to market.

T-cell therapies for the treatment of solid tumors are being developed by a number of companies, including but not limited to Arcellx, Inc., AstraZeneca plc, Autolus Therapeutics plc, Bristol Myers Squibb Co., Gilead Sciences Inc., Immunocore Holdings plc, Iovance Biotherapeutics Inc., the Janssen Pharmaceutical Companies of Johnson & Johnson, Nanjing Legend Biotech and Novartis AG. On February 16, 2024, the FDA approved the first TIL therapy, Iovance's lifileucel, for the treatment of unresectable or metastatic melanoma. We are also aware that other companies are developing therapies in modalities such as monoclonal antibodies and antibody drug conjugates for cancers that express ROR1, such as Boehringer Ingelheim International GmbH, CStone Pharmaceuticals and Merck & Co., Inc.

Among companies developing cell therapies for solid tumors, we believe we are substantially differentiated by our reprogramming technologies, knowledge, experience, scientific personnel and robust intellectual property portfolio. We believe there are many factors affecting the success of any of our product candidates, including efficacy, safety, accessibility, price and cost of manufacturing.

License, Collaboration and Success Payment Agreements

Fred Hutch License Agreement and Success Payment Agreement

In December 2018, we entered into a license agreement with Fred Hutchinson Cancer Center (Fred Hutch) (as amended in June 2019, September 2019, January 2020, and August 2020) that grants us a worldwide, sublicensable license under certain patent rights (exclusive) and certain technology (non-exclusive), to research, develop and commercialize products and processes for all fields of use utilizing CARs and/or TCRs. We paid Fred Hutch an upfront payment of $150,000. In connection with the license agreement, we entered into a letter agreement with Fred Hutch pursuant to which we issued to Fred Hutch 1,075,000 shares of our common stock.

The license agreement will expire, on a product-by-product and country-by-country basis, on the later of (a) the expiration of the last to expire valid claim of the patents rights covering such product in such country and (b) ten (10) years after the date of the first commercial sale of such product in such country. We may terminate the agreement at will in its entirety or with respect to any patent. Fred Hutch has the right to terminate the agreement in the event of our uncured breach.

We also entered into a letter agreement with Fred Hutch in December 2018 under which we agreed to make success payments to Fred Hutch, payable in cash or publicly tradable equity at our discretion. These success payments are based on increases in the per share fair market value of our common stock (as all our Series A convertible preferred stock were converted into an equivalent number of shares of our common stock upon the closing of our initial public offering in 2021) during the success payment period, which is a period of time that begins on the date of our letter agreement with Fred Hutch and ends on the earlier of: (a) the ninth anniversary of that date and (b) the earlier of (i) the date on which we

sell, lease, transfer or exclusively license all or substantially all of our assets to another company and (ii) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity). Success payments will be owed (if applicable) after measurement of the value of our common stock in connection with the following valuation dates during the success payment period: (1) the date of the first anniversary of our initial public offering; (2) the second anniversary of such date; (3) each two year anniversary thereafter (i.e., the four year anniversary, six year anniversary, etc. of such date); (4) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company; (5) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity); and (6) the last day of the nine-year period. Any success payment will generally be made within 45 days after the applicable valuation date, except that in the case of a merger or sale of all of our company's assets, the success payment will be made on the earlier of the 90th day following the transaction or the first date that transaction proceeds are paid to any of our stockholders. In the case of (1), (2) and (3), the value of our common stock will be determined by the average trading price of a share of our common stock over the consecutive 90-day period preceding the date the success payment is made; the value will otherwise be determined either, in the case of a merger or stock sale, by the consideration paid in the transaction for each share of our stock or the stock of the acquiring entity (or their parent or affiliate). The amount of a success payment is determined based on whether the value of our common stock meets or exceeds certain specified threshold values ascending from $18.29 per share to $91.44 per share, in each case subject to adjustment for any stock dividend, stock split, combination of shares or other similar events. Each threshold is associated with a success payment, ascending from $10.0 million at $18.29 per share to a cumulative total of $200.0 million at $91.44 per share, payable if such threshold is reached. Any previous success payments made to Fred Hutch are credited against the success payment owed as of any valuation date, so that Fred Hutch does not receive multiple success payments in connection with the same threshold. The success payments paid to Fred Hutch will not exceed, in aggregate, $200.0 million, which would be owed only when the value of the common stock reaches $91.44 per share. To date, no success payments have been incurred as the per share fair value of our common stock was below the price required for payment.

Stanford License Agreement and Success Payment Agreement

In January 2019, we entered into a license agreement with The Board of Trustees of the Leland Stanford Junior University (Stanford) that grants us a worldwide, sublicensable license under certain patent rights (exclusive), and certain other patent rights and technology (non-exclusive), to research, develop and commercialize products and processes for all fields of use utilizing CARs and/or TCRs. We also have the right to add certain Stanford patent applications covering certain inventions that are improvements to the existing patents and patent applications, as well as a right of first negotiation for other patent applications covering inventions made in the principal investigator's lab that relate to and are necessary or useful for utilizing CARs and/or TCRs.

We paid Stanford an upfront payment of $400,000. In connection with the license agreement, we entered into a letter agreement in January 2019 with Stanford pursuant to which we issued to Stanford 910,000 shares of our common stock. We are required to pay Stanford an annual maintenance fee in the mid tens of thousands of dollars on the second anniversary of entering into this agreement, and each anniversary thereafter until the date of the first commercial sale of a licensed product. We are obligated to pay Stanford up to a maximum of $3.7 million per target upon achievement of certain specified clinical and regulatory milestones. We are also obligated to pay Stanford $2.5 million collectively for all licensed products upon our achievement of a certain commercial milestone. In addition, the license agreement provides that we are required to pay Stanford low single-digit tiered royalties based on annual net sales of the licensed products by us and by our sublicensees. If we seek to challenge the validity of any of the licensed patents, during the pendency of such action our royalty rate will increase, and if the outcome of such challenge finds that patent is both valid and infringed our royalty rate will increase further. We are also required to pay Stanford (a) royalties in the mid-teens percentage of the payments that we receive from sublicensees of the rights solely licensed to us by Stanford, or (b) sublicensing fees if sublicensed with other intellectual property on a tiered basis up to $300,000.

The license agreement will expire, on a licensed product-by-licensed product and country-by-country basis, on the expiration of the last to expire valid claim of the licensed patents rights covering such licensed product in such country. We may terminate the agreement at will in its entirety or with respect to any licensed patent. Stanford has the right to terminate the agreement in the event of our uncured breach.

We also entered into a letter agreement with Stanford in October 2020, under which we agreed to make success payments to Stanford, payable in cash or publicly tradable equity at our discretion. These success payments are based on increases in the per share fair market value of our common stock (as all our Series A convertible preferred stock were converted into an equivalent number of shares of our common stock upon the closing of our initial public offering in 2021)

during the success payment period, which is a period of time that begins on the date of our letter agreement with Stanford and ends on the earlier of: (a) the ninth anniversary of that date and (b) the earlier of (i) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company and (ii) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity). Success payments will be owed (if applicable) after measurement of the value of our common stock in connection with the following valuation dates during the success payment period: (1) the date of the first anniversary of our initial public offering; (2) the second anniversary of such date; (3) each two year anniversary thereafter (i.e., the four year anniversary, six year anniversary, etc. of such date); (4) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company; (5) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity); and (6) the last day of the nine-year period. Any success payment will generally be made within 45 days after the applicable valuation date, except that in the case of a merger or sale of all of our company's assets, the success payment will be made on the earlier of the 90th day following the transaction or the first date that transaction proceeds are paid to any of our stockholders. In the case of (1), (2) and (3), the value of our common stock will be determined by the average trading price of a share of our common stock over the consecutive 90-day period preceding the date the success payment is made; the value will otherwise be determined either, in the case of a merger or stock sale, by the consideration paid in the transaction for each share of our stock or the stock of the acquiring entity (or their parent or affiliate). The amount of a success payment is determined based on whether the value of our common stock meets or exceeds certain specified threshold values ascending from $18.29 per share to $91.44 per share, in each case subject to adjustment for any stock dividend, stock split, combination of shares or other similar events. Each threshold is associated with a success payment, ascending from $10.0 million at $18.29 per share to a cumulative total of $200.0 million at $91.44 per share, payable if such threshold is reached. Any previous success payments made to Stanford are credited against the success payment owed as of any valuation date, so that Stanford does not receive multiple success payments in connection with the same threshold. The success payments paid to Stanford will not exceed, in aggregate, $200.0 million, which would be owed only when the value of the common stock reaches $91.44 per share. To date, no success payments have been incurred as the per share fair value of our common stock was below the price required for payment.

GSK Collaboration and License Agreement

In 2019, we entered into a collaboration and license agreement with GlaxoSmithKline (GSK) that became effective on July 7, 2019 and was amended in June 2020 and December 2021 (GSK Agreement) for potential T-cell therapies that apply our platform technologies and cell therapy innovations with TCRs or CARs under distinct collaboration programs. The GSK Agreement defined two initial collaboration targets, CD19 and NY-ESO-1, and allowed GSK to nominate seven additional targets through July 2024. After agreeing on the programs for those targets, we were expected to perform research and development services for each agreed program up until a defined point (GSK Option Point), at which time GSK would decide whether or not to exercise an option to obtain a license from us (License Option) and take over the future development and commercialization. For the LYL331 program (NY-ESO-1 TCR with c-Jun), GSK exercised the License Option in April 2021 and assumed sole responsibility for future development and commercialization of the program at its own cost and expense. No IND for LYL331 was submitted to the FDA. For the LYL132 program (NY-ESO-1 TCR with Epi-R), we filed an IND application, which cleared in January 2022, though no patients were treated. The program targeting CD19 was a research effort. No additional targets were nominated over the term of the GSK Agreement. GSK terminated the GSK Agreement effective December 24, 2022 and Lyell has discontinued any further work on these programs.

We received a non-refundable upfront payment of $45.0 million under the GSK Agreement. In connection with the GSK Agreement, in May 2019, we also entered into a stock purchase agreement with GSK (GSK Stock Purchase Agreement), pursuant to which we agreed to sell 30,253,189 shares of Series AA convertible preferred stock at a price of $6.78 per share, which was above the issuance date estimated fair value of $4.84 per share. The difference between the per share values resulted in $58.6 million additional deemed consideration, bringing the total upfront payment of the GSK Agreement to $103.6 million.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from our collaborators or other third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation and in-licensing opportunities to develop, strengthen and maintain our

proprietary position in the field of cell and gene therapy. We additionally plan to rely on data exclusivity, market exclusivity and patent term extensions, when available, and, as appropriate, have sought and in the future may seek again and rely on regulatory protection afforded through ODDs. Our commercial success may depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

We have in-licensed and procured, and filed for numerous patent applications, which include claims directed to compositions, methods of use, processes, dosing and formulations, and possess substantial know-how and trade secrets relating to the development and commercialization of our cell engineering technology platforms and related product candidates, including related manufacturing processes and protocols. Our intellectual property strategy is designed to provide multi-layered protection covering our T-cell reprogramming technologies, including but not limited to c-Jun, NR4A3, Epi-R and Stim-R, as well as various aspects of our product candidates. For all patent applications, we determine claiming strategy on a case-by-case basis. We may file patent applications containing claims for protection of all useful applications of our proprietary technology platforms and any products, as well as new applications and/or uses we discover for existing technology platforms and products. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims, to ensure that maximum coverage and value are obtained for our processes and compositions. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs. Notwithstanding these efforts, we cannot be sure that any patents will be granted with respect to any patent application we have licensed or filed or may license or file in the future, and we cannot be sure that any patents we have licensed or patents that may be licensed or granted to us in the future will not be challenged, invalidated or circumvented or that such patents will be commercially useful in protecting our technologies.

As of December 31, 2023, our patent portfolio consists of over 40 issued patents and over 150 pending patent applications that we either own or have licensed. Our portfolio covers various aspects of our T-cell reprogramming technologies, c-Jun, NR4A3, Epi-R and Stim-R, as well as our product candidates. The patents and patent applications in our portfolio are held primarily in the United States, Europe, Canada, Japan and Australia. For information related to our in-licensed intellectual property, see the subsection titled under “—License, Collaboration and Success Payment Agreements.”

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest nonprovisional filing date. In the United States, a patent’s term may be lengthened by patent term adjustment (PTA), which compensates a patentee for administrative delays by the USPTO in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In addition, in certain instances, the patent term of a U.S. patent that covers an FDA-approved drug may also be eligible for extension to recapture a portion of the term effectively lost as a result of clinical trials and the FDA regulatory review period, such extension is referred to as patent term extension. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. 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. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest nonprovisional filing date. The actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

As of December 31, 2023, our registered trademark portfolio contains over 135 registered trademarks and pending trademark applications, consisting of approximately one trademark registration and five pending trademark applications in the United States, and approximately 120 foreign trademark registrations and approximately 11 foreign pending trademark applications.

We may also rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and

processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our proprietary technology, inventions, improvements and product candidates, see the subsection titled "Risk Factors —Risks Relating to Our Intellectual Property."

Sales and Marketing

Given our stage of development, we have not yet established a commercial organization or distribution capabilities. We intend to either build a commercial infrastructure to support sales of any approved products or outsource some or all of this function to third parties. We intend to evaluate opportunities to work with partners that enhance our capabilities with respect to the development and commercialization of LYL797, LYL845, LYL119 and any other product candidates we may develop. In addition, we intend to commercialize our product candidates, if approved, in key markets either alone or with partners to maximize the worldwide commercial potential of our programs.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various nonclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct trials or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal, state, local and foreign statutes and regulations. The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements (GLP);
- submission to the FDA of an IND application, which must become effective before clinical trials may begin;
- approval by an Institutional Review Board (IRB) or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations (commonly referred to as GCP), regulations and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application (BLA), after completion of all pivotal clinical trials;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency and, if applicable, to assess compliance with the FDA's current Good Tissue Practices (cGTPs) requirements for the use of human cellular and tissue products, and of selected clinical investigation sites to assess compliance with GCPs;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Before testing any biological product candidate in humans, the product candidate enters the nonclinical testing stage. Nonclinical tests, also referred to as preclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests must comply with federal regulations and requirements including GLPs.

Prior to beginning the first clinical trial with a product candidate in the United States, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical trials. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology and pharmacodynamic characteristics of the product; chemistry, manufacturing and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

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 an Institutional Biosafety Committee (IBC) as set forth in the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (the NIH Guidelines). 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.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators 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 study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical trial sponsor, known as a Data Safety Monitoring Committee, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1—The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These trials are designed to test the safety, dosage tolerance, absorption, metabolism and excretion of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at

multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product in the intended therapeutic indication, particularly for long-term safety follow-up. These so-called Phase 4 trials may also be made a condition to approval of the BLA.

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

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from nonclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including trials initiated by independent investigators. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may also convene an advisory committee to provide clinical insight on application review questions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP and adequate to assure consistent production of the product within required specifications. For a product candidate that is also a human cellular or tissue product, the FDA also will not approve the application if the manufacturer is not in compliance with cGTPs. These are 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 (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion or transfer into a human recipient. The primary intent of the GTP 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. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities, or data collected from clinical trial sites are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for

approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a REMS, to ensure the benefits of the product outweigh its risks, or otherwise limit the scope of any approval. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-marketing trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Specifically, new biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or 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 biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for breakthrough therapy designation to expedite its development and review. A product candidate can receive breakthrough therapy designation if preliminary clinical evidence indicates that the product candidate, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a fast track designation and/or breakthrough therapy designation, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product candidate is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to 10 months under standard review).

Additionally, product candidates studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited

withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. 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.

Regenerative medicine advanced therapy (RMAT) designation is intended to facilitate an efficient development program for, and expedite review of, any drug or biologic that meets the following criteria: (i) the drug or biologic qualifies as a RMAT, which is defined as 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) the drug or biologic 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 or biologic has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates 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 clinical trial sites, including through expansion of trials to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through submission of clinical evidence, clinical trials, 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 such therapy. Fast Track Designation, Breakthrough Therapy Designations, Priority Review, Accelerated Approval and RMAT designation do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Orphan Drug Designation and Exclusivity

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

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for a particular drug or biologic for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our product candidate is determined to be contained within the competitor’s product for the same indication or disease.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if a second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Post-Approval Requirements

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution and advertising and promotion of the product. After approval, most changes to the approved product, such as

adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Changes to the manufacturing process or facility are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

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

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or untitled letters;
- clinical holds on clinical trials;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits or civil or criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe, in their independent medical judgment, that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), includes a subtitle called the Biologics Price Competition and Innovation Act (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency, can be shown through analytical studies, animal studies and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve (12) years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

A biological product can also obtain pediatric 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 runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and impact of the BPCIA is subject to significant uncertainty.

Government Regulation Outside of the United States

In addition to regulations in the United States, we may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

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

Applications for marketing approval in the EU and other third countries must also follow detailed laws and procedures that vary from those in the US.

Moreover, in countries outside of the US, including the EU and countries in Eastern Europe, Latin America or Asia, the requirements governing product licensing, pricing and reimbursement vary from country to country.

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

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security, price reporting and physician and other health care provider transparency laws and regulations. If our operations are found to be in violation of any of such laws or any other governmental

regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. 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. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances.

Additionally, the intent standard under the Anti-Kickback Statute and the criminal healthcare fraud statutes under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (FCA) (discussed below).

The FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-covered, uses.

HIPAA also created new federal criminal statutes that prohibit 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 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. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals and certain ownership and investment interests held by these physicians and their immediate family members.

We may also be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and its implementing regulations, impose requirements on covered entities, including certain healthcare providers, health plans, healthcare clearinghouses and their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to 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

attorneys' fees and costs associated with pursuing federal civil actions. 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.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical 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. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, track and report gifts, compensation and other remuneration made to physicians and other healthcare providers, 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 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.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payors, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations, and the level of reimbursement for such product by third-party payors. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a product is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. A third-party payor could also require that certain lines of therapy be completed or failed prior to reimbursing our therapy. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Additionally, any companion diagnostic tests developed for use with a product are required to obtain coverage and reimbursement for those tests separate and apart from the coverage and reimbursement sought for such product. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Healthcare Reform

In the United States, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA: increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid-managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology

by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; expanded eligibility criteria for Medicaid programs; created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS (CMMI) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the Tax Act was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." 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. President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (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 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 any such additional challenges and healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have also been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which began in 2013 and will remain in effect through 2032. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product 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 drug products. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented, but it is likely to have a significant impact on the pharmaceutical industry. Further 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 CMMI, 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 of 1980 (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 that 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. 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.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and 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 products (if approved). In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations. For example, it is possible that additional governmental action may be taken to address another health epidemic, as it did in response to the COVID-19 pandemic.

Other Data Privacy and Security Laws

In the ordinary course of our business, we may process or receive personal or sensitive data. We are, or may 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 and security in the jurisdictions in which we are established or in which we sell or market any approved products or run clinical trials. Such obligations may include those from, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 (CCPA), the California Privacy Rights Act (CPRA), the European Union's General Data Protection Regulation 2016/679 (EU GDPR), the EU GDPR as it forms part of United Kingdom (UK) law by virtue of section 3 of the European Union (Withdrawal) Act 2018 (UK GDPR) and the ePrivacy Directive. Several states within the United States have also enacted or proposed data privacy and security laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act. Additionally, we are, or may become, subject to various U.S. federal and state consumer protection laws, which require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

The CCPA, CPRA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business' collecting, using and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business' personal data processing activities, to delete the individual's personal data and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches that may include an award of statutory damages. In addition, the CPRA expanded the CCPA by giving California residents the ability to limit use of certain sensitive personal data, establishing restrictions on personal data retention, expanding the types of data breaches that are subject to the CCPA's private right of action and establishing a new California Privacy Protection Agency to implement and enforce the new law.

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the European Economic Area, which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein (collectively, the EEA) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authorities and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

See the section titled "Risks Related to Regulation and Legal Compliance" for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

The U.S. Foreign Corrupt Practices Act

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA), prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring us 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.

Employees and Human Capital Management

Our Mission

We are a clinical stage T-cell reprogramming company dedicated to developing novel cell therapies to improve the lives of people with malignant solid tumors. We strive to create an environment where everyone can do their best work, be themselves and thrive personally and professionally. Our culture is grounded by innovative science and a focus on patients with cancer who need better therapies. Their need drives our sense of urgency to achieve our important mission.

Our Values

We believe success comes when we align our core values with our mission to translate our ground-breaking science into therapies with the potential to transform patients' lives. Our core values are:

- *Science*: We value evidence over opinion and focus and execute on the critical efforts that matter most.
- *Courage*: We challenge the status quo – we are bold and willing to think and act differently.
- *Respect*: We always assume positive intent and seek to understand and communicate directly, transparently and honestly.
- *Collaboration*: We work together to create value, working across teams to solve our most challenging problems to continually improve and learn.

Our Employees

Our employees are one of our most valuable strengths; our people drive our ability to achieve our mission. We compete in the highly competitive biotechnology industry, and attracting, retaining and developing a diverse group of talented employees is crucial to our strategy and our ability to compete effectively. Our organization is designed to support our current research, product development and manufacturing efforts and is ready to scale to meet future plans for commercializing our product candidates, if approved. A strategic priority is attracting and retaining talent with the skills we need today and in the future. The labor market continues to reflect a limited pool of skilled individuals with substantial experience discovering, developing and manufacturing cell therapy medicines, and we expect this is likely to continue. We also operate in areas such as data capture and analytics. As a result, competition for talent is intense and the turnover rate can be high. We face substantial competition among numerous biopharmaceutical companies and academic institutions as well as technology companies for individuals with these skills. For these reasons, we continue to develop our culture through people systems that establish clear expectations, ensure employees have ongoing feedback and provide opportunities for skill and career development as well as competitive pay and benefits.

As of December 31, 2023, we had 224 employees, over 79% of whom were engaged in research and development activities, technical operations and process sciences. Our employees are highly skilled, and many hold advanced degrees. Many of our employees have experience with the development of cell therapies. All of our employees are located in California and Washington. None of our employees are subject to a collective bargaining agreement nor represented by labor unions. We consider our relationship with our employees to be good.

Developing our employees is important, and we focus on providing training and opportunities for development and advancement. Training, coaching, routine feedback and a systematic approach to employee advancement are key components of our talent strategy. We hold talent discussions regularly, which include promotion cycles across all functions and levels. In 2023, we have further enhanced our talent management practices, including establishing career frameworks for development positions, implementing individual goal setting for all staff and introducing a compensation approach that recognizes differentiated performance.

Since inception, our employee turnover has remained consistently below average for the U.S. life sciences industry generally, as well as for life sciences companies located in Northern California and the Pacific Northwest. Given our need to retain and attract talent, we continually assess employee turnover, effectiveness of recruitment initiatives, compensation and benefits programs, health and safety practices, diversity and inclusion and other matters relevant to human capital management. These outcomes and updates are routinely reviewed with our board of directors.

Our Compensation and Benefits

Given the highly competitive nature of our industry and the importance of recruitment and retention to our success, we strive to provide our employees with what we believe is a competitive and comprehensive total rewards package of compensation, benefits and services. This package includes competitive market pay, healthcare benefits for employees and family members, a flexible spending account, paid time off benefits, family leave, flexible work schedules, flexible work locations, 401(k) matching, an employee assistance program and a wellness program. In addition, we offer

employees the benefit of equity ownership in the company through stock option grants and/or restricted stock units. Our employees are also eligible to participate in an employee stock purchase plan, which offers the opportunity to purchase our common stock at a discount of 15%.

Our Commitment to Diversity, Belonging, Inclusion and Equity

We strongly believe in a diverse workplace where all employees can thrive in an inclusive environment free from discrimination, harassment, bias and prejudice. We aim to treat all individuals with respect and dignity and to provide all employees with equal opportunity and fair treatment. By embracing diversity and inclusion, we seek to create an organization committed to collaboration and innovation consistent with our values and in support of accomplishing our mission. Not only is a diverse, equitable and inclusive mindset and culture critical to an engaged and committed workplace, but it is also imperative to understanding and meeting the needs of the patients we seek to help with our medicines.

In 2020, with the support and sponsorship of our executive leadership team, we established a Diversity, Belonging, Inclusion and Equity (DBIE) working group comprised of a diverse group of employees tasked with designing and implementing specific initiatives to promote greater diversity, belonging, inclusion and equity at Lyell. We continue to externally benchmark our efforts with respect to best practices across industries. The DBIE working group is guided by a collaboratively developed DBIE mission statement. The working group is comprised of volunteers from our three work locations representing various levels in the organization. This team, sponsored by our Chief Executive Officer and Senior Vice President of Human Resources, creates an annual strategic and tactical plan to advance our focus on the importance of DBIE to our culture. Our DBIE team has continued to develop and implement an annual plan that includes many opportunities for learning and engagement open to all employees. In addition to the DBIE employee working group, our Human Resources practices emphasize diversity and inclusion as key indicators of success. Recruitment, progression and development processes emphasize the importance of fostering a workforce that is representative of our diverse patient population. While we are proud of our progress to date, we have and will continue to conduct relevant training and provide guidance with respect to best practices of similarly situated companies.

We believe in equitable pay and our compensation practices are reviewed regularly. We establish components and ranges of compensation based on market and benchmark data. Within this context, we strive to pay all employees equitably within a market-competitive range, taking into consideration factors such as role, market data for similar roles in related industry, internal equity, job location, relevant experience and individual performance. Ongoing pay progression is guided by our compensation philosophy; in 2023, this was enhanced to recognize differentiation in rewards, where our highest performing employees received the highest rewards. At the same time, we are committed to pay equity; we have a review process that is conducted on at least an annual basis. If we identify employees with unjustified pay gaps that do not align with our pay philosophy, we review and take appropriate action to ensure fidelity between our stated philosophy and actions.

Available Information

Our website address is www.lyell.com. We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act. The Securities and Exchange Commission (SEC) maintains a website at www.sec.gov that contains reports, proxy and information statements and other information that we file with the SEC electronically. Copies of our reports on Form 10-K, Forms 10-Q, Forms 8-K and amendments to those reports may also be obtained, free of charge, electronically on the investor relations page on our website located at ir.lyell.com as soon as reasonably practical after we file such material with, or furnish it to, the SEC.

We also use the Investors page on our website as a channel of distribution for important company information. Important information, including press releases, corporate and scientific presentations and financial information regarding our company, as well as corporate governance information, is routinely posted and accessible on the Investors page on our website. Information on or that can be accessed through our website is not part of this Annual Report on Form 10-K, and the inclusion of our website address is an inactive textual reference only.

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, as well as the other information contained in this Annual Report on Form 10-K, including our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of

operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Condition, Limited Operating History and Need for Additional Capital

We are an early clinical stage biopharmaceutical company and have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing net losses for the foreseeable future.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove safe and effective, gain regulatory approval or become commercially viable. We are an early clinical stage biopharmaceutical company, and we do not have any products approved by regulatory authorities and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. Since our inception, we have not generated any revenue from product sales and have incurred significant net losses. Substantially all of our net losses since inception have resulted from our research and development programs and general and administrative costs associated with our operations.

We do not expect to generate revenue from product sales for the foreseeable future, if at all. We also expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates, expand our manufacturing capabilities, in-license or acquire additional technologies and potentially begin to commercialize product candidates that may achieve regulatory approval. We 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 revenues. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. If any of our product candidates fails in research and development or clinical trials or does not gain regulatory approval, or, if approved, fails to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods.

We expect to incur additional expenses and operating losses in the foreseeable future, as we:

- continue nonclinical development of our current and future product candidates and initiate additional nonclinical studies;
- commence and continue clinical trials of our current and future product candidates;
- advance our genetic and epigenetic reprogramming technologies as well as other research and development efforts;
- attract, hire and retain qualified personnel;
- seek regulatory approval of our current and future product candidates;
- expand our manufacturing and process development capabilities;
- expand our operational, financial and management systems;
- acquire and license technology or technology platforms;
- continue to develop, protect and defend our intellectual property portfolio; and
- incur additional legal, accounting or other expenses in operating our business, including the additional costs associated with operating as a public company.

We operate in a rapidly evolving field and have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

We operate in a rapidly evolving field and, having commenced operations in June 2018, have a limited operating history, which makes it difficult to evaluate our business and prospects. Our primary activities to date have included clinical development of T-cell therapies, conducting research and development, acquiring technology, entering into strategic collaboration and license agreements, enabling and executing manufacturing activities in support of our product candidate development efforts, executing clinical trials, organizing and staffing the company, business planning, establishing our intellectual property portfolio, regulatory submissions and other preparations to initiate and execute clinical trials, raising capital and providing general and administrative support for these activities. Any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

We currently have no products approved for sale and have never generated revenue from product sales. We may never generate revenue from product sales or achieve profitability.

To date, we have not generated any revenues from product sales. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to successfully develop and subsequently obtain regulatory approval for and commercialize our product candidates. Our ability to generate revenues and achieve profitability also depends on a number of additional factors, including our ability to:

- successfully complete our research activities to identify the technologies and product candidates to further investigate in clinical trials;
- successfully complete development activities, including the necessary clinical trials;
- complete and submit regulatory submissions to the FDA, the EMA or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- develop manufacturing and distribution processes for our product candidates;
- produce commercial quantities of our products at acceptable cost levels;
- maintain adequate supply of our product candidates, including the starting materials and reagents needed;
- maintain the supply of our product candidates in a manner that is compliant with global legal requirements or to the extent necessary;
- establish and maintain manufacturing relationships with reliable third parties;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

Our revenues for any product for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. In addition, we anticipate incurring significant costs associated with commercializing any approved product. As a result, even if we generate revenue from product sales, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We expect to expend substantial resources for the foreseeable future to advance and expand our research pipeline, conduct nonclinical studies and pursue clinical development and manufacturing of our product candidates. We also expect to continue to expend resources for the development of our technology platforms. These expenditures will include costs associated with research and development, potentially acquiring or licensing new technologies, conducting nonclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize. In addition, we may be required to make substantial payments related to our

success payment agreements and other contingent consideration payments under our license and collaboration agreements. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the discovery, development and commercialization of our existing and potential product candidates, and other unanticipated costs may arise.

As of December 31, 2023, we had approximately $562.7 million in cash, cash equivalents and marketable securities. As a result of expense timing, as well as diligent expense management, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our working capital and capital expenditure needs into 2027. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital to complete clinical development of any of our current programs.

We do not have any committed external source of funds. Additional funds may not be available when we need them on terms that are acceptable to us, or at all, and our ability to raise additional capital may be adversely impacted by potentially unfavorable global economic conditions or conditions in the biotechnology sector of the market, including disruptions to, or volatility in the credit and financial markets in the United States and worldwide, actual or perceived changes in interest rates and economic inflation, the current or anticipated impact of geopolitical instability and otherwise. If adequate funds are not available to us on a timely basis, including pursuant to the Sales Agreement (as defined below), we may be required to delay, limit, reduce or terminate nonclinical studies, clinical trials or other development activities for our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

Our success payment obligations in our success payment agreements may result in dilution to our stockholders or may be a drain on our cash resources to satisfy the payment obligations.

We agreed to make success payments payable in cash or publicly-tradeable shares of our common stock at our discretion pursuant to our success payment agreements with Fred Hutch and Stanford. On each contractually prescribed measurement date, we may be required to make success payments based on increases in the per share fair value of our common stock. The total amount of success payments that we may become obligated to make is currently $400.0 million and may increase in the future due to amendments of our existing success payment agreements. For information related to our success payment obligations, see Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to the audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

In order to satisfy our obligations to make these success payments, if and when they are triggered, we may issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash to satisfy the success payment obligation in cash, which may adversely affect our financial position. In addition, these success payments may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third-party line of credit.

The success payment agreements may cause operating results to fluctuate significantly from quarter to quarter and year to year, which may reduce the usefulness of our consolidated financial statements.

Our success payment obligations are recorded as liabilities on our consolidated balance sheets. Under U.S. generally accepted accounting principles (GAAP), we are required to estimate the fair value of these liabilities as of each quarter end and changes in the estimated fair value are accreted to research and development expense over the service period of the collaboration agreement. Once the requisite service obligation to earn the potential success payment consideration is met under our continued collaboration agreements, the change in the success payment liabilities fair value is recognized in other income or expense, net. For example, in December 2022, Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration; accordingly in 2023 and future periods, the change in the success payments liability fair value is recognized in other income or expense, net.

Factors that may lead to increases or decreases in the estimated fair value of our success payment liabilities include, among others, changes in the value of the common stock, changes in volatility and changes in the risk-free rate. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP consolidated financial statements. See Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to the audited consolidated financial statement included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Risks Related to Our Business and Industry

We are early in our research and clinical development efforts. If we are unable to successfully develop, manufacture and commercialize product candidates or experience significant delays in doing so, our business may be harmed.

We are early in our research and clinical development efforts for our product candidates. Besides LYL797 and LYL845, which are in Phase 1 clinical development, our other proprietary product candidates are currently in preclinical development. We have not yet demonstrated our ability to successfully complete any clinical trials (including any Phase 3 or other 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 product commercialization. We have invested substantial resources in developing our technology platforms and our product candidates, conducting nonclinical studies, commencing clinical trials and building our manufacturing facilities and capabilities, each of which will be required prior to any regulatory approval and commercialization. Our ability to generate revenue from product sales, which we do not expect will occur for several years, if ever, will depend heavily on the successful research and development and eventual commercialization of one or more product candidates. The success of our efforts to identify and develop product candidates will depend on many factors, including the following:

- timely and successful completion of our nonclinical studies and research activities to identify and develop product candidates to investigate in clinical trials;
- submission of INDs to the FDA to proceed with clinical trials, or comparable applications to foreign regulatory authorities that allow the commencement of our planned clinical trials for our product candidates;
- successful enrollment and completion of clinical trials in compliance with GCP requirements with positive results;
- the level of efficacy observed with our product candidates;
- the prevalence and severity of adverse events experienced with any of our product candidates;
- successfully developing, or making arrangements with third parties for, manufacturing and distribution processes for our product candidates and for commercial manufacturing and distribution for any of our product candidates that receive regulatory approval;
- receipt of timely regulatory approvals from applicable authorities for our product candidates for their intended uses;
- protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing capabilities and infrastructure to obtain the tumor tissues needed to develop and, if successful, commercialize approved products;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other marketed therapies;
- maintaining compliance with regulatory requirements, including the cGMP requirements;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations.

Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use and expand our technology platforms to develop any product candidate.

We are seeking to identify and develop a broad pipeline of product candidates using our proprietary technology platforms. The scientific research that forms the basis of our efforts to develop product candidates with our technology platforms is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our technology platforms are both preliminary and limited. Additionally, although LYL797 and LYL845 are in Phase 1 clinical development, our current clinical data are limited, and nonclinical data from murine tumor models and in vitro experiments with tumor cell lines may not translate into humans or may not accurately predict the safety and efficacy of our product candidates in humans. As a result, we are exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates.

Given the novelty of our technology platforms, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory authorities may lack experience in evaluating the safety and efficacy of our product candidates developed using our technology platforms, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. There can be no assurance as to the length of clinical development, the number of patients that the FDA or comparable foreign regulatory authorities may require to be enrolled in clinical trials to establish the safety, purity and potency of our product candidates or the acceptability to the FDA or comparable foreign regulatory authorities of data generated in these clinical trials to support marketing approvals. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

We are highly dependent on our key personnel and, if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, manufacturing, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct substantially all of our operations at our facilities in the San Francisco, Seattle and Bothell metropolitan areas. These regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity that vests over time. The value to employees of equity incentives that vest over time may be significantly affected by factors beyond our control, including market conditions and volatility, and may at any time be insufficient to counteract more lucrative offers from other companies. Because the trading price of our common stock was significantly below the exercise price for many of the options we had granted to our employees, which made the value of our equity as a retention tool decrease substantially, our Board of Directors authorized a repricing of the exercise price of such options for certain employees in November 2023.

Despite our efforts to retain valuable employees, we may nevertheless experience attrition from members of our management, scientific and development teams. For example, over the past twelve months, there have been departures of executive officers, including most recently our chief medical officer. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Additionally, in the fourth quarter of 2023, we announced a reduction in workforce of approximately 25%. This reduction in force may yield unintended consequences and costs, such as difficulty retaining and motivating remaining employees, increased difficulty in our day-to-day operations and loss of institutional knowledge and expertise and difficulty in attracting and hiring qualified employees in the future. We may also be subject to reputational risks and

litigation risks and expenses and may not realize the savings or operational efficiencies anticipated, which could result in total costs and expenses that are greater than expected.

Any litigation or adversarial proceedings could be costly and time-consuming to defend.

We have been and may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by us or third parties in connection with commercial disputes or employment claims made by our current or former employees. Litigation or adversarial proceedings might result in substantial costs and may divert management's attention and resources, which might seriously harm our business, reputation, overall financial condition and operating results. For example, in February 2021, we filed a demand for arbitration seeking, among other things, rescission of each of the joint-development agreement and stock purchase agreement we entered with PACT Pharma, Inc. (PACT) and recovery of the consideration paid thereunder and in October 2022, we entered into a settlement agreement with PACT to resolve the outstanding legal dispute. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims and might not continue to be available on terms acceptable to us. Any claim brought by us or against us that is uninsured or underinsured could result in unanticipated costs, thereby harming our business.

If we cannot maintain our company culture as we grow, our success and our business may be harmed.

We believe our culture has been a key contributor to our success to date. Any failure to preserve our culture could negatively affect our ability to retain and recruit personnel, which is critical to our growth, and to effectively focus on and pursue our objectives. As we grow and are required to implement more complex organizational management structures, we may find it increasingly difficult to maintain the beneficial aspects of our culture. If we fail to maintain our company culture, our business may be adversely affected.

We currently have no marketing, sales or distribution infrastructure, and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us.

We currently have no marketing, sales and distribution capabilities. To support commercial marketing and distribution of any of our product candidates that complete clinical development and are approved, we would either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner or outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks, including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy.

If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition and results of operations.

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

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of the COVID-19 pandemic and actual or perceived changes in interest rates and economic inflation), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability and swings in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of supply chain disruptions, labor shortages, fluctuations in currency exchange rates, changes in interest rates, military conflict, acts of terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to geopolitical conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, including disruption to enrollment within our ongoing trials and

our ability to purchase necessary supplies on acceptable terms, if at all. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market-wide liquidity problems. For example, in March 2023, Silicon Valley Bank (SVB) was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (FDIC) as receiver. Similarly, later in March 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, and there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank and Silvergate Capital Corp, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships and, in turn, us. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the United States or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

Risks Related to Manufacturing

We currently manufacture drug products for our clinical trials ourselves. Delays in further qualifying or in receiving regulatory approvals for any manufacturing facility or product candidates, or in expanding our manufacturing capacity, could delay our development plans and thereby limit our ability to generate product revenues.

We have built our own manufacturing facility in Bothell, Washington. The facility is designed to support the production of nonclinical and clinical development product candidates and early commercialization of products, and ongoing facility and equipment qualification to support clinical production is required. If we are not able to further qualify

our existing facility or the appropriate regulatory approvals for the facility are delayed, or if we are unable to otherwise expand our manufacturing capacity, we may be unable to manufacture sufficient quantities of our product candidates, if at all, which would limit our development activities and our opportunities for growth.

In addition, our manufacturing facility will be subject to ongoing, periodic inspection by the FDA, competent authorities of EU Member States and other comparable regulatory authorities to ensure compliance with cGMPs and cGTPs. Our failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use. This may result in the modification or termination of or a hold on a clinical trial or may delay or prevent filing or approval of commercial marketing applications for our product candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet regulatory authority standards or specifications with consistent and acceptable production yield and costs;
- maintaining continuity among our key manufacturing-related electronic systems;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, the EU or other competent regulatory authorities.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil and/or criminal penalties, a requirement to terminate, vary, suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension, variation or withdrawal of approvals, license suspension or revocation, labelling restrictions or requirements in an approved label, seizures or recalls of product candidates or approved products, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our facility. Without further investment, advances in manufacturing techniques may render our facility and equipment inadequate or obsolete. We may also require further investment to build additional manufacturing facilities or expand the capacity of our existing ones.

The manufacturing of cellular therapies is very complex. We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates.

Developing commercially viable manufacturing processes for cellular therapies is a difficult and uncertain task and requires significant expertise and capital investment. We are developing and implementing manufacturing processes for our product candidates. In particular, for autologous cell therapies, the starting material is the patient's own cells, which inherently adds complexity and variability to the manufacturing process. In addition, our ability to consistently and reliably manufacture our cellular therapy product candidates is essential to our success, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, stability issues, consistency and timely availability of reagents or raw materials. Furthermore, our manufacturing processes may have significant dependencies on third parties, which will pose additional risks to our manufacturing capabilities. Additionally, we do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition to the factors mentioned above, the overall process of manufacturing cellular therapies is extremely susceptible to product loss due to low cell viability, contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, impact to key product quality attributes and other supply disruptions. Product defects can also occur unexpectedly. These deviations and disruptions could delay our programs. If we are not able to capably manage this complexity and variability, our ability to timely and successfully provide our product candidates to patients could be delayed. In addition, the complexities of utilizing a patient's own cells as the starting material requires that we have suitable cells capable of yielding a viable cellular therapy product, which may not be possible for severely immune-compromised or heavily pre-treated patients.

The process of successfully manufacturing products for clinical testing and commercialization may be particularly challenging, even if such products otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with microbes, viruses or other

pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated, unusable product or necessitate the closing of a manufacturing facility for an extended period of time to allow us to investigate and remedy the contamination. These types of contaminations could result in delays in the manufacture of products, which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects.

Any adverse developments affecting manufacturing operations for our product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in supply that could delay the development of our product candidates. If we are unable to obtain sufficient supply of our product candidates, whether due to production shortages or other supply interruptions, our clinical trials or regulatory approvals may be delayed. We may also have to write off inventory, incur other charges and expenses for supply of product that fails to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. In addition, parts of the supply chain may have long lead times or may come from a small number of suppliers. If we are not able to appropriately manage our supply chain, our ability to successfully produce our product candidates could be delayed or harmed. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

Furthermore, the manufacturing facilities in which our product candidates will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, health epidemics and numerous other factors. If any of these events were to occur and impact our manufacturing facilities, our business would be materially and adversely affected.

If our sole clinical or commercial manufacturing facility or any of our potential contract manufacturing organizations is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.

We operate a single manufacturing facility in Bothell, Washington and may rely on potential third-party contract manufacturing organizations to meet our current and future manufacturing needs. If our manufacturing facility or any facility in our manufacturing network, or the equipment in these facilities, is either damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity, if at all. In the event of a temporary or protracted loss of a facility or its equipment, we may not be able to transfer manufacturing to a third party in the time required to maintain supply. Even if we are able to transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements or may require regulatory approval before selling any products manufactured at that facility. Such an event could substantially delay our clinical trials or commercialization of our product candidates.

Currently, we maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

We may rely on third parties to manufacture our product candidates, which subjects us to risks and could delay or prevent our development and/or commercialization, if approved, of our product candidates.

We may rely on third parties to manufacture our current or future product candidates. We may be unable to identify manufacturers for our product candidates or the materials required to develop the cellular therapy on acceptable terms or at all because the number of potential manufacturers is limited. We are currently evaluating third-party manufacturing options, including an automated manufacturing platform from Cellares for the manufacture of our LYL797 CAR T-cell therapy. Utilizing a third-party GMP manufacturer will require the transfer and testing of manufacturing and analytical methods to demonstrate substantially equivalent processes and performance for regulatory filings and interactions as required. Such potential third-party manufacturers may be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

Furthermore, the facilities used by manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies and comparable foreign regulatory authorities to ensure strict compliance with government regulations and corresponding foreign standards. Despite our efforts to audit and verify regulatory compliance, third-party manufacturers may be found on regulatory inspection by the FDA or comparable foreign regulatory authorities to be noncompliant with cGMP regulations and requirements in relation to the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we will not be able to obtain and/or maintain regulatory approval for our product candidates manufactured in these facilities. In addition, we have limited

control over the ability of our third-party manufacturers to maintain adequate control, quality assurance and qualified personnel required to meet our clinical and commercial needs, if any. If the FDA or a comparable foreign regulatory authority does not approve the manufacture of our product candidates at these facilities or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that any approvals we have obtained could be revoked, which would adversely affect our business and reputation. Moreover, noncompliance with cGMP regulations or requirements may result in shutdown of the third-party vendor or invalidation of drug product lots or processes. In some cases, a product recall may be warranted or required, which would materially affect our ability to supply and market our products.

We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products. Also, our third-party manufacturers could breach or terminate their agreement with us because of their own financial difficulties or business priorities at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

Furthermore, our third-party manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or comparable foreign regulatory authorities or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue.

Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.

Our product candidates require many specialty raw materials. As a result, we may be required to outsource aspects of our manufacturing supply chain. Many of the specialty raw materials may be manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

In addition, those suppliers may not have the capacity to support commercial products manufactured by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA or comparable foreign regulatory authority inspection, or medical crises such as widespread contamination. We may not be able to contract with these companies on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing. In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. These factors could cause the delay of studies or trials, regulatory submissions, required approvals or commercialization of product candidates that we develop, cause us to incur higher costs and prevent us from commercializing our product candidates successfully.

Risks Related to Our Dependence on Third Parties

We intend to rely on third parties to conduct, supervise and monitor a significant portion of our research and nonclinical studies and clinical trials for our product candidates, and, if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We intend to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP-compliant clinical trials on our product candidates properly and on time. For example, we are

relying on CROs to conduct significant parts of our LYL797 and LYL845 Phase 1 clinical trials. Negotiating budgets and contracts with CROs and study sites may result in delays to our development timelines and increased costs. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our clinical trials or nonclinical studies will not be our employees, and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials or nonclinical studies may be extended, delayed or terminated, and we may not be able to obtain regulatory approval or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our nonclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as 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. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, 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 before approving our marketing applications. 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 applicable GCPs. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations and requirements may require us to add patients to or repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, state or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If any of our relationships with the third parties that we currently use or that we may use in the future terminates, we may not be able to enter into arrangements with alternative third parties or do so on commercially reasonable terms. As a result, delays occur, which can materially impact our ability to meet desired research and clinical development timelines.

We do and will continue to or intend to rely on outside scientists and clinical trial investigators and their third-party research institutions for research and development and early clinical testing of our product candidates. These scientists, investigators and institutions may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our technology platforms.

We rely on our third-party research institution collaborators for some research capabilities. However, the research we are funding constitutes only a small portion of the overall research of each research institution. Other research being conducted by these institutions may at times receive higher priority than research on the programs we are funding. We typically have less control of the research, clinical trial protocols and patient enrollment than we might with activity led by our employees.

The outside scientists and clinical trial investigators who conduct the research and development upon which portions of our product candidate pipeline depends are not our employees; rather, they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. These factors could adversely affect the timing of the clinical trials, the timing of receipt and reporting of clinical data, the timing of our IND submissions and comparable foreign applications and our ability to conduct our current and planned clinical trials. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to, and have an adverse effect on, our business.

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

We have entered into research and development collaborations in the past, and may in the future, enter into additional license and collaboration arrangements. Any collaboration arrangement that we enter into is subject to numerous risks, which may include the following:

- the collaborator has significant discretion in determining the efforts and resources that they will apply to a program or product candidate under the collaboration;
- the collaborator may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- the collaborator may delay or halt clinical trials, provide insufficient funding for a clinical trial, preferentially enroll patients on a portion of a clinical trial not testing our product candidates, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- the collaborator could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- the collaborator may not commit sufficient resources to marketing and distribution of our products;
- the collaborator may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and the collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- the collaboration may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- the collaborator 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 commercialize such intellectual property.

In particular, failure by any collaborator to meet its obligations under our collaboration agreements or to apply sufficient efforts at developing and commercializing collaboration products may adversely affect our business, financial condition and our results of operations. For example, we were previously party to a research and development collaboration with GSK for our NY-ESO-1 program and other potential product opportunities and, effective December 2022, GSK terminated the agreement and discontinued its development of product candidates targeting NY-ESO-1, including the second-generation product candidates that incorporated our genetic and epigenetic reprogramming technologies. No patients had been treated with these product candidates and, given the early stage of these second-generation programs, the termination was not based on any clinical efficacy or safety data from these programs. We have also discontinued any further work on these programs.

We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates, our research and any future product candidates that we may pursue. Such alliances will be subject to many of the risks set forth above. Moreover, any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex.

As a result of these risks, we may not be able to realize the benefit of our existing collaboration or any future collaborations or licensing agreements we may enter into. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We may not realize the benefits of potential future collaborations, licenses, product acquisitions or other strategic transactions.

We have entered into, and may desire to enter into in the future, collaborations, licenses or other strategic transactions for the acquisition of products or business opportunities, in each case where we believe such arrangement will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex, and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates or programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive benefit/risk profile. Any delays in entering into new strategic alliance agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. There are other risks and uncertainties involved in these transactions, including unanticipated liabilities related to acquired intellectual property rights, products or companies and disruption in our relationship with collaborators or suppliers as a result of such a transaction. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

We depend on the enrollment and retention of patients in our current and planned clinical trials for our product candidates. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.

Successful and timely completion of clinical trials require that we enroll and retain a sufficient number of patient candidates. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, manufacturing failures resulting in patients being unable to be treated, patient withdrawal or adverse events. These types of developments have in the past, and could in the future, cause us to delay a trial or halt further development.

Our clinical trials compete with other clinical trials that are in the same therapeutic areas as our product candidates, 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. We may also encounter additional challenges and slower than anticipated enrollment in our clinical trials if any of our competitors obtain FDA approval before us in the same therapeutic areas as our product candidates.

Moreover, enrolling patients in clinical trials for diseases in which there is an approved standard of care is challenging, as patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care do not enroll in clinical trials. This may limit the number of eligible patients able to enroll in our clinical trials who have the potential to benefit from our product candidates and could extend development timelines or increase costs for these programs. For example, lifileucel was approved for the treatment of unresectable or metastatic melanoma, and, if it is adopted as a standard of care, its availability may adversely impact enrollment in our trials of LYL845 in melanoma. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these prior treatment regimens may render our therapies less effective in clinical trials.

Because the number of qualified clinical investigators and clinical trial sites is 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.

We may experience delays in enrollment in our current and planned clinical trials due to factors outside our control. For example, some patients may not be able to comply with clinical trial protocols due to lack of healthcare support or potential interruptions of healthcare services. Our ability to recruit and retain patients, principal investigators and site staff may also be hindered, which would adversely affect our trial operations.

Patient enrollment depends on many additional 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;
- perceived risks and benefits of the product candidate under evaluation, including any perceived risks associated with genetically modified product candidates;
- 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 that the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available approved or investigational therapies.

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.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our ability to enroll clinical trials or our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Additionally, our commercial opportunities will be reduced or eliminated if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of our current or future target diseases. Competition could result in reduced sales and pricing pressure on our product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

Risks Related to Regulation and Legal Compliance

We are in the first phase of clinical development of our product candidates, and our future success is dependent on the successful development and regulatory approval of our product candidates.

We currently have no products approved for commercial sale, and we are in the first phase of clinical development of our product candidates. Besides LYL797 and LYL845, which are in Phase 1 clinical development, our other proprietary product candidates are currently in preclinical development. The future success of our business is substantially dependent on our ability to obtain regulatory approval for our product candidates for the indications we seek, and, if approved, to successfully commercialize one or more product candidates in a timely manner. Each of our programs and product candidates will require clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence from and to the satisfaction of the FDA and comparable foreign regulatory authorities, that the product candidate is safe, pure and potent for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial 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 none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Furthermore, the regulatory approval process for novel product candidates, such as T-cell product candidates and next-generation T-cell programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

Our cellular therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.

Our future success is dependent on the successful development of our cellular therapies in general and our development product candidates, in particular. Because these programs represent a new approach to the treatment of cancer, developing and, if approved, commercializing our product candidates subject us to a number of challenges. Moreover, we cannot be sure that the manufacturing processes used in connection with our cellular therapy product candidates will yield a sufficient supply of satisfactory products that are safe, pure and potent, scalable or profitable.

In addition to oversight by the FDA and by IRBs under guidelines promulgated by the NIH, gene therapy clinical trials, such as those for LYL797, which evaluates T cells expressing a synthetic CAR and overexpressing c-Jun, are also subject to review and oversight 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. 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. Although the FDA decides whether trials of cell therapies that involve genetic engineering may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

Actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other comparable foreign regulatory authorities may ask for specific post-marketing requirements, and additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

Physicians, hospitals and third-party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel therapy, may decide the therapy is too complex to adopt without appropriate training or not cost-efficient and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

The results of research, nonclinical studies or earlier clinical trials are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in research, nonclinical studies and early clinical trials does not ensure that later clinical trials will generate similar results and otherwise provide adequate data to demonstrate the efficacy and safety of an investigational product. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in late-stage clinical trials, even after seeing promising results in earlier nonclinical studies or clinical trials. Thus, even if the results from our initial research and nonclinical activities appear positive, we do not know whether subsequent late-stage clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any product candidates.

Moreover, final study results may not be consistent with interim study results. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Clinical development involves a lengthy and expensive process with an uncertain outcome.

We are in the first phase of clinical development of our product candidates. Besides LYL797 and LYL845, which are in Phase 1 clinical development, our other proprietary product candidates are currently in preclinical development. The risk of failure of our product candidates is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

The clinical testing that will be required for any product candidates we choose to advance is expensive and can take many years to complete, and its outcome is inherently uncertain. The FDA may not clear the IND applications for any planned clinical trials. Even if cleared by the FDA and initiated, we cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our current and planned clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through nonclinical and clinical trials.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

To date, we have not fully enrolled or completed any clinical trials required for the approval of our product candidates. We may experience delays in initiating, enrolling or conducting our current and planned clinical trials, and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned, will achieve expected enrollment rates or will be completed on schedule, if at all. Identifying candidate patients with ROR1+ tumors for the LYL797 clinical study and obtaining sufficient and specific tumor tissues for the LYL845 clinical study is necessary to support our Phase 1 clinical trials. Our inability to identify candidates with ROR1+ tumors or obtain specific tumor tissues or sufficient amounts of tumor tissues in a timely manner or at all could delay or preclude our ability to execute and complete the clinical trials. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including in connection with:

- inability to generate sufficient nonclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching agreement with the FDA or other regulatory authorities, including comparable foreign regulatory authorities, as to the design or implementation of our clinical trials;
- obtaining regulatory authorization to commence a clinical trial;
- reaching an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining IRB approval at each trial site or positive ethics committees opinions;

- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with applicable regulatory requirements, including the FDA's and comparable foreign regulatory authorities' GCP requirements, or other applicable regulatory requirements;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidate for use in clinical trials; or
- suspensions or terminations by IRBs or ethics committees of the institutions at which such trials are being conducted, by the Data Safety Monitoring Committee for such trial or by the FDA or other regulatory authorities including comparable foreign regulatory authorities due to a number of factors, including those described above.

Further, a clinical trial may be suspended or terminated by us, the IRBs or ethics committees for the institutions in which such trials are being conducted, the Data Safety Monitoring Committee for such trial or the FDA or other regulatory authorities, including comparable foreign regulatory authorities, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities, including comparable foreign regulatory authorities, resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

We cannot predict with any certainty whether or when we might complete a given clinical trial, if at all. If we experience delays or quality issues in the conduct, completion or termination of any clinical trial of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

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 other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not continue the development of nor receive approval to market any product candidates, which could prevent us from ever generating product revenues or achieving profitability. For example, previous clinical trials utilizing CAR T cells to treat hematologic tumors have shown an increased risk of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome. Adverse events may also be associated with the lymphodepletion or IL-2 regimen utilized with cellular therapies. Additionally, ROR1 is expressed on a number of normal tissues. As a result, ROR1 could cause on-target, off-tumor toxicity. c-Jun is also potentially an oncogene and could cause healthy cells to transform into malignant cells. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. The side effects experienced could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

In the event that any of our product candidates receives regulatory approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit approvals of such products and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy (REMS) plan or risk management plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the dose or the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote or manufacture the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any products.

Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as we make changes to our manufacturing processes 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 interim, topline or preliminary data from our nonclinical studies and clinical trials, which are 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. Further, modifications or improvements to our manufacturing processes for a therapy may result in changes to the characteristics or behavior of the product candidate that could cause our product candidates to perform differently and affect the results of our ongoing clinical trials. As a result, the topline 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. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose preliminary or interim data from our nonclinical studies and clinical trials. Preliminary or interim data from clinical trials 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. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. If the interim, topline or preliminary data 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, any of our potential product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

The FDA and comparable foreign regulatory approval processes are lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approvals of our product candidates, our business will be substantially harmed.

We expect the novel nature of our product candidates to create challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of T-cell therapies for cancer. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe, pure and potent for their intended uses. Results from nonclinical studies and clinical trials can be interpreted in different ways. Even if we believe the nonclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may also require us to conduct additional nonclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of products in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We could also encounter delays if physicians experience unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles, including treatments offered by our competitors if they obtain FDA approval before us in the same therapeutic areas as our product candidates. For example, enrollment in clinical trials of LYL845 for melanoma may be adversely impacted by the commercial availability of lifileucel, a TIL therapy that was approved by the FDA in February 2024 for the treatment of melanoma. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product if approved.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and requirements, as well as, for the manufacture of certain of our product candidates, the FDA's cGTPs for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs, cGTPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, quality control and distribution.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include issuing warning letters or untitled letters, imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission (FTC) strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular way and adequately substantiated by clinical data. The promotion of a drug product in a manner that is false, misleading, unsubstantiated or for unapproved (or off-label) uses may result in enforcement letters, inquiries and investigations and civil and criminal sanctions by the FDA, FTC and other regulatory authorities. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies and comparable foreign regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required that companies enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. Equivalent requirements and penalties are provided in the EU both at the EU level and at the national level in individual EU Member States.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authority may impose restrictions on that product or us,

including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

- issue warning letters;
- issue, or require us to issue, safety-related communications, such as safety alerts, field alerts, “Dear Doctor” letters to healthcare professionals, or import alerts;
- impose civil or criminal penalties;
- suspend, limit, vary or withdraw regulatory approval;
- suspend, vary or terminate any of our nonclinical studies and clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our and our contract manufacturers’ facilities; or
- seize or detain products, refuse to permit the import or export of products, or require us to conduct a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, during the Trump administration several executive actions were taken, including the issuance of a number of Executive Orders, that imposed significant burdens on, or otherwise delayed, the FDA’s ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how similar orders in the future would be implemented, and the extent to which they would impact the FDA’s ability to exercise its regulatory authority. If executive actions are taken that impose restrictions on the FDA’s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

We have received Orphan Drug Designation (ODD) for LYL845 in the United States, and we may seek ODD in other regions or indications in the future, or for other product candidates. We may not be able to obtain or maintain ODD for any product candidates, and we may be unable to take advantage of the benefits associated with ODD, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product as an orphan product if it is intended to treat a rare disease or condition, which is generally defined as a diagnosed patient population of fewer than 200,000 individuals in the United States, or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States.

We have received ODD from the FDA for LYL845 for the treatment of stage IIB-IV melanoma; however, we may not be able to maintain this status. There can be no assurance that the FDA or other comparable foreign regulatory authority will grant ODD for LYL845 to treat any other condition for which we may apply. We may also seek ODD for other and future product candidates, and we may be unsuccessful in obtaining this designation.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product candidate that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, it is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity. More than one product

may be approved by the FDA for the same orphan indication or disease, as long as the products are different drugs. The failure to successfully obtain orphan drug market exclusivity would adversely affect our business.

ODD neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek ODD for LYL845 for other indications or for any future product candidates for applicable indications, we may never receive such designations.

We may be subject to applicable fraud and abuse, including anti-kickback and false claims, transparency, health information privacy and security and other healthcare laws. Failure to comply with such laws, may result in substantial penalties.

We may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any product candidates for which we obtain marketing approval. The healthcare laws that may affect us include: the federal fraud and abuse laws, including the federal anti-kickback, and false claims and civil monetary penalties laws; federal data privacy and security laws, including the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act; and federal transparency laws related to ownership and investment interests and payments and/or other transfers of value made to or held by physicians (including doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction. Similar requirements are applicable in foreign countries. Outside the United States, interactions between pharmaceutical companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Ensuring that our operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid or comparable foreign programs, additional reporting requirements and/or oversight if a corporate integrity agreement or similar agreement is executed to resolve allegations of non-compliance with these laws and the curtailment or restructuring of operations. In addition, violations may also result in reputational harm, diminished profits and lower future earnings. For additional detail on healthcare laws that may affect our business, see "Other Healthcare Laws" in the business section of this Annual Report on Form 10-K for the year ended December 31, 2023.

Changes in healthcare policies, laws and regulations may impact our ability to obtain approval for, or commercialize our product candidates, if approved.

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives, as well as executive, judicial and Congressional challenges to existing healthcare laws that have significantly affected, and could continue to significantly affect, the healthcare industry. For example, there have been efforts to repeal, substantially modify or invalidate some or all of the provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), some of which have been successful. While the U.S. Supreme Court dismissed in June 2021 a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress, such efforts may continue.

In addition, there continues to be heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. presidential executive orders, 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 government payor programs and review the relationship between pricing and manufacturer patient programs. For example, President Biden issued an executive order in July 2021 supporting legislation to enact drug pricing reforms and, in response, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices in September 2021 with specific legislative and administrative policies that Congress could enact to help improve affordability of, and access to, prescription drugs. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things: (i) directs 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" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Additionally, the IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in the 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. 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 started taking effect progressively in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. Further, 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 Centers for Medicare and Medicaid Services (CMS) Innovation Center, 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

For additional detail on healthcare reform that may affect our business, see "Healthcare Reform" in the business section of this Annual Report on Form 10-K for the year ended December 31, 2023.

The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Our cell therapies are novel and may require additional education and support to achieve reimbursement, if at all.

Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We or our collaborators will be required to fulfill applicable regulatory requirements for companion diagnostic testing and to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we may seek for our product candidates.

Similarly, a significant trend in the healthcare industry is cost containment. Governmental authorities have announced initiatives to control the cost of prescription drugs through the use of march-in rights under the Bayh-Dole Act and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. For additional detail on healthcare reform that may affect cost containment, see "Healthcare Reform" in the business section of this Annual Report on Form 10-K for the year ended December 31, 2023. As such, cost containment

reform efforts may result in an adverse effect on our operations. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates will be physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

Disruptions at the FDA and other government agencies or comparable foreign regulatory authorities caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including, as applicable, government budget and funding levels, statutory, regulatory, and policy changes, the authority's ability to hire and retain key personnel and accept the payment of user fees and other events that may otherwise affect the authority's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of the FDA and other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies and authorities may also slow the time necessary for new biologics or modifications to be cleared or approved biologics to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough FDA employees and stop critical activities.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities, including comparable foreign regulatory authorities, to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We, and our partners and vendors, are subject to stringent and evolving United States and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

We, and our partners and vendors, including CROs, collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, process) personal data and other sensitive information (collectively, sensitive data) in connection with the operations of our business, such as storage or otherwise processing sensitive data to support the conduct of our clinical trials. These processing activities subject us, and our partners and vendors, to various federal, state, local and foreign data protection and privacy laws, regulations, guidance and industry standards and may be subject to external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security. If we fail to comply with applicable requirements for processing sensitive data, including in connection with the development of our product candidates or otherwise, or if a partner or vendor fails to comply with the same or misuses sensitive data we provide to it, we may be subject to litigation, regulatory investigations, enforcement actions, fines and criminal or civil penalties, mass arbitration demands, additional reporting requirements and/or oversight, bans on processing personal data and orders to destroy or not use personal data, as well as negative publicity, reputational harm and other adverse business consequences.

In the United States, our and our partners' and vendors' operations are subject to numerous federal and state laws and regulations, including state data breach notification laws and federal and state data privacy laws and regulations that govern the collection, use, disclosure and protection of health information and other personal information, including information of our employees. For example, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), imposes specific requirements relating to the privacy, security and transmission of individually identifiable protected health information, and we could potentially face substantial criminal or civil penalties if we knowingly receive protected health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of such health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Even when HIPAA does not apply, failure to take appropriate steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act and other similar laws (e.g., wiretapping laws).

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut and Utah—have enacted comprehensive data privacy and security laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their

personal data. As applicable, such rights may include the right to access, correct or delete certain personal data and to opt-out of certain data processing activities. The exercise of these rights may impact our business and ability to advance our product candidates effectively. Certain states also impose more stringent requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA), applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability.

Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. These state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other and have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources achieve compliance and restrict our ability to process certain personal information or sensitive.

Outside the United States, an increasing number of laws, regulations and industry standards may govern data privacy and security. For example, the European Union’s General Data Protection Regulation (EU GDPR) and the United Kingdom’s GDPR (UK GDPR), impose strict requirements for processing personal data.

Any clinical trial programs, including related regulatory filings, and research collaborations that we engage in outside the United States in the future may implicate international laws and regulations concerning data protection and privacy, including those governing various aspects of clinical research in the EU and the UK.

We expect that we will need to expend significant capital and other resources to ensure ongoing compliance with applicable data privacy and security laws. Claims that we have violated individuals’ privacy rights or breached our contractual obligations related to data privacy and security, even if we are not found liable, could be expensive and time-consuming to defend and could result in negative publicity that could harm our business. Moreover, even if we take all necessary action to comply with legal and regulatory requirements, we could be subject to a data breach or other unauthorized access of sensitive data, which could subject us to fines and penalties, as well as litigation and reputational damage. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business or financial condition, including but not limited to: delays in development of our product candidates due to inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our planned candidate pipeline development and business operations. If we fail to keep apprised of and comply with applicable international, federal, state or local regulatory requirements and changes thereto, we could be subject to a range of regulatory actions that could affect our or any vendors' or partners’ ability to seek to commercialize our product candidates. Any threatened or actual government enforcement action, or litigation when private rights of action are available, could also generate negative publicity, damage our reputation, result in liabilities, fines and adverse business consequences and require that we devote substantial resources that could otherwise be used in support of other aspects of our business.

Risks Relating to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements to protect the intellectual property related to our technology and product candidates. We own or possess certain intellectual property, and other intellectual property are owned or possessed by our partners and are in-licensed to us. When we refer to “our” technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office (USPTO) and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. There is also no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity, enforceability or patentability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity, enforceability or patentability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in these patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable. Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek licenses from third parties who own or have rights to intellectual property that may be useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain such licenses from third parties on commercially reasonable terms, or at all.

In addition, the USPTO and various foreign governmental or inter-governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during and after the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete, irreversible loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market, which could have a material adverse effect on our business.

United States patent applications containing or that at any time contained a claim not entitled to a priority date before March 16, 2013 are subject to the “first to file” system implemented by the America Invents Act (2011). The first to file system requires us to be cognizant going forward of the time from invention to filing of a patent application. 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 or our partners were the first to file any patent application related to a product candidate.

In addition, our registered or unregistered trademarks or trade names may be challenged, infringed or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we view as valuable to building name recognition among potential partners and customers in our markets of interest. At times, competitors or other third parties have adopted or may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion and/or litigation. 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, protect or defend our proprietary rights related to trademarks 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.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first nonprovisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon

issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. While the patent term of certain patents can also be extended with respect to a specific product to recapture time lost in clinical trials and regulatory review by the FDA, a patent's life also can be shortened by a terminal disclaimer over an earlier filed patent or patent application. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing infringing products made using our inventions in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful, the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, we or our partners may have limited remedies, which could materially diminish the value of such patent. If we or our partners are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

If we are sued for infringing or misappropriating the intellectual property rights of third parties, the resulting litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing, and may develop, product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products, methods of making or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

Third parties may assert infringement or misappropriation claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our

product candidates or their use or manufacture. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims.

If we or our partners are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving that a patent is invalid is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted from other activities. If one or more claims of any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expired. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. If we are unable to obtain a necessary license on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third-party's trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates.

Defending against intellectual property claims, regardless of their merit, could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. In the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any of these license agreements may require us to pay royalties and other fees that could be significant. As a result of all of the foregoing, any actual or threatened intellectual property claim could prevent us from developing or commercializing a product candidate or force us to cease some aspect of our business operations.

We have in-licensed a portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could potentially lose the ability to continue the development and potential commercialization of one or more of our product candidates.

We hold rights under license agreements with our partners. Our discovery and development technology platforms are built, in part, around intellectual property rights in-licensed from our partners. Under our existing license agreements, we are subject to various obligations, which may include diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable to pay damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners could adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates and our ability to commercialize the affected product candidates. Furthermore, disagreements under any of these license agreements may arise, including those related to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes may 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; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

These disagreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.

Presently we have rights to the intellectual property, through licenses from third parties and under patent applications that we own or will own, to develop our product candidates. 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 will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations, manufacturing methods or technologies 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. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms; such failure would harm our business. 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. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may 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.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

We have acquired or licensed, or may require in the future, intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). For example, 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. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have an adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual property rights, to protect our or our partners' trade secrets or to determine the validity or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid. In patent litigation in the United States, defendant counterclaims alleging noninfringement, invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert noninfringement, invalidity or unenforceability of a patent. The outcome following legal assertions of noninfringement, unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity of patent rights, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Interference, derivation or opposition proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non-U.S. patent authority may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, inter partes review, post-grant review or other pre-issuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can. Accordingly, despite our or our partners' efforts, we or our partners may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as the laws in the United States. Even if we are successful in the relevant proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted from other activities. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question and/or may require us to pay the other party attorneys' fees. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. 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, intellectual property. Such an outcome could have a material adverse effect on 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.

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

In addition to seeking 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 other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

Trade secrets can be difficult to protect. We seek to protect our proprietary, confidential technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the U.S. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could adversely affect our business, results of operations and financial condition.

We may be subject to claims that our employees, consultants or independent contractors have breached non-compete or non-solicit obligations and/or wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise breached non-compete or non-solicit obligations with respect to such individuals' prior employers, or used or disclosed confidential information of these third parties or such individuals' former employers. Dealing with such claims and negotiating with potential claimants could result in substantial cost and be a distraction to our management and employees. In addition, litigation may be necessary to defend against these claims, and even if we are successful in defending against these claims, such litigation could result in further costs to us and distraction to our management and employees.

Risks Related to Ownership of Our Common Stock

Delaware law and provisions in our amended and restated certificate of incorporation and bylaws might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our organizational documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;

- permit stockholders to take actions only at a duly called annual or special meeting and not by unanimous written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend certain provisions of the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL) prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, which is generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws, or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be 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, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees, or stockholders to us or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation and bylaws; and
- any action asserting a claim governed by the internal affairs doctrine.

Furthermore, to prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (Securities Act). However, these provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents or our other stockholders, which may discourage such lawsuits against us and such other persons, or may result in additional expense to a stockholder seeking to bring a claim against us. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations and financial condition.

If we fail to maintain proper and effective internal controls over financial reporting or identify additional material weaknesses in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may significantly harm our business and the value of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act (Section 404) requires that we evaluate and determine the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Our independent registered public accounting firm is also required to

attest to the effectiveness of our internal control over financial reporting. These assessments need to include the disclosure of any material weaknesses in such internal control. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. We and our independent auditors have previously identified a material weakness in our internal control over financial reporting, and we cannot assure you that we will not identify other material weaknesses in the future.

Furthermore, we may not have identified all material weaknesses, and our current controls and any new controls that we develop may become inadequate because of changes in personnel or conditions in our business or otherwise. Accordingly, we cannot assure you that any future material weaknesses will not result in a material misstatement of our consolidated financial statements and/or our failure to meet our public reporting obligations. In addition, if we and/or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective in the future, investor confidence in the accuracy and completeness of our consolidated financial statements would be adversely affected, which could significantly harm our business and the value of our common stock. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

General Risk Factors

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act, and we must maintain disclosure controls and procedures designed to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement, causing us to fail to make a required related party transaction disclosure or identify a potential conflict of interest. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

The market price of our common stock has been, and may continue to be, volatile, which could result in substantial losses for investors.

The market price of our common stock has been, and may continue to be, volatile and may fluctuate substantially as a result of a variety of factors, many of which are beyond our control. Some of the factors that may cause the market price of our common stock to fluctuate are listed below and other factors described in this “Risk Factors” section:

- the timing and results of nonclinical studies and clinical trials for our product candidates;
- failure or discontinuation of any of our product development and research programs;
- the success of existing or new competitive product candidates or technologies;
- results of clinical trials or regulatory approvals of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes including those concerning patent applications, issued patents, or other proprietary rights;
- labor discord or disruption, geopolitical events, social unrest, war, armed conflicts, tensions in U.S.-China relations, terrorism, political instability, acts of public violence, boycotts, hostilities and social unrest and health pandemics;
- the level of expenses related to any of our research programs or clinical development programs;
- actual or anticipated changes in our estimates as to our financial results or development timelines;

- whether our financial results, forecasts and development timelines meet the expectations of securities analysts or investors;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- market conditions in the healthcare sector;
- general economic, industry and market conditions beyond our control, such as inflationary pressures, labor shortages and supply chain disruptions, bank failures and other macroeconomic factors and associated economic downturn; and
- the other factors described in this “Risk Factors” section.

In recent years, stock markets in general, and the market for biotechnology companies in particular, have 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 have affected and may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company’s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management’s attention and resources from our business.

If securities or industry analysts do not publish research or reports about our business, or if they publish negative or neutral evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or securities analysts publish about us or our business. If one or more of the analysts covering our business initiate coverage with a neutral or sell rating or downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

Sales of a substantial number of shares of our common stock by our existing stockholders could cause the price of our common stock to decline.

At any time, sales of a substantial number of shares of our common stock in the public market could occur, or there could be a perception in the market that the holders of a large number of shares of common stock intend to sell shares, and any such event could reduce the market price of our common stock. As of December 31, 2023, we have 253,957,709 shares of common stock outstanding. Substantially all of the shares of our common stock outstanding and shares issued upon the exercise of stock options outstanding under our equity incentive plans, subject to applicable securities law restrictions, may be able to be sold in the public market.

Moreover, certain holders of shares of our common stock have rights, subject to conditions, to require us to file registration statements with the SEC covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing securities issued in any such transactions. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. In February 2024, we entered into a Sales Agreement pursuant to which we may offer and sell, from time to time, up to $150.0 million in shares of our common stock. To the extent that we raise additional capital through the sale of equity or debt securities, including pursuant to the Sales Agreement, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term

but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships, alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or our products, or grant licenses on terms unfavorable to us. Certain of the foregoing transactions may require us to obtain stockholder approval, which we may not be able to obtain.

Future acquisitions, strategic investments, partnerships or alliances could be difficult to identify and integrate, divert the attention of management, disrupt our business, dilute stockholder value and adversely affect our operating results and financial condition.

We may in the future seek to acquire or invest in businesses, products or technologies that we believe could complement or expand our technology platforms, enhance our technical capabilities, or otherwise offer growth opportunities. The pursuit of potential acquisitions or strategic investments may divert the attention of management and cause us to incur various expenses in identifying, investigating and pursuing suitable acquisitions or investments, whether or not such transactions are completed. In addition, we have only limited experience in acquiring or investing in other businesses, and we may not successfully identify desirable targets, or if we acquire additional businesses, we may not be able to integrate them effectively following the acquisition. Acquisitions could also result in dilutive issuances of equity securities or the incurrence of debt, as well as unfavorable accounting treatment and exposure to claims and disputes by third parties, including intellectual property claims. We also may not generate sufficient financial returns to offset the costs and expenses related to any acquisitions. In addition, if an acquired business fails to meet our expectations, our business, operating results and financial condition may suffer.

The requirements of being a public company require our management to devote substantial time to compliance initiatives and corporate governance practices and could divert management's attention and strain our resources.

As a public company, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. Section 404, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements and rules of The Nasdaq Stock Market LLC (Nasdaq Listing Rules) and other applicable U.S. rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We continue to need to hire additional accounting, finance and other personnel in connection with our efforts to comply with the requirements of being a public company, and our management and other personnel will continue to need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements have and will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, the rules and regulations applicable to us as a public company have made it more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

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 Tax Cuts and Jobs Act of 2017 (the Tax Act), the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) and the recently enacted IRA made many significant changes to the U.S. tax laws. For example, the Tax Act made broad and complex changes to the U.S. tax code, including, among other things, reducing the federal corporate tax rate. Additionally, beginning in 2022, the Tax Act required the capitalization of research and experimentation expenses (R&E expenses) with amortization periods over five and fifteen years pursuant to Section 174 of the U.S. Internal Revenue Code of 1986, as amended (the Code). If the requirement to capitalize Section 174 expenditures is not modified, it may impact our effective tax rate and our cash tax liability in future years. There have been legislative proposals to repeal or defer the Section 174 R&E expense capitalization rules, including legislation recently passed by the U.S. House of Representatives that would restore the deductibility of U.S. based R&E expenses but not non-U.S. R&E expenses, but there can be no assurance that any such legislation will ultimately be enacted. Future guidance from the U.S. Internal Revenue Service and other tax authorities with respect to any such tax legislation may affect us, and certain aspects of the Tax Act could be repealed or modified in future legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our U.S. operations and the deductibility of expenses under the Tax Act or future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges in the current or future taxable years and

could increase our future U.S. tax expense. The foregoing items, as well as any other future changes in tax laws, could have a material adverse effect on our business, cash flow, financial condition or results of operations.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under the Tax Act, as modified by the CARES Act, our net operating losses (NOLs) generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. There is variation in how states have responded and may continue to respond to the Tax Act and CARES Act. 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 NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past, including as a result of our initial public offering (IPO), and may experience future ownership changes as a result of subsequent shifts in our stock ownership (some of which may be outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs 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 a material portion of our NOLs and tax credits.

If our information technology systems or those of third parties upon which we rely, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm and other adverse consequences.

We and the third parties on which we rely face a variety of evolving threats that could cause security incidents, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by artificial intelligence, natural disasters, fire, terrorism, war, telecommunication and electrical failures and other similar threats. Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. 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, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to advance our programs, loss of sensitive data, reputational harm and diversion of funds. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

We exercise little or no control over the third parties on which we rely, which increases our vulnerability to problems with their systems. In addition, our reliance on these third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, clinical research and development and other functions. We also rely on third-party service providers to provide other products, 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 data 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' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, and we have not experienced any material system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will detect all vulnerabilities on a timely basis, prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon

our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs, and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), which could result in financial, legal, business and reputational harm to us. For example, any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with potentially costly federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, including expending significant resources or modifying our business practices such as our clinical trial activities, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data or to notify relevant stakeholders, including affected individuals, regulators and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. See Risk Factor titled “We, and our partners and vendors, are subject to stringent and evolving United States and foreign laws, regulations and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences” above for more information about risk related to data privacy and security obligations.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our data privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

Indemnity provisions in various agreements potentially expose us to substantial liability for intellectual property infringement, data protection and other losses.

Our agreements with third parties may include indemnification provisions under which we agree to indemnify them for losses suffered or incurred as a result of claims of intellectual property infringement or other liabilities relating to or arising from our contractual obligations. Large indemnity payments could harm our business and financial condition. Although we normally contractually limit our liability with respect to such obligations, we may still incur substantial liability. Any dispute with a third party with respect to such obligations could have adverse effects on our relationship with that third party and relationships with other existing or new partners, harming our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We rely on information technology and data to operate our business and develop and advance our pipeline of product candidates. Our critical information technology includes computer networks, third-party hosted services, communications systems, software and infrastructure, and our critical data includes confidential, personal, proprietary and sensitive data (collectively, Information Assets). Accordingly, we maintain certain risk assessment processes intended to identify cybersecurity threats, determine their likelihood of occurring and assess potential material impact to our business. Based on our assessment, we implement and maintain risk management processes designed to protect the confidentiality, integrity and availability of our Information Assets and mitigate harm to our business.

Risks from cybersecurity threats are among those that we review and address in our general risk management program. We identify such threats by, among other things, monitoring the threat environment using manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors,

conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, conducting threat assessments for internal and external threats and conducting vulnerability assessments to identify vulnerabilities.

We rely on a multidisciplinary team (including from our information security function, management and third-party service providers, as described further below) to assess how cybersecurity threats could impact our business. We routinely assess the likelihood that such threats could result in a material impact to our Information Assets, business and clinical operations, core business functions, personnel, reputation and identified critical business objectives.

Based on our assessment process and depending on the environment, we implement and maintain various technical, physical and organizational measures designed to manage and mitigate material risks from cybersecurity threats to our Information Assets, including, for example: policies and procedures designed to address cybersecurity threats, including an incident response plan, disaster recovery and business continuity plans; incident detection and response; internal and/or external audits to assess our exposure to cybersecurity threats, compliance with risk mitigation procedures and effectiveness of relevant controls; documented risk assessments; background checks on our personnel; encryption of data; network security controls; access controls; physical security; asset management; systems monitoring; employee training; penetration testing; and cyber insurance. We prioritize our efforts based on the threats that we believe are more likely to lead to a material impact to our business, such as ransomware, theft of intellectual property and interruption of services and processes on which we rely.

We work with third parties that assist us to identify, assess and manage cybersecurity risks, including professional services firms, cybersecurity consultants, cybersecurity software providers, managed cybersecurity service providers and penetration testing firms.

To operate our business, we utilize certain third-party service providers to perform a variety of functions, such as outsourced business functions, professional services, software-as-a-service platforms, managed services, property management, cloud-based infrastructure, data center facilities, encryption and authentication technology and corporate productivity services. Depending on the nature of the services provided, the sensitivity and quantity of information processed and the identity of the service provider, our vendor management process may include reviewing the cybersecurity practices of such provider, contractually imposing obligations on the provider related to the services they provide and/or the information they process, conducting security assessments, conducting on-site inspections and requiring their completion of written questionnaires regarding their cybersecurity programs. For service providers that provide particularly critical services to us or process particularly sensitive information for us, we engage industry leaders with robust and documented cybersecurity programs.

For additional information about the risks from cybersecurity threats that may materially affect us and how they may do so, see the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, including "If our information technology systems or those third parties upon which we rely, or our data, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions, litigation, fines and penalties, disruptions of our business operations, reputational harm and other adverse consequences."

Governance

Our cybersecurity risk management strategy relies on input from management, including our Chief Operating Officer, Mr. Stephen Hill, to help us understand cybersecurity risks, establish priorities and determine the scope and details of our cybersecurity program and to implement it. Mr. Hill has held senior management positions at numerous pharmaceutical companies for over a decade. Management is responsible for hiring appropriate personnel, integrating cybersecurity considerations into our overall risk management strategy and for communicating key priorities to employees and other stakeholders. Our cybersecurity incident response and vulnerability management processes involve management, who participate in our disclosure controls and procedures.

Management meets regularly to discuss cybersecurity risk and to review our cybersecurity program. Management is also responsible for approving budgets, helping prepare for cybersecurity incidents, responding to cybersecurity incidents, approving cybersecurity policies and procedures, reviewing audit reports and reporting to our board of directors, testing incident response plans and engaging vendors that provide cybersecurity services. Management participates in cybersecurity incident response efforts by being members of the incident response team and helping direct our response to cybersecurity incidents.

Our board of directors has overall responsibility for evaluating key business risks faced by us, including cyber security and information technology. The audit committee of our board of directors assists the board of directors in the oversight and assessment of risks relating to data privacy, technology and information security, including cybersecurity.

Our audit committee holds regular meetings to discuss issues including our cybersecurity threats and has a dedicated agenda during such meetings that are designed to assist our board of directors and our audit committee in exercising their oversight function. The meetings involve presentations and reports from our management and specifically includes updates of current cybersecurity threats faced by us and steps we are taking to address them.

Item 2. Properties.

California

Our current corporate headquarters are located in South San Francisco, California, where we lease approximately 108,000 square feet of office and laboratory space, pursuant to a lease agreement that commenced in February 2020 and expires in March 2031.

Washington

We lease approximately 34,000 square feet of office and laboratory space in Seattle, Washington, pursuant to a lease agreement that commenced in January 2019 and expires in December 2028. We lease approximately 73,000 square feet of manufacturing, office and laboratory space in Bothell, Washington, pursuant to a lease agreement that commenced in February 2020 and expires in May 2030.

We believe that these existing facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we have been or may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business.

We are currently not party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority.

Regardless of outcome, any such proceedings or claims is subject to inherent uncertainties and can have an adverse impact on us because of defense and settlement costs, diversion of resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

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 traded on the Nasdaq Global Select Market under the symbol "LYEL" since June 17, 2021. Prior to that date, there was no public trading market for our common stock.

Holders

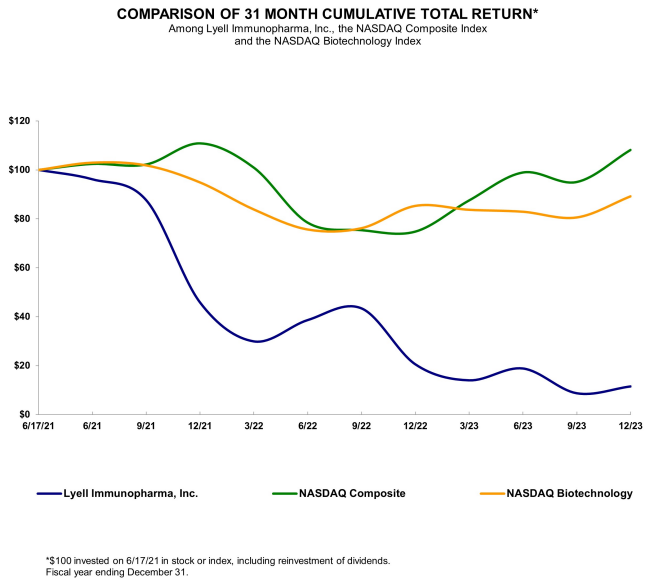
On February 22, 2024, there were 60 holders of record of our common stock. The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in "street names" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividends

Since inception, we have not paid dividends on our common stock. We currently intend to retain all future earnings, if any, for use in our business and currently do not plan to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Stock Performance Graph

The following stock performance graph compares the value of an investment in (i) our common stock, (ii) Nasdaq Composite Index and (iii) Nasdaq Biotechnology Index for the period from June 17, 2021 (the date our common stock commenced trading on the Nasdaq Global Select Market) through December 31, 2023. The figures represented below assume an investment of $100 in our common stock at the closing price on June 17, 2021 and in the Nasdaq Composite Index and Nasdaq Biotechnology Index on June 17, 2021 and the reinvestment of any dividends into shares of common stock. However, no dividends have been declared on our common stock to date. The comparisons in the table are required by the Securities and Exchange Commission and are not intended to forecast or be indicative of possible future performance of our common stock.



The above Stock Performance Graph and related information shall not be deemed “soliciting material” or to be “filed” with the Securities and Exchange Commission nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

Unregistered Sales of Equity Securities

None.

Repurchases of Equity Securities

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 audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. 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 in the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. See also the section titled "Special Note Regarding Forward-Looking Statements."

This section under Management's Discussion and Analysis of Financi al Condition and Results of Operations generally discusses 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 that are not included in this Annual Report on Form 10-K can be found in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Overview

We are a clinical-stage cell therapy company advancing a pipeline of product candidates for patients with solid tumors utilizing our proprietary ex vivo genetic and epigenetic T-cell reprogramming technologies. Our investigational therapies use the patient's own cells as the starting point to generate highly tumor-reactive, longer-lasting functional T cells with enhanced ability to defeat solid tumors. Our innovative reprogramming technologies address what we believe are the primary barriers that limit consistent and long-lasting responses to T-cell therapy in solid tumors: T-cell exhaustion and lack of durable stemness. Our technologies are designed to generate T cells with the ability to persist and self-renew while driving durable tumor cytotoxicity, even in the setting of an immunosuppressive tumor microenvironment. We apply our technologies with the aim of developing T-cell therapies with improved and durable antitumor responses for patients with solid tumors. Our technologies can be applied in a target agnostic manner to multiple T-cell modalities, including chimeric antigen receptor (CAR), tumor-infiltrating lymphocytes (TIL) and T-cell receptor (TCR) therapies.

Our growing pipeline of promising cell product candidates targets solid tumor indications with large unmet needs that are collectively responsible for approximately 180,000 deaths in the United States annually. Each of our programs provide opportunities to expand into additional indications beyond the patient populations we are initially targeting.

For additional information regarding our business, see "Business" in Part I, Item 1 of this Annual Report on Form 10-K.

Pipeline Programs and Operational Updates

Pipeline Programs

We are advancing four wholly-owned product candidates. Two product candidates, LYL797 and LYL845 are in Phase 1 clinical development. Two additional product candidates, LYL119 and a second-generation tumor infiltrating lymphocyte (TIL) product candidate, are in preclinical development and our T-cell rejuvenation technology is in research.

LYL797 – A ROR1-targeted Chimeric Antigen Receptor (CAR) T-cell product candidate genetically reprogrammed to overexpress c-Jun and epigenetically reprogrammed using Lyell's proprietary Epi-R™ manufacturing protocol, designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial of LYL797 is ongoing. The study includes patients with relapsed or refractory triple-negative breast cancer (TNBC) or non-small cell lung cancer (NSCLC).
- Initial clinical and translational data from at least 20 patients in the Phase 1 trial of LYL797 are expected in the first half of 2024.
- Initiated a CAR T-cell manufacturing proof-of-concept collaboration with Cellares as part of an overall manufacturing strategy to build scale and reduce cost. Under the collaboration, the companies have agreed on a proof-of-concept technology transfer process for the manufacture of Lyell's LYL797 CAR T-cell therapy, using Cellares' Cell Shuttle™.

- Announced initial results from Lyell's ROR1 screening program indicating that expression of ROR1 in TNBC and NSCLC, 53% (N=77) and 33% (N=18), respectively, is consistent with what has been reported in the literature. The screening program is designed to support Lyell's current and future clinical trials.
- Presented a LYL797 Trial in Progress poster at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC).

LYL845 – A novel epigenetically reprogrammed TIL product candidate using Lyell's proprietary Epi-R ™ manufacturing protocol, designed for differentiated potency and durability

- Enrollment in the Phase 1 clinical trial for LYL845 is ongoing. The study includes patients with relapsed and/or refractory metastatic or locally advanced melanoma, NSCLC and colorectal cancer.
- Initial clinical and translational data from the Phase 1 trial of LYL845 are expected in the second half of 2024.
- Received FDA Orphan Drug designation (ODD) for LYL845 for the treatment of stage IIB-IV melanoma.
- Presented nonclinical data at SITC highlighting the Epi-R P2 manufacturing process, which is designed to shorten TIL manufacturing time to less than three weeks without impacting cell number and phenotype. Epi-R P2 is expected to be incorporated into the Phase 1 trial of LYL845 in 2024.
- Presented a LYL845 Trial in Progress poster at SITC.

LYL119 – A ROR1-targeted CAR T-cell product candidate incorporating Lyell's four stackable and complementary reprogramming technologies for enhanced cytotoxicity

- LYL119 is a ROR1-targeted CAR T-cell product enhanced with Lyell's four novel genetic and epigenetic reprogramming technologies: c-Jun overexpression, NR4A3 knockout, Epi-R manufacturing protocol and Stim-R™ T-cell activation technology.
- An IND application for LYL119 is expected to be submitted in the first half of 2024.
- Presented posters highlighting preclinical development of LYL119 at the American Society for Gene and Cell Therapy and at SITC. In preclinical studies, LYL119 demonstrated superior cytotoxicity and sustained cytokine production upon repeated antigen stimulation compared to various controls lacking one or more of the reprogramming technologies and showed robust in vivo antitumor efficacy and prolonged survival in a mouse xenograft tumor model at very low cell doses.

Rejuvenation – Novel partial reprogramming technology designed to maintain T-cell identity while reducing cells' epigenetic age

- Presented nonclinical data at the International Society for Stem Cell Research (ISSCR) 2023 Annual Meeting demonstrating that Lyell's T-cell Rejuvenation technology generates cells with improved expansion capacity and increased expression of biomarkers associated with T-cell stemness, that also exhibit improved antitumor properties compared with non-rejuvenated T-cell controls in sequential cell-killing assays.
- Presented nonclinical data at SITC demonstrating that TIL generated with Lyell's Rejuvenation technology retain a broad TCR repertoire and demonstrate improved T-cell function and antitumor properties.

Corporate Updates

- Appointed Matt Lang, J.D., Chief Business Officer. Mr. Lang, who also serves as Lyell's Chief Legal Officer and Corporate Secretary, is an experienced company builder who has successfully led growth in complex organizations.

Macroeconomic Environment

Our 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, escalating armed conflicts and turmoil in the Middle East, tensions in U.S.-China relations, inflationary pressures, interest rate environment, instability in the banking industry and overall market volatility. The first half of 2023 was marked by significant market uncertainty, inflationary pressures, banking upheaval and supply constraints. Although these negative impacts improved throughout the fiscal year, economic uncertainty persists and could continue in 2024, and these market dynamics and similar adverse market conditions may negatively impact our business.

For a further discussion of trends, uncertainties and other factors that could impact our operating results, see the section entitled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K.

Reduction in Workforce

In the fourth quarter of 2023, we implemented a reduction in our workforce of approximately 25% to reduce operating costs and improve operating efficiency. The restructuring prioritized investment in our clinical stage programs and core research platforms and streamlined operations. In connection with this reduction in workforce, we incurred approximately $5.5 million in expenses for one-time severance payments and other employee-related costs for the year ended December 31, 2023.

License, Collaboration and Success Payment Agreements

For a detailed description of our license, collaboration and success payment agreements, see the section titled " *Business—License, Collaboration and Success Payment Agreements*" in Part I, Item 1 of this Annual Report on Form 10-K and Notes 2 and 3 to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Components of Results of Operations

Revenue

We have no products approved for sale and have never generated any revenue from product sales.

We have generated revenue primarily from the recognition of the upfront payment under the Collaboration and License Agreement, entered into in 2019 and amended in June 2020 and December 2021 (GSK Agreement) with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, GSK). GSK terminated the GSK Agreement effective December 2022 and we do not expect further revenue from the collaboration. See Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional details regarding termination of the GSK Agreement.

In the future, we may generate additional revenue from other collaborations, strategic alliances, licensing agreements, product sales, or a combination of these.

Operating Expenses

Research and Development

To date, research and development expenses consist of costs incurred by us for the discovery and development of our technology platforms and product candidates, and include costs incurred in connection with strategic collaborations, costs to license technology, personnel-related costs, including stock-based compensation expense, facility and technology related costs, research and laboratory expenses, as well as other expenses, which include consulting fees and other costs. Upfront payments and milestones paid to third parties in connection with technology platforms that have not reached technological feasibility and do not have an alternative future use are expensed as incurred. Research and development costs also include expenses related to the reduction in workforce, which was substantially completed in 2023.

Research and development expenses also include non-cash expenses related to the change in the estimated fair value of the success payment obligations over their respective requisite service terms granted to Fred Hutchinson Cancer Center (Fred Hutch) and The Board of Trustees of the Leland Stanford Junior University (Stanford). See the subsection titled "Critical Accounting Policies and Estimates— *Success Payments*" below. As of December 31, 2022, Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. For the year ended December 31, 2023 and future periods, the change in the Fred Hutch success payment liability fair value is recognized in other income (expense), net, as the requisite service obligation had been met. Research and development expenses related to our success payment liabilities are unpredictable and may vary significantly from year-to-year due to changes in our assumptions used in the calculation.

We deploy our employee and infrastructure resources across multiple research and development programs for identifying and developing product candidates and establishing manufacturing capabilities. Due to the stage of development and number of ongoing programs and our ability to use resources across several programs, most of our research and development costs are not recorded on a program-specific basis. These include costs for personnel, laboratory and other indirect facility and operating costs.

Research and development activities account for a significant portion of our operating expenses. We anticipate that our research and development expenses will increase over the foreseeable future as we expand our research and

development efforts including completing nonclinical studies, commencing planned clinical trials, conducting and completing current and planned clinical trials, seeking regulatory approvals of our product candidates, identifying new product candidates and incurring costs to acquire and license technology platforms. A change in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. Because we are early in our research and clinical development efforts of our product candidates, and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the nonclinical development, clinical development and commercialization of product candidates or whether, or when, we may achieve profitability.

Our research and development expenses may vary significantly based on factors such as:

- the number and scope of nonclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional collaboration or license agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates. We may obtain unexpected results from our nonclinical studies and clinical trials.

General and Administrative

General and administrative costs include personnel-related expenses, including stock-based compensation expense for personnel in executive, legal, finance and other administrative functions, legal costs, transaction costs related to collaboration and licensing agreements, as well as fees paid for accounting and tax services, consulting fees and facilities costs not otherwise included in research and development expenses. Legal costs include those related to corporate, dispute and patent matters. General and administrative costs also include expenses related to the reduction in workforce, which was substantially completed in 2023.

We anticipate that our general and administrative expenses will increase over the foreseeable future to support our continued research and development activities, operations generally, future business development opportunities, consulting fees, as well as the costs of operating as a public company such as costs related to accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission (SEC) requirements, director and officer insurance costs and investor and public relations costs.

Other Operating Income, Net

Other operating income, net consists primarily of service and occupancy fees received associated with subleases as well as losses on t he retirement of property and equipment.

Interest Income, Net

Interest income, net consists primarily of interest earned on our cash, cash equivalents and marketable securities balances.

Other Income (Expense), Net

Other income (expense), net consists primarily of the change in fair value associated with our success payment liabilities to Fred Hutch for the year ended December 31, 2023 and primarily of a gain to record the PACT Series D convertible preferred shares for the year ended December 31, 2022 and changes in the fair value of an equity warrant investment held for the years ended December 31, 2022 and 2021.

Impairment of Other Investments

Impairment of other investments consists of reductions in the value of certain other investments.

Results of Operations

Years Ended December 31, 2023, 2022 and 2021

The following table summarizes our results of operations for the periods presented (in thousands):

	Year Ended December 31,			Change	
	2023	2022	2021	2023 vs 2022	2022 vs 2021
Revenue	$ 130	$ 84,683	$ 10,650	$ (84,553)	$ 74,033
Operating expenses:					
Research and development	182,945	159,188	138,693	23,757	20,495
General and administrative	66,983	117,307	89,057	(50,324)	28,250
Other operating income, net	(2,790)	(4,754)	(2,324)	1,964	(2,430)
Total operating expenses	247,138	271,741	225,426	(24,603)	46,315
Loss from operations	(247,008)	(187,058)	(214,776)	(59,950)	27,718
Interest income, net	23,453	7,053	1,165	16,400	5,888
Other income (expense), net	1,846	1,887	(161)	(41)	2,048
Impairment of other investments	(12,923)	(5,000)	(36,447)	(7,923)	31,447
Total other income (loss), net	12,376	3,940	(35,443)	8,436	39,383
Net loss	$ (234,632)	$ (183,118)	$ (250,219)	$ (51,514)	$ 67,101

Revenue

Revenue was $0.1 million and $84.7 million for the years ended December 31, 2023 and 2022, respectively. The GSK Agreement was terminated in December 2022 and, therefore, no further research and development pursuant to the GSK Agreement was performed in 2023, which drove the decrease in revenue of $84.6 million for the year ended December 31, 2023. The revenue for the year ended December 31, 2022 was primarily due to $83.6 million in revenue adjustments driven by the mutual agreement with GSK to conclude certain research activities in June 2022 and GSK's subsequent termination of the GSK Agreement, both of which resulted in changes to the measure of proportional cumulative performance. See Note 3, *License, Collaboration and Success Payment Agreements – GSK*, in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information about the termination of the GSK Agreement.

Research and Development Expenses

The following table summarizes the components of our research and development expenses for the periods presented (in thousands):

	Year Ended December 31,			Change	
	2023	2022	2021	2023 vs 2022	2022 vs 2021
Personnel	$ 81,717	$ 70,483	$ 60,499	$ 11,234	$ 9,984
Facilities and technology	51,688	52,153	39,092	(465)	13,061
Research activities, collaborations and outside services	50,470	41,682	35,389	8,788	6,293
Success payments	(930)	(5,130)	3,713	4,200	(8,843)
Total research and development expenses	$ 182,945	$ 159,188	$ 138,693	$ 23,757	$ 20,495

Research and development expenses were $182.9 million and $159.2 million for the years ended December 31, 2023 and 2022, respectively. The increase of $23.8 million was primarily due to an increase of $17.5 million in research and laboratory costs principally due to clinical trials as part of the $8.8 million increase in research activities, collaborations and outside services, partially offset by a reduction of $5.2 million in collaboration and license fees primarily related to the completion of certain sponsored research agreements and a reduction of $3.6 million in professional services; an increase of $11.2 million in personnel-related expenses to support our growth, including $4.6 million for one-time severance payments and other employee-related costs in connection with the reduction in workforce that occurred during the fourth quarter of 2023; a change of $4.2 million in success payments associated with the decrease in fair value of our Fred Hutch and Stanford success payment liabilities, including a $3.9 million change due to recognizing the Fred Hutch success payment liability fair value change in other income (expense), net for the year ended December 31, 2023; partially offset by a decrease of $0.5 million in facilities and technology costs, primarily related to lower software implementation costs.

General and Administrative Expenses

General and administrative expenses were $67.0 million and $117.3 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $50.3 million was primarily due to a decrease of $36.3 million in stock-based compensation expense, primarily related to significant awards being fully expensed, a decrease of $9.7 million in outside services primarily due to a decrease in legal and consulting expenses and a decrease of $2.8 million in other administrative expenses. Included in general and administrative expenses for the year ended December 31, 2023 is $0.9 million for one-time severance payments and other employee-related costs in connection with the reduction in workforce that occurred during the fourth quarter of 2023.

Other Operating Income, Net

Other operating income, net was $2.8 million and $4.8 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $2.0 million was due primarily to increased losses on property and equipment disposals offsetting sublease income and operating fees related to our subleases.

Interest Income, Net

Interest income, net was $23.5 million and $7.1 million for the years ended December 31, 2023 and 2022, respectively. The increase of $16.4 million was primarily driven by higher interest rates in 2023.

Other Income (Expense), Net

Other income (expense), net was $1.8 million and $1.9 million for the years ended December 31, 2023 and 2022, respectively. Other income (expense), net of $1.8 million consisted primarily of a gain associated with the change in fair value associated with our Fred Hutch success payment liabilities. For fiscal 2023, changes in the Fred Hutch success payment liability were recognized in other income (expense) net as Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration as of December 2022. Other income (expense), net of $1.9 million for the year ended December 31, 2022 consisted primarily of a gain of $2.9 million for the year ended December 31, 2022 to record the estimated fair value of PACT Pharma Inc. (PACT) Series D convertible preferred shares acquired, offset by a decrease of $1.1 million in the fair value of an equity warrant investment held for the year ended December 31, 2022.

Impairment of Other Investments

For the year ended December 31, 2023, the $12.9 million impairment consisted of the full impairment of two of our other investments. For the year ended December 31, 2022, the $5.0 million impairment consisted of the full impairment of one of our other investments. See Note 5, *Other Investments*, in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8, of this Annual Report on Form 10-K for additional information.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through the sale and issuance of convertible preferred stock, the sale of common stock in connection with our IPO and business development activities. As of December 31, 2023, we had $562.7 million in cash, cash equivalents and marketable securities. Since our inception, we have incurred significant operating losses. We have not yet commercialized any product candidates and we do not expect to generate revenue from sales of any product candidates for a number of years, if ever. We had an accumulated deficit of $1.0 billion as of December 31, 2023. From June 29, 2018 (inception) through December 31, 2023, we raised an aggregate of $1.4 billion in gross proceeds from the sales of our convertible preferred stock and the IPO.

On February 28, 2024, we entered into a sales agreement (the Sales Agreement) with Cowen and Company, LLC as the Company's sales agent (Agent) with respect to an at-the-market offering program. In accordance with the terms of the Sales Agreement, we may offer and sell from time to time through the Agent shares of our common stock having an aggregate offering amount of up to $150.0 million (the Placement Shares). Sales of the Placement Shares, if any, will be made at prevailing market prices on Nasdaq at the time of sale, or as otherwise agreed with the Agent, by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415 of the Securities Act. We will pay commissions to the Agent of up to 3% of the gross proceeds of the sale of the Placement Shares sold under the Sales Agreement and reimburse the Agent for certain expenses. Neither us nor the Agent is obligated to sell any shares and, to date, we have not made any sales under the Sales Agreement.

Future Funding Requirements

We expect to incur additional losses in the foreseeable future as we conduct and expand our research and development efforts, including conducting nonclinical studies and clinical trials, developing new product candidates, establishing internal manufacturing capabilities and funding our operations generally. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our working capital and capital expenditure needs into 2027. However, we anticipate that we will need to raise additional capital in the future to fund our operations, including further development of our product candidates and the commercialization of any approved product candidates. In addition, we regularly consider fund-raising opportunities and may decide, from time to time, to raise additional capital, including pursuant to the Sales Agreement, based on various factors, including market conditions and our plans of operation. We are subject to the risks typically related to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

Our future capital requirements will depend on many factors, including:

- the scope, timing, progress, costs and results of discovery, nonclinical development and clinical trials for our current and future product candidates and any additional nonclinical studies;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- further investment to build additional manufacturing facilities or expand the capacity of our existing ones;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to maintain existing, and establish new, collaborations, licenses, product acquisitions or other strategic transactions and the fulfillment of our financial obligations under any such agreements, including the

timing and amount of any success payment, future contingent payments, milestone, royalty or other payments due under any such agreement;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs and estimated financial impact of our reduction in workforce in the fourth quarter of 2023;
- the costs of operating as a public company, including legal, accounting and other related expenses as well as costs relating to maintaining or expanding our operational, financial and management systems;
- addressing or responding to any potential disputes or litigation; and
- the extent to which we acquire or invest in businesses, products and technology platforms.

Until such time as we complete nonclinical and clinical development and receive regulatory approval of our product candidates and can generate significant revenue from product sales, if ever, we expect to finance our operations from the sale of additional equity or debt financings, or other capital which come in the form of strategic collaborations, licensing, or other arrangements. In the event that additional capital is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible debt securities, including pursuant to the Sales Agreement, it may result in dilution to our existing stockholders. Debt financing or preferred equity financing, if available, may result in increased fixed payment obligations, and the existence of securities with rights that may be senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that may restrict our operations. If we raise funds through strategic collaboration, licensing, or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from actual or perceived changes in interest rates and economic inflation, and otherwise. If we are unable to raise additional capital when desired, our business, results of operations and financial condition would be adversely affected.

Material Cash Requirements

We continually evaluate our liquidity and capital resources to ensure that we can adequately and efficiently finance our operations. As of December 31, 2023, our material cash requirements consisted primarily of paying salaries and benefits, administering clinical trials, conducting research, improving our manufacturing capabilities, providing the technology and facilities necessary to support our operations, funding operating lease obligations and other payments related to our collaborative agreements. See Note 3, *License, Collaboration and Success Payment Agreements*, and Note 9, *Leases*, in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8, of this Annual Report on Form 10-K for additional information.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Net cash (used in) provided by:			
Operating activities	$ (163,694)	$ (169,555)	$ (126,249)
Investing activities	184,048	(11,540)	(121,573)
Financing activities	1,743	10,635	401,244
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 22,097	$ (170,460)	$ 153,422

Operating Activities

During the year ended December 31, 2023, net cash used in operating activities was $163.7 million, primarily reflecting our net loss of $234.6 million, partially offset by non-cash items primarily related to stock-based compensation expense of $47.1 million, depreciation and amortization expense of $20.3 million and impairment of other investments of $12.9 million. Non-cash net amortization and accretion on marketable securities of $9.6 million also contributed to net cash used in operating activities.

During the year ended December 31, 2022, net cash used in operating activities was $169.6 million, primarily reflecting our net loss of $183.1 million, partially offset by non-cash items mainly related to stock-based compensation expense of $81.9 million, depreciation and amortization expense of $18.0 million and impairment of other investments of $5.0 million. Non-cash deferred revenue of $84.7 million also contributed to net cash used in operating activities.

Investing Activities

During the year ended December 31, 2023, cash provided by investing activities was $184.0 million, consisting of net maturities, sales and purchases of marketable securities of $186.7 million, partially offset by purchases of property and equipment of $2.7 million. During the year ended December 31, 2022, cash used in investing activities was $11.5 million, consisting of purchases of property and equipment of $24.3 million offset by net maturities, sales and purchases of marketable securities of $12.7 million.

Financing Activities

During the year ended December 31, 2023, cash provided by financing activities was $1.7 million, consisting of $1.9 million in proceeds from our employee stock purchase plan and $0.3 million in proceeds from the exercise of stock options, partially offset by $0.5 million in taxes paid related to the net share settlement of equity awards. During the year ended December 31, 2022, cash provided by financing activities was $10.6 million, consisting of $9.6 million in proceeds from the exercise of stock options and $1.5 million in proceeds from our employee stock purchase plan, partially offset by $0.5 million in taxes paid related to the net share settlement of equity awards.

Critical Accounting Policies and Significant Judgments and Estimates

Our audited consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the audited consolidated financial statements, as well as the reported revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. While our significant accounting policies are described in more detail in the notes to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

Revenue Recognition

We recognize revenue from research services generally as services are provided while revenue from non-refundable upfront fees are recognized over time by measuring progress towards satisfaction of the relevant performance obligation using the input method (*i.e.*, cumulative actual costs incurred relative to total estimated costs).

The estimation of measure of progress is complex, involves significant judgment and is affected by our estimates of the total costs required to complete the performance obligations including the total internal personnel costs and external costs to be incurred. Changes in these estimates can have a material effect on our revenue recognition.

For a further description of our revenue recognition, see Note 2, *Basis of Presentation and Significant Accounting Policies,* in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8, of this Annual Report on Form 10-K.

Success Payments

We are required to make success payments to Fred Hutch and Stanford based on increases in the per share market value of our common stock, payable in cash or cash equivalents or, at our discretion, publicly tradeable shares of our common stock. The success payments are accounted for under Accounting Standards Codification (ASC) 718, *Compensation – Stock Compensation*, and are initially recorded at fair value with a corresponding charge to research and development expense. The liabilities are marked to market at each balance sheet date with all changes in value recognized in research and development expense in the Consolidated Statements of Operations and Comprehensive Loss. Once their service periods are complete , the success payment fair value changes are recorded in other income (expense), net. We will continue to adjust the liabilities for changes in fair value until the earlier of the achievement or expiration of the success payment obligation. To determine the estimated fair value of the success payments, we use a Monte Carlo simulation

model, which models the value of the liability based on several key variables that require judgment, including the expected fair value and volatility of our common stock, estimated term and number of valuation measurement dates.

Stock-based Compensation

Stock-based compensation cost is recognized for restricted stock awards (RSAs), restricted stock units (RSUs), employee stock purchases related to the Employee Stock Purchase Plan and stock options. Stock-based compensation cost is measured at the grant date based on the fair value of the award. The fair value of stock-based awards is recognized as an expense on a straight-line basis over the requisite service period, with forfeitures recognized as they occur.

We use the Black-Scholes model to determine the fair value of our options. The Black-Scholes option pricing model requires the use of assumptions, including stock price volatility, the expected life of stock options, risk-free interest rate and the fair value of the underlying common stock on the date of grant. Our restricted stock awards and restricted stock units are valued based on the fair market value of the award on the grant date.

Valuation of Other Investments

We have non-marketable equity investments that are accounted for using the measurement alternative. Under the measurement alternative, the carrying value is measured at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Determining whether an observed transaction is similar to a security within our portfolio requires judgment based on the rights and obligations of the investments. Recording upward and downward adjustments to the carrying value of our equity investments as a result of observable price changes requires quantitative assessments of the fair value of our investments using various valuation methodologies and involves the use of estimates.

We determine at the inception of each arrangement whether an investment or other interest is considered a variable interest entity (VIE). If the investment or other interest is determined to be a VIE, we evaluate whether we are considered the primary beneficiary. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to direct the activities that most significantly impact the VIE's economic performance; and (ii) has the obligation to absorb losses or the right to receive benefits from the VIE. For any investments in VIEs in which we are considered the primary beneficiary, the assets, liabilities and results of operations of the VIE would be included in our consolidated financial statements. As of December 31, 2023 and 2022, there were no VIEs for which we were the primary beneficiary.

Non-marketable equity investments are also subject to periodic impairment reviews. Our quarterly impairment analysis considers both qualitative and quantitative factors that may have a significant effect on the investment's fair value. Qualitative factors considered include the companies' financial and liquidity position, access to capital resources and the time since the last adjustment to fair value, among others. When indicators of impairment exist, we prepare quantitative assessments of the fair value of our equity investments using both the market and income approaches that require judgment and the use of estimates, including discount rates, investee revenues and costs, and comparable market data of private and public companies reasonably available, among others. When our assessment indicates that an impairment exists, we write down the investment to its fair value.

We perform quarterly qualitative assessments of potential indicators of impairment and determined that indicators existed for certain of our other investments during the years ended December 31, 2023, 2022 and 2021. While there was no single event or factor in each instance, we considered the underlying companies' operating cash flow requirements over the next year, liquid asset balances to fund those requirements and the uncertainty regarding the underlying companies' ability to raise funds as indicators of impairment. Due to these indicators, we assessed the valuation of these investments and determined the fair values to be negligible and the impairments to be other-than-temporary in nature. As a result, we recorded impairment expense of $12.9 million for our PACT Series D convertible preferred stock and another investment for the year ended December 31, 2023, $5.0 million for one investment for the year ended December 31, 2022 and $36.4 million for our PACT Series C-1 convertible preferred stock investment for the year ended December 31, 2021. The impairment expenses were recorded within impairment of other investments on the Consolidated Statements of Operations and Comprehensive Loss and as a reduction of the other investments on the Consolidated Balance Sheets.

Recently Adopted and Recent Accounting Pronouncements

See Note 2, *Basis of Presentation and Significant Accounting Policies,* in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for information about recent accounting pronouncements, the timing of their adoption and our assessment, to the extent we have made one yet, of their potential impact on our financial condition or results of operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. Our primary risks include interest rate sensitivities.

Interest Rate Risk

We had cash equivalents of $127.7 million as of December 31, 2023, which consisted of money market funds and highly liquid investments purchased with original maturities of three months or less from the purchase date. We also had marketable securities of $417.1 million as of December 31, 2023. The primary objective of our investment activities is to preserve capital to fund our operations, and we currently do not hedge our interest rate risk exposure. Because our marketable securities are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material effect on our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K. We had no debt outstanding as of December 31, 2023.

Foreign Currency Exchange Risk

All of our employees and operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in their local currency. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 1% change in exchange rates during any of the periods presented would not have a material effect on our consolidated 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 our clinical trial costs. We believe that inflation has not had a material effect on our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 8. Financial Statements and Supplementary Data.

LYELL IMMUNOPHARMA, INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
Years ended December 31, 2023, 2022 and 2021

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Lyell Immunopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lyell Immunopharma, Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2024 expressed an unqualified opinion thereon.

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

Critical Audit Matter

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

Accrued clinical expenses

Description of the Matter	During 2023, the Company incurred $182.9 million of research and development expenses and accrued $5.3 million for research and development expenses as of December 31, 2023, which includes clinical expenses. As described in Note 2 to the consolidated financial statements, clinical expenses are a component of research and development expense. The Company accrues and expenses clinical trial services performed by third parties based upon actual work completed in accordance with agreements established with its service providers. The Company estimates the actual costs through discussions with internal personnel and external service providers as to the progress of the clinical services and the agreed-upon fee to be paid for such services. Auditing management's accounting for accrued clinical expenses is especially challenging because amounts owed to external service providers are accrued based upon estimates of the progress of the clinical services with each respective contract. These estimates require the application of judgment by management that is dependent on inputs, such as the number of sites activated, the number of patients enrolled and the number of patient visits which may be compiled from multiple sources.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design, and tested the operating effectiveness of internal controls over the completeness and measurement of accrued clinical expenses. To test the accrued clinical expenses, our audit procedures included, among other things, testing the accuracy and completeness of the underlying data used in the estimate, inspecting contracts with third-party service providers and obtaining information directly from third parties.

/s/ Ernst & Young LLP

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

San Mateo, California
February 28, 2024

Lyell Immunopharma, Inc.
Consolidated Balance Sheets
(in thousands, except per share amounts)

	As of December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 145,647	$ 123,554
Marketable securities	400,576	516,598
Prepaid expenses and other current assets	8,463	11,143
Total current assets	554,686	651,295
Restricted cash	284	280
Marketable securities, non-current	16,506	70,117
Other investments	32,001	44,924
Property and equipment, net	102,654	123,023
Operating lease right-of-use assets	39,663	43,242
Other non-current assets	4,235	4,680
Total assets	$ 750,029	$ 937,561
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,817	$ 3,917
Accrued liabilities and other current liabilities	28,126	28,755
Success payment liabilities	1,576	4,356
Total current liabilities	34,519	37,028
Operating lease liabilities, non-current	56,894	63,168
Other non-current liabilities	3,664	4,113
Total liabilities	95,077	104,309
Commitments and contingencies (Note 16)		
Stockholders' equity:		
Preferred stock, $ 0.0001 par value; 10,000 shares authorized at December 31, 2023 and 2022, respectively; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $ 0.0001 par value; 500,000 shares authorized at December 31, 2023 and 2022, respectively; 253,958 and 249,567 shares issued and outstanding at December 31, 2023 and 2022, respectively	25	25
Additional paid-in capital	1,657,133	1,608,306
Accumulated other comprehensive loss	(94)	(7,599)
Accumulated deficit	(1,002,112)	(767,480)
Total stockholders' equity	654,952	833,252
Total liabilities and stockholders' equity	$ 750,029	$ 937,561

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

Lyell Immunopharma, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share amounts)

	Year Ended December 31,		
	2023	2022	2021
Revenue[1]	$ 130	$ 84,683	$ 10,650
Operating expenses:			
Research and development	182,945	159,188	138,693
General and administrative	66,983	117,307	89,057
Other operating income, net	(2,790)	(4,754)	(2,324)
Total operating expenses	247,138	271,741	225,426
Loss from operations	(247,008)	(187,058)	(214,776)
Interest income, net	23,453	7,053	1,165
Other income (expense), net	1,846	1,887	(161)
Impairment of other investments	(12,923)	(5,000)	(36,447)
Total other income (loss), net	12,376	3,940	(35,443)
Net loss	(234,632)	(183,118)	(250,219)
Other comprehensive loss:			
Net unrealized gain (loss) on marketable securities	7,505	(5,976)	(1,879)
Comprehensive loss	$ (227,127)	$ (189,094)	$ (252,098)
Net loss per common share, basic and diluted	$ (0.93)	$ (0.74)	$ (1.84)
Weighted-average shares used to compute net loss per common share, basic and diluted	250,983	247,080	135,918

(1) Includes related-party revenue of zero , $ 84,653 and $ 10,509 for the years ended December 31, 2023, 2022 and 2021, respectively.

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

Lyell Immunopharma, Inc.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)
(in thousands)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	194,474	$1,010,968	15,570	$ 2	$ 41,357	$ 256	$ (334,143)	$ (292,528)
Proceeds from initial public offering, net of $ 33,198 in issuance costs	—	—	25,000	2	391,800	—	—	391,802
Conversion of convertible preferred stock to common stock	(194,474)	(1,010,968)	194,474	20	1,010,948	—	—	1,010,968
Issuance of common stock upon exercise of stock options	—	—	2,750	—	9,442	—	—	9,442
Stock-based compensation	—	—	4,944	—	62,201	—	—	62,201
Other comprehensive loss	—	—	—	—	—	(1,879)	—	(1,879)
Net loss	—	—	—	—	—	—	(250,219)	(250,219)
Balance as of December 31, 2021	—	$ —	242,738	$ 24	$ 1,515,748	$ (1,623)	$ (584,362)	$ 929,787
Issuance of common stock upon exercise of stock options	—	—	3,601	1	9,576	—	—	9,577
Issuance of common stock under employee stock purchase plan	—	—	475	—	1,519	—	—	1,519
Issuance of common stock in connection with restricted stock units, net of tax	—	—	153	—	(461)	—	—	(461)
Stock-based compensation	—	—	2,600	—	81,924	—	—	81,924
Other comprehensive loss	—	—	—	—	—	(5,976)	—	(5,976)
Net loss	—	—	—	—	—	—	(183,118)	(183,118)
Balance as of December 31, 2022	—	$ —	249,567	$ 25	$ 1,608,306	$ (7,599)	$ (767,480)	$ 833,252
Issuance of common stock upon exercise of stock options	—	—	2,996	—	306	—	—	306
Issuance of common stock under employee stock purchase plan	—	—	987	—	1,894	—	—	1,894
Issuance of common stock in connection with restricted stock units, net of tax	—	—	408	—	(457)	—	—	(457)
Stock-based compensation	—	—	—	—	47,084	—	—	47,084
Other comprehensive income	—	—	—	—	—	7,505	—	7,505
Net loss	—	—	—	—	—	—	(234,632)	(234,632)
Balance as of December 31, 2023	—	$ —	253,958	$ 25	$ 1,657,133	$ (94)	$ (1,002,112)	$ 654,952

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

Lyell Immunopharma, Inc.
Consolidated Statements of Cash Flows
(in thousands)

	Year Ended December 31,		
	2023	**2022**	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (234,632)	$ (183,118)	$ (250,219)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	47,084	81,924	62,201
Depreciation and amortization expense	20,250	18,020	13,624
Impairment of other investments	12,923	5,000	36,447
Net amortization and accretion on marketable securities	(9,596)	(930)	1,901
Change in fair value of success payment liabilities	(2,780)	(5,130)	3,713
Non-cash lease (income) expense	(1,873)	(1,553)	911
Loss on property and equipment disposals, net	1,509	103	1,210
Change in fair value of equity warrant	—	1,067	256
Gain on other investments	—	(2,923)	—
Gain on net operating lease liability disposal	—	—	(308)
Changes in operating assets and liabilities:			
Prepaid expenses, other current assets and other assets	3,125	(1,968)	(6,987)
Accounts payable	1,464	667	91
Accrued liabilities and other current liabilities	(719)	(463)	4,542
Deferred revenue	—	(84,653)	(10,508)
Operating lease liabilities, non-current	—	4,855	13,202
Other non-current liabilities	(449)	(453)	3,675
Net cash used in operating activities	(163,694)	(169,555)	(126,249)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property and equipment	(2,686)	(24,276)	(65,504)
Purchases of marketable securities	(476,880)	(406,316)	(673,465)
Sales and maturities of marketable securities	663,614	419,052	617,396
Net cash provided by (used in) investing activities	184,048	(11,540)	(121,573)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from exercise of stock options	306	9,577	9,442
Proceeds from employee stock purchase plan	1,894	1,519	—
Taxes paid related to net share settlement of equity awards	(457)	(461)	—
Proceeds from initial public offering, net of issuance costs	—	—	391,802
Net cash provided by financing activities	1,743	10,635	401,244
Net increase (decrease) in cash, cash equivalents and restricted cash	22,097	(170,460)	153,422
Cash, cash equivalents and restricted cash at beginning of period	123,834	294,294	140,872
Cash, cash equivalents and restricted cash at end of period	$ 145,931	$ 123,834	$ 294,294
Represented by:			
Cash and cash equivalents	$ 145,647	$ 123,554	$ 293,828
Restricted cash	284	280	466
Total	$ 145,931	$ 123,834	$ 294,294
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for amounts included in the measurement of lease liabilities	$ 10,845	$ 10,870	$ 8,546
Cash received for amounts related to tenant improvement allowances	$ —	$ 4,761	$ 13,295
Non-cash investing and financing activities:			
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 29	$ 1,325	$ 4,605
Remeasurement of operating lease right-of-use asset for lease modification	$ —	$ 31	$ 3,873
Acquisition of PACT Series D convertible preferred shares	$ —	$ 2,923	$ —
Conversion of convertible preferred stock to common stock upon closing of initial public offering	$ —	$ —	$ 1,010,968

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

Lyell Immunopharma, Inc.
Notes to Consolidated Financial Statements

1. Organization

Lyell Immunopharma, Inc. (the "Company") was incorporated in Delaware in June 2018. The Company is a clinical-stage cell therapy company advancing a pipeline of product candidates for patients with solid tumors utilizing its proprietary ex vivo genetic and epigenetic T-cell reprogramming technologies. The Company's primary activities since incorporation have been to develop T-cell therapies, conduct research and development, acquire technology, enter into strategic collaboration and license arrangements, enable and execute manufacturing activities in support of its product candidate development efforts, organize and staff the Company, conduct business planning, establish its intellectual property portfolio, submit regulatory submissions, execute clinical trials, raise capital and provide general and administrative support for these activities.

Initial Public Offering

In June 2021, the Company successfully completed its initial public offering ("IPO") of its common stock. In connection with its IPO, the Company issued and sold 25,000,000 shares of common stock at an IPO price of $ 17.00 per share. The Company received $ 391.8 million in net proceeds, after deducting underwriting discounts and commissions of $ 29.8 million and offering expenses of $ 3.4 million. Upon the closing of the IPO, 194,474,431 shares of convertible preferred stock then outstanding converted into an equal number of shares of common stock. The related carrying value of the converted preferred stock of $ 1.0 billion was reclassified to common stock and additional paid in-capital.

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany transactions and balances have been eliminated in consolidation.

Liquidity and Management's Plan

The Company discovers and develops product candidates that involve experimental technologies. The product candidates may require several years and substantial expenditures to complete and ultimately may be unsuccessful. The Company plans to finance operations with available cash resources or from the issuance of equity or debt securities. The Company believes that its available cash, cash equivalents and marketable securities as of December 31, 2023 will be adequate to fund its operations at least through the next 12 months from the date these consolidated financial statements are issued.

Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect reported amounts and related disclosures. Specific accounts that require management estimates include, but are not limited to, stock-based compensation, valuation of success payments, valuation of other investments, revenue recognition and accrued expenses. 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 value of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

In June 2022, the Company recorded adjustments to revenue related to a change in estimate in connection with the Collaboration and License Agreement, entered into in 2019 and amended in June 2020 and December 2021 ("GSK Agreement") with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, "GSK"). The Company and GSK mutually agreed to conclude research activities on an undisclosed target for hematological cancers in June 2022. As a result, the Company decreased the related estimated project costs, which resulted in an increase in the measure of proportional cumulative performance. These adjustments increased revenue by $ 83.6 million, decreased net loss by $ 83.6 million and resulted in a $ 0.34 reduction in the Company's basic and diluted net loss per common share for the year ended December 31, 2022.

Comprehensive Loss

Comprehensive loss includes net loss and certain changes in stockholders' equity that are excluded from net loss. For the years ended December 31, 2023, 2022 and 2021, this was comprised of net unrealized gains and losses on the Company's marketable securities.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in commercial paper and money market accounts.

Restricted cash is cash held in a bank account and is used as collateral associated with the Company's corporate credit card program.

Marketable Securities

The Company generally invests its excess cash in investment grade short- to intermediate-term fixed income securities. Such investments are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of comprehensive loss. Realized gains and losses on available-for-sale securities are included in other income (expense), net. The cost of investments sold is based on the specific-identification method. The Company classifies those investments that are not required for use in current operations and that mature in more than 12 months as non-current marketable securities in the accompanying consolidated balance sheets.

Each reporting period, the Company evaluates whether declines in fair value below carrying value are due to expected credit losses, as well as the Company's ability and intent to hold the investment until a forecasted recovery occurs. Expected credit losses, if any, are recorded as an allowance through other income (expense), net.

Valuation of Other Investments

The Company determines at the inception of each arrangement whether an investment or other interest is considered a variable interest entity ("VIE"). If the investment or other interest is determined to be a VIE, the Company evaluates whether it is considered the primary beneficiary. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to direct the activities that most significantly impact the VIE's economic performance; and (ii) has the obligation to absorb losses or the right to receive benefits from the VIE. For any investments in VIEs in which the Company is considered the primary beneficiary, the assets, liabilities and results of operations of the VIE would be included in its consolidated financial statements. As of December 31, 2023 and 2022, there were no VIEs for which the Company was the primary beneficiary.

The Company accounts for its strategic equity interests in common stock and in-substance common stock in non-publicly traded companies for which it does not have the ability to exercise significant influence in accordance with Accounting Standards Codification ("ASC") 321, *Investments – Equity Securities* ("ASC 321"). Upon acquisition, these investments are measured at cost, which represents the then fair value. Under ASC 321, the Company can elect to subsequently measure the investments at initial cost, minus impairment and any changes, plus or minus, resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer ("measurement alternative"). This election must be made for each investment separately. The Company has made this election for all investments in this category and will continue to measure these investments using this method until they no longer qualify to be measured in accordance with this method. Changes in the carrying value of other investments are recognized through net loss. Each reporting period, the Company performs a qualitative assessment to evaluate whether the investment is impaired. The Company's assessment includes a review of recent operating results and trends, recent sales/acquisitions of the investee securities and other factors that raise concerns about the investee's ability to continue as a going concern. If the investment is impaired, an impairment charge is recognized in the amount by which the carrying amount of the investment exceeds the estimated fair value of the investment, with the impairment charge recognized through net loss. See Note 5, *Other Investments*, for details related to investment impairments recognized during the years ended December 31, 2023, 2022 and 2021.

Additionally, the Company holds an equity warrant investment giving it the right to acquire stock of a non-publicly traded company. Equity warrant investments are recorded within other assets at the estimated fair value, with gains and losses recognized in other income (expense), net. For the year ended December 31, 2022, in conjunction with the impairment of one of the Company's other investments, the associated equity warrant investment's fair value was

determined to be negligible. The Company reduced the equity warrant investment's fair value to zero for the year ended December 31, 2022. See Note 6, *Fair Value Measurements*, for additional details regarding the equity warrant investment.

Property and Equipment, Net

Property and equipment primarily consist of laboratory equipment, computer equipment and software, furniture and fixtures and leasehold improvements. Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method based on the estimated useful lives of the related assets, which are generally three to five years . For leasehold improvements, amortization is calculated using the straight-line method based on the shorter of the useful life or the lease term. When assets are retired or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is recorded in other operating income, net in the period realized. Maintenance and repairs are expensed as incurred. The Company reviews its property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Valuation of Long-lived Assets

Long-lived assets are reviewed each reporting period for impairment or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable, which may warrant adjustments to carrying values or estimated useful lives. Recoverability is measured by comparison of the carrying amount of an asset group to the future net undiscounted cash flows that the assets are expected to generate. If the carrying amount of an asset group exceeds its estimated future cash flows, an impairment charge is recognized in the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There has been no impairment of long-lived assets for any of the periods presented.

Leases

The Company leases certain office, laboratory and manufacturing spaces. In addition to minimum rent, the leases require payment of real estate taxes, insurance, common area maintenance charges and other executory costs. At inception of a contract, the Company determines whether an arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. For all leases, the Company determines the classification of the lease as either operating or financing. As of December 31, 2023 and 2022, all of the Company's leases were classified as operating leases.

The Company recognizes right-of-use ("ROU") assets and lease liabilities at the lease commencement date based on the present value of future lease payments over the lease term. As the Company's leases do not provide an implicit rate, an incremental borrowing rate at each lease commencement date is used to determine the present value of future lease payments. The incremental borrowing rate is the rate of interest that the Company would pay to borrow equivalent funds on a collateralized basis at the lease commencement date. To estimate the incremental borrowing rate, a credit rating applicable to the Company is estimated using a synthetic credit rating analysis since the Company does not currently have a rating agency-based credit rating. The ROU asset includes any lease payments made prior to the lease commencement date and is reduced by any lease incentives received or deemed payable to the Company. The lease term may include options to extend or terminate the lease when it is reasonably certain that a lease option will be exercised. Lease expense is recognized on a straight-line basis over the lease term within operating expenses on the Consolidated Statements of Operations and Comprehensive Loss.

The Company has elected the practical expedient to not separate lease and non-lease components for real estate leases. Additionally, the Company has elected the short-term lease recognition exemption for all short-term leases and as a result, lease liabilities and ROU assets are not included on the consolidated balance sheets for leases with an initial term of 12 months or less.

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in

determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

The Company's financial instruments, in addition to those presented in Note 6, *Fair Value Measurements*, include cash, restricted cash, other investments, accounts payable and accrued liabilities and other current liabilities. The carrying amount of cash, restricted cash, accounts payable and accrued liabilities and other current liabilities approximate fair value because of the short-term nature of these instruments. As described in Note 5, *Other Investments*, other investments are carried at cost, minus impairment and any changes, plus or minus, resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements within the scope of ASC 606, *Revenue from Contracts with Customers* , ("ASC 606") the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the performance obligation is satisfied.

In applying the ASC 606 framework, the Company must apply judgment to determine the nature of the promises within a revenue contract and whether those promises represent distinct performance obligations. In determining the transaction price, the Company does not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of cumulative revenue when the uncertainty is resolved. Milestone and other forms of variable consideration that the Company may earn are subject to significant uncertainties of research and development related achievements, which generally are deemed not probable until such milestones are actually achieved. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Additionally, the Company develops assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. The Company then allocates the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation, for which it recognizes revenue as or when the performance obligations are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the variable consideration and any related constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis.

Under the Company's license agreements, the Company grants the license to a customer as it exists at the point of transfer and the nature of the license is a right to use the Company's intellectual property as transferred. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time.

Research and Development Expense

The Company records expense for research and development costs as incurred. Research and development expenses consist of costs incurred by the Company for the discovery and development of its technology platforms and product candidates and includes costs incurred in connection with strategic collaborations, costs to license technology, personnel-related costs, including stock-based compensation expense, facility and technology related costs, research and laboratory expenses, as well as other expenses, which include consulting fees and other costs. Upfront payments and milestones paid to third parties in connection with technology platforms that have not reached technological feasibility and do not have an alternative future use are expensed as incurred.

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Notes to Consolidated Financial Statements—(Continued)

Clinical expenses are a component of research and development expense. The Company accrues and expenses clinical trial services performed by third parties based upon actual work completed in accordance with agreements established with its service providers. The Company estimates the costs through discussions with internal personnel and external service providers as to the progress or stage of completion of services and the agreed-upon fees to be paid for such services.

General and Administrative Expense

General and administrative costs are expensed as incurred and include personnel-related expenses, including stock-based compensation expense for personnel in executive, legal, finance and other administrative functions, legal costs, transaction costs related to collaboration and licensing agreements, as well as fees paid for accounting and tax services, consulting fees and facilities costs not otherwise included in research and development expenses. Legal costs include those related to corporate, dispute and patent matters.

Success Payments

The Company granted rights to success payments to Fred Hutchinson Cancer Center ("Fred Hutch") and The Board of Trustees of the Leland Stanford Junior University ("Stanford") pursuant to the terms of its research and collaboration agreements with each of those entities. Pursuant to the terms of these agreements, on each contractually prescribed measurement date, the Company may be required to make success payments based on increases in the estimated per share fair value of the Company's common stock. See Note 3, *License, Collaboration and Success Payment Agreements*. The success payments are accounted for under ASC 718, *Compensation – Stock Compensation*, with the expense being recorded in research and development expenses. Once the service period is complete, the instrument continues to be remeasured each reporting period with all changes in value recognized immediately in other income (expense), net.

The success payment liability is estimated at fair value at inception and at each subsequent reporting period, and the expense is accreted over th e service period of the research and collaboration agreement. To determine the estimated fair value of the success payments, the Company uses a Monte Carlo simulation methodology which models the future movement of stock prices based on several key variables combined with empirical knowledge of the process governing the behavior of the stock price. The following variables were incorporated in the estimated fair value of the success payment liability: estimated fair value of the Company's common stock, expected volatility, risk-free interest rate and the estimated number and timing of valuation measurement dates on the basis of which payments may be triggered. The computation of expected volatility was estimated based on available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption.

Concentrations of Credit Risk and Off-balance Sheet Risk

The Company maintains its cash, cash equivalents and restricted cash with high quality, accredited financial institutions. Restricted cash is cash held in a bank account and is used as collateral associated with the Company's corporate credit card program. Cash, cash equivalents and restricted cash amounts, at times, may exceed federally insured limits. The Company also makes short-term investments in money market funds, U.S. Treasury securities, U.S. government agency securities and corporate debt securities, which can be subject to certain credit risk. However, the Company mitigates the risks by investing in high-grade instruments, limiting exposure to any one issuer or type of investment and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any credit losses in such accounts and does not believe it is exposed to significant risk on these funds. The Company has no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Claims and Contingencies

From time to time, the Company may become involved in litigation and proceedings relating to claims arising from the ordinary course of business. The Company accrues a liability if the likelihood of an adverse outcome is probable and the amount is estimable. If the likelihood of an adverse outcome is only reasonably possible (as opposed to probable), or if an estimate is not determinable, the Company provides disclosure of a material claim or contingency.

Lyell Immunopharma, Inc.
Notes to Consolidated Financial Statements—(Continued)

Stock-based Compensation

Under ASC 718, the Company measures and recognizes expense for restricted stock awards ("RSAs"), restricted stock units ("RSUs"), employee stock purchases related to the Employee Stock Purchase Plan and stock options granted to employees, directors and consultants based on the fair value of the awards on the date of grant. The fair value of stock options is estimated using the Black-Scholes option pricing model. The Black-Scholes option pricing model requires inputs based on certain subjective assumptions including: stock price volatility, the expected term of stock options, the risk-free interest rate, expected dividends, and the fair value of the underlying common stock on the date of grant.

The expected volatility is based on the historical volatility of the stock of similar entities within the Company's industry over periods commensurate with the Company's expected term assumption. The expected term of stock option grants represents the period the options are expected to remain outstanding and is based on the "simplified" method where the expected term is the midpoint between the vesting date and the end of the contractual term for each option. The Company generally uses the simplified method as provided for under the applicable guidance for entities with a limited history of relevant stock option exercise activity. The Company bases the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term. In reference to the expected dividend yield assumption, the Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend.

Stock-based compensation expense for RSAs, RSUs and stock options is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures as they occur.

The Company also granted stock options that vest in conjunction with certain performance conditions to certain key employees. At each reporting date, the Company is required to evaluate whether achievement of the performance conditions is probable. Compensation expense is recorded over the appropriate service period based upon the Company's assessment of accomplishing each performance provision.

Income Taxes

The Company determines its deferred tax assets and liabilities based on the differences between the financial reporting and tax basis of assets and liabilities. The deferred tax assets and liabilities are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that the deferred tax asset will not be recovered. The Company applies judgment in the determination of the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Company recognizes any material interest and penalties related to unrecognized tax benefits in income tax expense.

Segments

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

Recently Issued Accounting Pronouncements

Segment Reporting

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which expands disclosures about a public entity's reportable segments and requires more enhanced information about a reportable segment's expenses, interim segment profit or loss, and how a public entity's chief operating decision maker uses reported segment profit or loss information in assessing segment performance and allocating resources. Entities with a single reportable segment are required to provide all the updated and existing segment disclosures required by Topic 280. The amendments are effective for annual periods beginning after December 15, 2023 and interim periods within fiscal years

beginning after December 15, 2024 on a retrospective basis. The Company is assessing the effect of the new disclosure requirements and does not anticipate the adoption will have a material impact.

Income Taxes

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which includes amendments that further enhance income tax disclosures, primarily through standardization and disaggregation of rate reconciliation categories and income taxes paid by jurisdiction. The amendments are effective for annual periods beginning after December 15, 2024 and may be applied either prospectively or retrospectively. The Company is assessing the effect of the new disclosure requirements and does not anticipate the adoption will have a material impact.

3. License, Collaboration and Success Payment Agreements

Fred Hutch

License Agreement - In 2018, the Company entered into a license agreement with Fred Hutch that grants the Company a worldwide, sublicensable license under certain patent rights (exclusive) and certain technology (non-exclusive) to research, develop and commercialize products and processes for all fields of use employing chimeric antigen receptors (“CARs”) and/or T-cell receptors (“TCRs”), subject to certain exceptions.

The Company is required to pay Fred Hutch annual license maintenance payments of $ 50,000 on the second anniversary of the effective date, and each anniversary of the effective date thereafter until the first commercial sale of a licensed product.

Collaboration - In 2018, the Company entered into a research and collaboration agreement with Fred Hutch (“Fred Hutch Collaboration Agreement”) focused on research and development of cancer immunotherapy products. The Company funded aggregate research performed by Fred Hutch of $ 12.0 million under the Fred Hutch Collaboration Agreement with the research conducted in accordance with a research plan and budget approved by the parties. The Fred Hutch Collaboration Agreement has a six-year term. The Company incurred $ 0.9 million, $ 1.7 million and $ 4.2 million in expense in connection with the Fred Hutch Collaboration Agreement for the years ended December 31, 2023, 2022 and 2021, respectively.

Success Payments - In 2018, the Company granted Fred Hutch rights to certain success payments, pursuant to the terms of the Fred Hutch Collaboration Agreement. The potential payments for the Fred Hutch success payments are based on multiples of increased value ranging from 10 x to 50 x based on a comparison of the per share fair market value of the Company’s common stock relative to the original $ 1.83 per share issuance price of the Company’s Series A convertible preferred stock, which converted into an equal number of shares of the Company’s common stock in connection with the Company’s IPO. The aggregate success payments to Fred Hutch are not to exceed $ 200.0 million, which would only occur upon a 50 x increase in value. Each threshold is associated with a success payment, ascending from $ 10.0 million at $ 18.29 per share to $ 200.0 million at $ 91.44 per share, payable if such threshold is reached during the measurement period. Any previous success payments made are credited against the success payment owed as of any valuation date, such that Fred Hutch does not receive multiple success payments in connection with the same threshold. The term of the success payment agreement ends on the earlier to occur of (i) the nine-year anniversary of the date of the agreement and (ii) a change in control transaction.

The following table summarizes the aggregate potential success payments, which are payable to Fred Hutch in cash or cash equivalents, or at the Company’s discretion, publicly-tradeable shares of the Company’s common stock:

Multiple of initial equity value at issuance	10 x	20 x	30 x	40 x	50 x
Per share common stock price required for payment	$ 18.29	$ 36.58	$ 54.86	$ 73.15	$ 91.44
Aggregate success payment(s) (in millions)	$ 10	$ 40	$ 90	$ 140	$ 200

The success payments will be owed if the per share fair value of the Company’s common stock on the contractually specified valuation measurement dates during the term of the success payment agreement equals or exceeds the above outlined multiples. The valuation measurement dates are triggered by the following events: the one-year anniversary of the Company’s IPO and each two-year anniversary of the Company’s IPO thereafter, the closing of a change in control transaction and the last day of the term of the success payment agreement, unless the term has ended due to the

closing of a change of control transaction. As of December 31, 2023, no success payments have been incurred as the per share fair value of the Company's common stock was below the price required for payment.

The success payment liability was estimated at fair value at inception and at each subsequent reporting period and the associated expense was accreted over the service period of the success payment obligations as research and development expense through 2022. As of December 31, 2022, the Company's associated success payment liability was fully accreted to fair value as Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. For the year ended December 31, 2023 and future periods, the change in the Fred Hutch success payment liability fair value is recognized in other income (expense), net. The success payment liability was $ 0.7 million and $ 2.5 million as of December 31, 2023 and 2022, respectively. With respect to the Fred Hutch Collaboration Agreement success payment obligations, the Company recognized gains of $ 1.9 million and $ 3.9 million for the years ended December 31, 2023 and 2022, respectively and success payment expense of $ 1.2 million for the year ended December 31, 2021.

Stanford

License Agreement - In 2019, the Company entered into a license agreement with Stanford to license specified patent rights. The Company is required to pay Stanford annual license maintenance payments of $ 50,000 on the second anniversary of the effective date, and each anniversary of the effective date thereafter until the date of the first commercial sale of a licensed product.

Milestone payments to Stanford of up to a maximum of $ 3.7 million per target are payable upon achievement of certain specified clinical and regulatory milestones. The Company is also obligated to pay Stanford $ 2.5 million collectively for all licensed products upon the achievement of a certain commercial milestone. Additionally, low single-digit tiered royalties based on annual net sales of the licensed products are payable to Stanford.

Collaboration Agreement - In October 2020, the Company entered into a research and collaboration agreement with Stanford ("Stanford Collaboration Agreement"), focused on research and development of cellular immunotherapy products. The Stanford Collaboration Agreement has a four-year term. The Company is committed to fund aggregate research performed by Stanford of $ 12.0 million under the Stanford Collaboration Agreement, and the research will be conducted in accordance with a research plan and budget approved by the parties. The Company incurred $ 3.0 million in expense in connection with the Stanford Collaboration Agreement for each of the years ended December 31, 2023, 2022, and 2021, respectively.

Success Payments - In October 2020, the Company granted Stanford rights to certain success payments, pursuant to the terms of the Stanford Collaboration Agreement. The potential payments for the Stanford Collaboration Agreement success payments are based on multiples of increased value ranging from 10 x to 50 x based on a comparison of the per share fair market value of the Company's common stock relative to the original $ 1.83 per share issuance price of the Company's Series A convertible preferred stock, which converted into an equal number of shares of the Company's common stock in connection with the closing of the Company's IPO. The aggregate success payments to Stanford are not to exceed $ 200.0 million, which would only occur upon a 50 times increase in value. Each threshold is associated with a success payment, ascending from $ 10.0 million at $ 18.29 per share to $ 200.0 million at $ 91.44 per share, payable if such threshold is reached during the measurement period. Any previous success payments made are credited against the success payment owed as of any valuation date, so that Stanford does not receive multiple success payments in connection with the same threshold. The term of each success payment agreement ends on the earlier to occur of (i) the nine year anniversary of the date of the agreement and (ii) a change in control transaction.

The following table summarizes the aggregate potential success payments, which are payable to Stanford in cash or cash equivalents, or at the Company's discretion, publicly-tradeable shares of the Company's common stock:

Multiple of initial equity value at issuance	10 x	20 x	30 x	40 x	50 x
Per share common stock price required for payment	$ 18.29	$ 36.58	$ 54.86	$ 73.15	$ 91.44
Aggregate success payment(s) (in millions)	$ 10	$ 40	$ 90	$ 140	$ 200

The success payments will be owed if the per share fair value of the Company's common stock on the contractually specified valuation measurement dates during the term of the success payment agreement equals or exceeds the above outlined multiples. The valuation measurement dates are triggered by the following events: the one-year anniversary of the Company's IPO and each two-year anniversary of the Company's IPO thereafter, the closing of a change in control transaction and the last day of the term of the success payment agreement, unless the term has ended due to the

closing of a change of control transaction. As of December 31, 2023, no success payments have been incurred as the per share fair value of the Company's common stock was below the price required for payment.

The estimated fair values of the success payments to Stanford as of December 31, 2023 and 2022 were $ 1.1 million and $ 3.3 million, respectively. The success payment liability is estimated at the fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Stanford Collaboration Agreement as research and development expense. The success payment liability was $ 0.9 million and $ 1.9 million as of December 31, 2023 and 2022, respectively. With respect to the Stanford Collaboration Agreement success payment obligations, the Company recognized gains of $ 0.9 million and $ 1.2 million for the year ended December 31, 2023 and 2022, respectively and success payment expense of $ 2.5 million for the year ended December 31, 2021.

GSK

In 2019, the Company entered into the GSK Agreement with GSK for potential T-cell therapies that apply the Company's platform technologies and cell therapy innovations with TCRs or CARs under distinct collaboration programs. The GSK Agreement defined two initial collaboration targets, LYL331 and LYL132, and allowed GSK to nominate seven additional targets through July 2024, though no additional targets were nominated over the life of the GSK Agreement. The Company was expected to perform research and development services for each selected target up until a defined point (the "GSK Option Point"), at which time GSK would decide whether or not to exercise an option to obtain a license from the Company ("License Option") and take over the future development and commercialization. In April 2021, GSK exercised the License Option on LYL331 (NY-ESO-1 TCR with c-Jun) and assumed sole responsibility for future development and commercialization of the program at its own cost and expense. The investigational new drug ("IND") application for LYL132 was cleared in January 2022, though no patients were treated, and the IND for LYL331 was not submitted to the U.S. Food and Drug Administration. GSK terminated the GSK Agreement effective December 24, 2022 and Lyell has also discontinued any further work on these programs. There are no future performance obligations associated with the GSK Agreement.

The Company received a non-refundable upfront payment of $ 45.0 million under the GSK Agreement. In connection with the GSK Agreement, in May 2019, the Company also entered into a stock purchase agreement with GSK, pursuant to which the Company agreed to sell 30,253,189 shares of Series AA convertible preferred stock at a price of $ 6.78 per share, which was above the issuance date estimated fair value of $ 4.84 per share. The difference between the per share values resulted in $ 58.6 million additional deemed consideration, bringing the total upfront consideration of the GSK Agreement to $ 103.6 million.

The GSK Agreement was deemed to be within the scope of ASC 606, *Revenue from Contracts with Customers*, because GSK engaged the Company to initially provide research and development services, which were outputs of its ongoing activities, in exchange for consideration. In June 2022, the Company recorded adjustments to revenue related to a change in estimate in connection with the GSK Agreement due to GSK and the Company mutually agreeing to conclude research activities on an undisclosed target for hematological cancers. The change in estimate decreased the related estimated project costs, which resulted in an increase in the measure of proportional cumulative performance. These adjustments increased revenue by $ 83.6 million, decreased net loss by $ 83.6 million and resulted in a $ 0.34 reduction in the Company's basic and diluted net loss per common share for the year ended December 31, 2022.

The Company recognized revenue related to the research and development services related to the two initial targets of zero , $ 84.7 million and $ 10.5 million for the years ended December 31, 2023, 2022 and 2021 respectively. As of December 31, 2023, there were no contract assets or contract liabilities related to the license contract.

PACT

In June 2020, the Company entered into a commitment agreement ("PACT Commitment Agreement") with PACT Pharma, Inc. ("PACT") to jointly develop and test an anti-cancer T-cell therapy against solid tumors, in connection with which it also purchased PACT Series C-1 convertible preferred stock, which was recorded in other investments at $ 36.4 million in the Company's Consolidated Balance Sheet. In December 2021, the Company recorded a $ 36.4 million impairment expense for its investment in PACT.

In February 2021, the Company filed a demand for arbitration seeking, among other things, rescission of the PACT Commitment Agreement. On October 1, 2022, the Company entered into a settlement agreement to resolve its outstanding legal dispute with PACT, pursuant to which PACT issued shares of PACT's Series D convertible preferred stock to the Company in exchange for the Company's tender of its PACT Series C-1 convertible preferred stock. The settlement agreement also included the termination of the PACT Commitment Agreement. The Company recorded a gain

of $ 2.9 million in October 2022 for the estimated fair value of the PACT Series D convertible preferred stock, which was included in other investments in the Company's Consolidated Balance Sheet as of December 31, 2022. In September 2023, the Company performed a qualitative assessment of potential indicators of impairment of the PACT Series D convertible preferred stock investment, resulting in $ 2.9 million impairment expense for the year ended December 31, 2023. See Note 5, *Other Investments*, for additional details regarding the PACT investment impairment.

4. Cash Equivalents and Marketable Securities

The fair value and amortized cost of cash equivalents and marketable securities by major security type are as follows (in thousands):

	December 31, 2023			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 62,075	$ —	$ —	$ 62,075
U.S. Treasury securities	374,214	237	(95)	374,356
U.S. government agency securities	48,924	3	(177)	48,750
Corporate debt securities	59,668	—	(62)	59,606
Total cash equivalents and marketable securities	$ 544,881	$ 240	$ (334)	$ 544,787

Classified as:	Fair Value
Cash equivalents	$ 127,705
Marketable securities	400,576
Marketable securities, non-current	16,506
Total cash equivalents and marketable securities	$ 544,787

	December 31, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 67,970	$ —	$ —	$ 67,970
U.S. Treasury securities	277,056	—	(5,257)	271,799
U.S. government agency securities	135,460	1	(1,416)	134,045
Corporate debt securities	221,608	3	(930)	220,681
Total cash equivalents and marketable securities	$ 702,094	$ 4	$ (7,603)	$ 694,495

Classified as:	Fair Value
Cash equivalents	$ 107,780
Marketable securities	516,598
Marketable securities, non-current	70,117
Total cash equivalents and marketable securities	$ 694,495

The fair values of securities held by the Company in an unrealized loss position for less than 12 months were $ 117.8 million and $ 287.8 million, as of December 31, 2023 and 2022, respectively. The fair values of securities held by the Company in an unrealized loss position for greater than 12 months were $ 43.6 million and $ 278.7 million as of December 31, 2023 and 2022, respectively. As of December 31, 2023 and 2022, all of the Company's marketable securities had a maturity date of two years or less, were available for use and were classified as available-for-sale. The Company does not intend to sell these securities nor does the Company believe that it will be required to sell these securities before recovery of their amortized cost basis. The Company determined that there was no material change in the credit risk of the above investments as of both December 31, 2023 and 2022. As such, an allowance for credit losses has not been recognized. Gross realized gains and losses were *de minimis* for the years ended December 31, 2023 and 2022 and as a

result, amounts reclassified out of accumulated other comprehensi ve loss for the years ended December 31, 2023 and 2022 were also *de minimis*. See Note 6, *Fair Value Measurements*, for additional information regarding cash equivalents and marketable securities.

5. Other Investments

From time to time, the Company makes minority ownership strategic investments. As of December 31, 2023 and 2022, the aggregate carrying amounts of the Company's strategic investments in non-publicly traded companies were $ 32.0 million and $ 44.9 million, respectively. These investments are measured at initial cost, minus impairment, if any, and plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Cumulative impairments of strategic investments in equity investments without readily determinable fair values still held as of December 31, 2023 and 2022 were $ 15.0 million and $ 5.0 million, respectively.

As a part of the acquisition of each of the Company's other investments, the Company determines whether an investment or other interest is considered a variable interest. The Company held an interest in one entity as of December 31, 2023 and two entities as of December 31, 2022, that were concluded to be variable interests for which the Company was not the primary beneficiary as the Company did not have the not have the power to direct the activities that most significantly impact the economic performance of the VIEs. As of December 31, 2023 and 2022, the carrying value and maximum exposure to loss of the Company's variable interests were $ 13.0 million and $ 15.9 million, respectively, which are recorded in other investments in the Company's Consolidated Balance Sheets.

In October 2022, the Company received shares of PACT's Series D non-voting convertible preferred stock (See Note 3, *License, Collaboration and Success Payment Agreements*). The Company recognized its investment in PACT preferred stock at its estimated fair value of $ 2.9 million on October 1, 2022, which was included in the Company's Consolidated Balance Sheet within other investments as of December 31, 2022.

During the years ended December 31, 2023, 2022 and 2021, the Company performed qualitative assessments of potential indicators of impairment and determined that indicators existed for certain of its other investments. While there was no single event or factor in each instance, the Company considered the underlying companies' operating cash flow requirements over the next year, liquid asset balances to fund those requirements and the underlying companies' inability to raise funds as indicators of impairment. Due to these indicators, the Company assessed the valuation of these investments and determined the fair values to be negligible and the impairments to be other-than-temporary in nature. As a result, the Company recorded impairment expenses of $ 2.9 million for the PACT Series D convertible preferred stock investment and $ 10.0 million for another investment for the year ended December 31, 2023, $ 5.0 million for an investment for the year ended December 31, 2022 and $ 36.4 million for the PACT Series C-1 convertible preferred stock investment for the year ended December 31, 2021. The impairment expenses were recorded within impairment of other investments on the Consolidated Statements of Operations and Comprehensive Loss and as reductions to the investment balances within other investments on the Consolidated Balance Sheets.

6. Fair Value Measurements

The following table sets forth the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy (in thousands):

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 62,075	$ —	$ —	$ 62,075
U.S. Treasury securities	—	374,356	—	374,356
U.S. government agency securities	—	48,750	—	48,750
Corporate debt securities	—	59,606	—	59,606
Total financial assets	$ 62,075	$ 482,712	$ —	$ 544,787
Financial liabilities:				
Success payment liabilities	$ —	$ —	$ 1,576	$ 1,576
Total financial liabilities	$ —	$ —	$ 1,576	$ 1,576

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	December 31, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 67,970	$ —	$ —	$ 67,970
U.S. Treasury securities	—	271,799	—	271,799
U.S. government agency securities	—	134,045	—	134,045
Corporate debt securities	—	220,681	—	220,681
Total financial assets	$ 67,970	$ 626,525	$ —	$ 694,495
Financial liabilities:				
Success payment liabilities	$ —	$ —	$ 4,356	$ 4,356
Total financial liabilities	$ —	$ —	$ 4,356	$ 4,356

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Level 2 marketable securities include U.S. Treasury securities, U.S. government agency securities and corporate debt securities, which securities are valued using third-party pricing sources. The pricing services applied industry standard valuation models. Inputs utilized include market pricing based on real-time trade data for the same or similar securities and other significant inputs derived from or corroborated by observable market data.

The Company's success payment liabilities are Level 3 financial instruments, which are estimated using Monte Carlo simulations. Monte Carlo simulations model the future movement of stock prices based on several key variables combined with empirical knowledge of the process governing the behavior of the stock price. The following variables were incorporated in the estimated fair value of the success payment liabilities: fair value of the Company's common stock, expected volatility, the risk-free interest rate and the estimated number and timing of valuation measurement dates on the basis of which payments may be triggered. The computation of expected volatility was estimated based on available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption.

The following assumptions were incorporated into the calculation of the estimated fair value of the Fred Hutch success payment liability:

	December 31,	
	2023	2022
Fair value of common stock	$ 1.94	$ 3.47
Risk-free interest rate	3.51 % - 5.19 %	3.58 % - 4.65 %
Expected volatility	80.0 %	80.0 %
Expected term (in years)	0.46 - 3.97	0.46 - 4.97

The following assumptions were incorporated into the calculation of the estimated fair value of the Stanford success payment liability:

	December 31,	
	2023	2022
Fair value of common stock	$ 1.94	$ 3.47
Risk-free interest rate	3.51 % - 5.19 %	3.58 % - 4.65 %
Expected volatility	80.0 %	80.0 %
Expected term (in years)	0.46 - 5.75	0.46 - 6.75

The Company utilizes estimates and assumptions in determining the estimated success payment liabilities and associated changes in fair value. A small change in the valuation of the Company's common stock may have a relatively large change in the estimated fair value of the success payment liability and associated changes in fair value.

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The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial assets and liabilities (in thousands):

	Equity Warrant Investment	Success Payment Liabilities
Balance at December 31, 2021	$ 1,067	$ 9,486
Change in fair value [1]	(1,067)	(5,130)
Balance at December 31, 2022	—	4,356
Change in fair value [1]	—	(2,780)
Balance at December 31, 2023	$ —	$ 1,576

(1) The change in the fair value associated with the Fred Hutch success payment liabilities for the year ended December 31, 2023 is recorded in other income (expense), net. The change in the fair value associated with the Fred Hutch success payment liabilities for the year ended December 31, 2022, and the change in the fair value associated with the Stanford success payment liabilities for the years ended December 31, 2023 and 2022, respectively, are recorded as research and development expenses. (See Note 3, License, Collaboration and Success Payment Agreements). Changes in fair value associated with the equity warrant investment held are recorded in other income (expense), net.

In October 2022, the Company received non-voting PACT Series D convertible preferred stock with an estimated fair value of $ 2.9 million using the cost approach (See Note 3, *License, Collaboration and Success Payment Agreements*). Under this approach, the fair value of an asset is measured by the cost to reconstruct or replace such asset with another one of like utility. The fair value of PACT was estimated by using significant unobservable inputs, including an estimate of insignificant fair value associated with PACT intangible assets. Accordingly, the Company classified the fair value measurement of PACT preferred stock on October 1, 2022 as Level 3 under the fair value hierarchy. In June 2023, the Company performed a qualitative assessment of potential indicators of impairment of the PACT Series D convertible preferred stock investment, resulting in a $ 2.9 million impairment expense for the year ended December 31, 2023. See Note 5, *Other Investments*, for additional details regarding the PACT investment impairment.

7. Property and Equipment, Net

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

	December 31,	
	2023	2022
Leasehold improvements	$ 118,319	$ 116,930
Laboratory equipment	33,368	31,982
Computer equipment and software	1,672	1,630
Furniture and fixtures	814	717
Construction in progress	128	4,148
Property and equipment, at cost	154,301	155,407
Less: Accumulated depreciation and amortization	(51,647)	(32,384)
Total property and equipment, net	$ 102,654	$ 123,023

Depreciation and amortization expense was $ 20.2 million , $ 18.0 million and $ 13.5 million for the years ended December 31, 2023, 2022 and 2021, respectively.

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Notes to Consolidated Financial Statements—(Continued)

8. Accrued Liabilities and Other Current Liabilities

Accrued liabilities and other current liabilities consisted of the following (in thousands):

	December 31,	
	2023	2022
Accrued compensation and related benefits	$ 14,634	$ 15,447
Current lease liabilities	6,273	4,534
Accrued research and development expenses	5,331	4,760
Other	1,493	2,352
Accrued legal	395	930
Accrued property and equipment	—	732
Total accrued liabilities and other current liabilities	$ 28,126	$ 28,755

9. Leases

The Company's lease portfolio is comprised of operating leases for laboratory, office and manufacturing facilities located in South San Francisco, California, and Seattle and Bothell, Washington with contractual periods expiring between December 2028 and March 2031. In addition to minimum rent, the leases require payment of real estate taxes, insurance, common area maintenance charges and other executory costs. These additional charges are considered variable lease costs and are recognized in the period in which the costs are incurred.

In 2018, the Company entered into an operating lease for approximately 34,000 square feet of office and laboratory space in Seattle, Washington, with an initial lease term expiring in December 2028. The Company has two five-year options to extend the lease, which are not reasonably assured.

In 2019, the Company entered into two operating lease agreements for a combined approximately 73,000 square feet of space to develop a cell therapy manufacturing facility located in Bothell, Washington, with initial terms expiring in May 2030. The Company has two 90 -month options to extend the leases, which are not reasonably assured.

In 2019, the Company entered into an operating lease agreement for approximately 108,000 square feet of office and laboratory space located in South San Francisco, California. The initial lease term expires in January 2031 with the option to extend the term for another 10 years, which is not reasonably assured. In January 2021, the Company amended the lease term to extend the lease expiration to March 2031, which resulted in an increase to the right-of-use asset and lease liability of $ 4.2 million.

The following table summarizes the Company's future minimum operating lease commitments, including expected lease incentives to be received, as of December 31, 2023 (in thousands):

Year Ending December 31:	
2024	$ 11,347
2025	11,859
2026	12,209
2027	12,569
2028	12,940
Thereafter	22,585
Total undiscounted lease payments	83,509
Less: imputed interest	(20,342)
Total operating lease liabilities	$ 63,167

Reported as of December 31, 2023:	
Short-term portion of lease liabilities (included in accrued liabilities and other current liabilities)	$ 6,273
Operating lease liabilities, non-current	56,894
Total	$ 63,167

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Notes to Consolidated Financial Statements—(Continued)

The operating lease costs for all operating leases were $ 9.0 million, $ 9.3 million and $ 9.4 million for the years ended December 31, 2023, 2022 and 2021, respectively. The operating lease costs and total commitments for short-term leases were *de minimis* for the years ended December 31, 2023, 2022 and 2021. Variable lease costs for operating leases were $ 5.4 million, $ 5.1 million and $ 4.1 million for the years ended December 31, 2023, 2022 and 2021, respectively. The weighted-average remaining lease terms for operating leases were 6.8 years and 7.8 years as of December 31, 2023 and 2022, respectively. The weighted-average discount rates for operating leases were 8.5 % as of both December 31, 2023 and 2022.

In May 2021, the Company entered into a sublease, whereby the Company agreed to sublease approximately 11,000 square feet of its space in South San Francisco, California currently leased by the Company. The sublease is classified as an operating lease and will expire in March 2031. The Company recognized sublease income for this sublease of $ 0.8 million for both the years ended December 31, 2023 and 2022 and $ 0.4 million for the year ended December 31, 2021.

In September 2021, the Company entered into a sublease with Sonoma Biotherapeutics, Inc. (“Sonoma”), a related party, whereby the Company agreed to sublease approximately 18,000 square feet of space in South San Francisco, California currently leased by the Company. See Note 17, *Related-Party Transactions*. As a part of the sublease, in September 2021, the Company received a $ 4.6 million tenant improvement contribution payment, which will be recognized over the term of the sublease. The sublease is classified as an operating lease and will expire in March 2031. The Company recognized Sonoma sublease income of $ 1.9 million for both the years ended December 31, 2023 and 2022 and $ 0.6 million for the year ended December 31, 2021.

The Company’s sublease income is recognized within other operating income, net in the Consolidated Statements of Operations and Comprehensive Loss.

10. Convertible Preferred Stock

Upon the closing of the IPO, 194,474,431 shares of convertible preferred stock then outstanding converted into an equal number of shares of common stock. As of December 31, 2023, no shares of convertible preferred stock were outstanding.

11. Stockholders’ Equity

Preferred Stock

The Company is authorized to issue 10.0 million shares of preferred stock with a par value $ 0.0001 per share. As of December 31, 2023 and 2022, no shares of preferred stock were outstanding.

Common Stock

The Company is authorized to issue 500.0 million shares of common stock with a par value of $ 0.0001 per share. As of December 31, 2023 and 2022, there were 253,957,709 shares and 249,567,343 shares of the Company’s common stock outstanding, respectively.

12. Stock-based Compensation

2021 Equity Incentive Plan

In June 2021, the Company adopted the 2021 Equity Incentive Plan (“2021 Plan”), which on the date of the underwriting agreement related to the Company’s IPO became effective with an initial reserve of 26,662,087 shares, plus any shares subject to outstanding awards granted under the 2018 Equity Incentive Plan (“2018 Plan”) that, on or after the effectiveness of the 2021 Plan, terminate or expire before exercise or settlement, are not issued because the award is settled in cash, are forfeited because of the failure to vest or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares reserved for issuance under the 2021 Plan automatically increases on January 1 of each year for a period of ten years , beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to (1) 5 % of the total number of shares of the Company’s common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by the Company’s board of directors no later than December 31 of the immediately preceding year. On January 1, 2023, the Company reserved an additional 12,478,367 shares of common stock for issuance under the 2021 Plan representing 5 % of

the total common shares outstanding as of December 31, 2022. Under the 2021 Plan, the Company may grant incentive stock options, non-statutory stock options, RSAs, RSUs, stock appreciation rights, performance awards and other stock-based awards. Terms of stock awards, including vesting requirements, are determined by the Company's board of directors or by a committee authorized by the Company's board of directors, subject to provisions of the 2021 Plan. The term of any stock option granted under the 2021 Plan cannot exceed ten years . Generally, awards granted by the Company vest over four years , but may be granted with different vesting terms. In conjunction with adopting the 2021 Plan, the Company discontinued the 2018 Plan with respect to new equity awards.

As of December 31, 2023 , 26,390,351 shares were available for future issuance pursuant to the 2021 Plan.

2021 Employee Stock Purchase Plan

In June 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP"), which became effective immediately prior to the execution of the underwriting agreement related to the Company's IPO with an initial reserve of 2,470,000 shares. The 2021 ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15 % of their earnings, subject to plan limitations. Unless otherwise determined by the Company's board of directors, employees are able to purchase shares at 85 % of the lower of the fair market value of the Company's common stock on the first date of an offering or on the purchase date. The number of shares of the Company's common stock reserved for issuance under the 2021 ESPP automatically increases on January 1 of each year for a period of ten years , beginning on January 1, 2022 and continuing through January 1, 2031, by the lesser of (1) 1 % of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, and (2) 4,940,000 shares; provided, however, that the Company's board of directors may act to provide a lesser increase in number of shares. The Company's board of directors elected to reserve no additional shares under the 2021 ESPP for the year beginning January 1, 2023. The Company may specify offerings with durations not more than 27 months and may specify shorter purchase periods within each offering. Under the 2021 ESPP, 986,391 , 475,363 and zero shares have been issued for the years ended December 31, 2023, 2022 and 2021, respectively.

As of December 31, 2023 , 3,461,629 shares were available for future issuance pursuant to the 2021 ESPP.

2018 Equity Incentive Plan

In 2018, the Company established the 2018 Plan that provided for the grant of incentive stock options, non-statutory stock options, RSAs, RSUs, stock appreciation rights and other stock-based awards. Terms of stock awards, including vesting requirements, were determined by the board of directors or by a committee authorized by the Company's board of directors, subject to provisions of the 2018 Plan. The term of any stock option granted under the 2018 Plan cannot exceed ten years . Generally, awards granted by the Company vest over four years , but could have been granted with different vesting terms. Pursuant to the terms of the 2021 Plan, any shares subject to outstanding options originally granted under the 2018 Plan that terminate, expire or lapse for any reason without the delivery of shares to the holder thereof become available for issuance pursuant to awards granted under the 2021 Plan. While no shares are available for future issuance under the 2018 Plan, it continues to govern outstanding equity awards granted thereunder.

Stock-based Compensation Expense

Stock-based compensation expense by classification included within the Consolidated Statements of Operations and Comprehensive Loss was as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Research and development	$ 18,207	$ 16,721	$ 15,328
General and administrative	28,877	65,203	46,873
Total stock-based compensation expense	$ 47,084	$ 81,924	$ 62,201

Stock-based compensation expense for the year ended December 31, 2021 included the impact of an award accelerated in connection with the Company's IPO of $ 2.6 million.

Stock Options and RSA Modifications

In November 2023, the Board of Directors of the Company approved, effective November 16, 2023, a one-time repricing of certain stock option awards that had been granted to date under the 2021 Plan and 2018 Plan. The repricing

impacted stock options with exercise prices greater than $ 2.37 held by employees who remained employed as-of November 16, 2023 and were not impacted by the reduction in workforce. The original exercise prices of the repriced stock options ranged from $ 2.61 to $ 17.95 per share for 200 total grantees with 23,416,860 shares repriced. Each stock option was repriced to have a per share exercise price of $ 1.87 , which was the closing price of the Company's common stock on November 16, 2023. To receive the new exercise price, option holders must remain employed with the Company through November 15, 2024. Additionally, the vesting schedule for the unvested shares underlying repriced stock options held by executives at the level of senior vice president and above was extended for an additional year. There were no changes to the vesting schedules for employees below the level of senior vice president. No changes were made to the expiration dates of or number of shares underlying the repriced stock options. Incremental stock-based compensation expense resulting from the repricing was $ 8.9 million in the aggregate. Expense for vested awards will be recognized through November 15, 2024 and expense for unvested awards will be recognized over the remaining service life of the option.

In December 2022, the Company's former chief executive officer ("CEO") resigned. Under the terms of the separation agreement, the former CEO will be available to provide consulting services to the Company through June 15, 2024, with vested options continuing to be exercisable and unvested options continuing to vest through that date. The Company concluded that the obligation to provide consulting services was nonsubstantive, and therefore resulted in a modification of their options due to the reduction of their service level. As the remaining service period was determined to be nonsubstantive, the entire incremental expense of $ 3.7 million associated with the modification was recognized in the fourth quarter of 2022.

In 2021, the Company had modifications due to the reduction in the service level for a previous CEO, who resigned as Executive Chairman in the fourth quarter of 2021, as well as an increase to certain awards' post-termination exercise periods. The modifications in 2021 impacted both vested and unvested awards. Expense associated with vested awards is recognized in the period of the modification and expense associated with unvested awards is recognized over the remaining service life of the options or RSAs. The Company also had option modifications in 2021 for one individual resulting in incremental stock-based compensation expense of $ 1.0 million.

The following table shows the total incremental stock-based compensation expense associated with modifications for previous CEOs by the year in which the modification occurred in the years December 31, 2023, 2022 and 2021 (in thousands):

	December 31,		
	2023	2022	2021
Previous CEO - Options [1]	$ —	$ 3,741	$ —
Previous CEO - Options [2]	—	—	21,948
Previous CEO - RSA [2]	—	—	10,908
Total	$ —	$ 3,741	$ 32,856

(1) The modification for Previous CEO - Options for 2022 is for Ms. Elizabeth Homans, who resigned in December 2022.

(2) The modifications for Previous CEO - Options and Previous CEO - RSA for 2021 are for Dr. Richard Klausner, who resigned as Executive Chairman in October 2021 and is now the Chair of Lyell's Board.

At December 31, 2023, total stock-based compensation cost related to unvested awards not yet recognized was $ 65.3 million, which is expected to be recognized over a remaining weighted-average period of 2.7 years.

Restricted Stock Awards

The Company had no unvested RSAs as of both December 31, 2023 and 2022. The fair value of RSAs vested during the years ended December 31, 2023, 2022 and 2021 was zero , $ 15.2 million and $ 57.1 million, respectively.

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Restricted Stock Units

A summary of the Company's RSU activity was as follows:

	Number of Shares	Weighted-Average Value at Grant Date Per Share
Unvested RSUs as of December 31, 2022	872,077	$ 5.98
RSUs granted	2,621,177	$ 2.22
RSUs vested	(598,024)	$ 3.75
RSUs forfeited or canceled	(822,375)	$ 3.22
Unvested RSUs as of December 31, 2023	2,072,855	$ 2.96

The fair value of RSUs vested during the years ended December 31, 2023 and 2022 was $ 1.4 million and $ 1.5 million, respectively. No RSUs vested during the year ended December 31, 2021.

Stock Options

A summary of the Company's stock option activity was as follows:

	Number of Stock Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding as of December 31, 2022	53,849,045	$ 5.09	7.84	$ 24,887
Granted	12,399,063	$ 2.29		
Exercised	(2,996,262)	$ 0.10		
Canceled or forfeited	(7,655,015)	$ 5.03		
Options outstanding as of December 31, 2023	55,596,831	$ 4.75	6.89	$ 7,368
Options exercisable as of December 31, 2023	33,965,690	$ 5.06	5.76	$ 7,303

The fair value of stock options granted to employees, directors and consultants was estimated on the date of grant using the Black-Scholes option pricing model using the following weighted-average assumptions:

	Year Ended December 31,		
	2023	2022	2021
Risk-free interest rate	4.13 %	2.93 %	0.80 %
Expected volatility	88.0 %	87.3 %	78.7 %
Expected term (in years)	6.06	6.03	6.10
Expected dividend yield	0 %	0 %	0 %

The weighted-average grant date fair value of options granted for the years ended December 31, 2023, 2022 and 2021 was $ 1.69 per share, $ 3.60 per share and $ 6.59 per share, respectively. The intrinsic value of options exercised during the years ended December 31, 2023, 2022 and 2021 was $ 6.5 million, $ 13.9 million and $ 16.1 million, respectively.

13. Income Taxes

The Company has reported pre-tax operating losses for all periods presented. The Company's net losses are derived solely from within the U.S. The Company has not reflected any benefit for corresponding tax net operating loss carryforwards in the accompanying consolidated financial statements. The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

As of December 31, 2023 and 2022, the Company had U.S. federal net operating loss ("NOL") carryforwards of approximately $ 455.2 million and $ 383.3 million, respectively, which were available to reduce future taxable income and do not expire. The Company also had U.S. state NOL carryforwards of $ 537.2 million that begin to expire in 2038. The Company had gross U.S. federal and state tax credits of $ 24.2 million and $ 15.8 million as of December 31, 2023 and

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2022, respectively, which may be used to offset future tax liabilities. The federal NOL carryforward period is indefinite, while the tax credits will begin to expire in 2039. The attributed carryforwards may become subject to annual limitations in the event of certain cumulative changes in the ownership interest of significant stockholders. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. As of December 31, 2023, the Company had a capital loss carryforward of $ 52.5 million, which will expire in 2028.

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations follows:

	Year Ended December 31,		
	2023	2022	2021
Federal statutory tax	21.00 %	21.00 %	21.00 %
State tax, net of federal benefit	7.45	5.10	6.39
Valuation allowance	(29.10)	(28.89)	(22.43)
Collaboration revenue	—	6.72	—
Stock-based compensation	(2.25)	(6.11)	(5.92)
Tax credits	2.96	2.33	0.99
Other	(0.06)	(0.15)	(0.03)
Effective income tax rate	0.00 %	0.00 %	0.00 %

The principal components of the Company's net deferred tax assets were as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 133,141	$ 106,530
Tax credit carryforwards	22,409	14,317
Capital loss carryforward	14,368	—
Accrued liabilities and allowances	3,143	3,692
Deferred revenue	793	904
Amortization	5,243	4,585
Capitalized research and development	51,159	26,199
Investment basis difference	4,104	14,235
Lease liability	17,284	17,656
Stock-based compensation	11,244	7,471
Other	470	1,171
Gross deferred tax assets	263,358	196,760
Valuation allowance	(248,420)	(180,132)
Deferred tax assets, net of valuation allowance	14,938	16,628
Deferred tax liabilities:		
Operating lease right-of-use assets	(10,853)	(11,277)
Property and equipment	(4,085)	(5,351)
Deferred tax liabilities	(14,938)	(16,628)
Net deferred tax assets	$ —	$ —

The Tax Cuts and Jobs Act contained 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 incident 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. The Company has included the impact of this provision, which results in a deferred tax asset of approximately $ 51.2 million as of December 31, 2023.

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The Company maintains a full valuation allowance on its net U.S. deferred tax assets. The assessment regarding whether a valuation allowance is required considers the evaluation of both positive and negative evidence when concluding whether it is more likely than not that deferred tax assets are realizable. In making this assessment, significant weight is given to evidence that can be objectively verified. In its evaluation, the Company considered its cumulative loss in recent years and its forecasted losses in the near-term as significant negative evidence. Based upon a review of the four sources of income identified within ASC 740, *Accounting for Income Taxes* ("ASC 740"), the Company determined that the negative evidence outweighed the positive evidence and a full valuation allowance on its U.S. net deferred tax assets will be maintained. The valuation allowance relates primarily to net U.S. deferred tax assets from net operating loss carryforwards, research and development tax credit carryforwards, research and development expenses capitalized and amortized for tax but deducted for GAAP and stock-based compensation.

The Company will continue to assess the realizability of its deferred tax assets and adjust the valuation allowance as required by ASC 740. The increase in the valuation allowance was $ 68.3 million and $ 52.9 million for the years ended December 31, 2023 and 2022, respectively.

The Company evaluates its uncertain tax positions based on a determination of whether it is more likely than not such position will be sustained based upon its technical merits and upon examination by the relevant income tax authorities with all facts known. The Company applies judgment in its measurement of an uncertain tax position recorded in its consolidated financial statements and tax return. As of December 31, 2023 and 2022, there are no penalties or accrued interest recorded in the consolidated financial statements.

The Company is generally subject to examination by the U.S. federal and local income tax auth orities for all tax years in which a loss carryforward is available. The Company is currently not under examination by the Internal Revenue Service or other jurisdictions for any tax years.

The following table summarized changes to the Company's unrecognized tax benefits (in thousands):

	Year Ended December 31,	
	2023	2022
Beginning balance	$ 400	$ 796
Additions based on tax position related to the current year	—	—
Adjustments based on prior year tax positions	—	(396)
Ending balance	$ 400	$ 400

The Company does not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months.

14. Net Loss Per Share

Basic and diluted net loss per share is calculated by dividing net loss by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company's potentially dilutive shares, which include unvested RSAs, unvested RSUs and options to purchase common stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. Shares subject to options to purchase common stock, unvested RSAs and unvested RSUs were all excluded from consideration in the calculation of diluted net loss per share in all periods presented due to their anti-dilutive effects.

15. Employee Benefit Plan

In January 2019, the Company adopted a 401(k) retirement and savings plan (the "401(k) Plan") covering all of its employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the IRS. Beginning in 2022, the Company sponsors a defined-contribution savings plan with matching 401(k) contributions based upon the amount of the employees' contributions subject to certain limitations. The Company made matching contributions to the 401(k) Plan on behalf of participants of $ 1.2 million and $ 1.0 million for the year ended December 31, 2023 and 2022, respectively, and none for the year ended December 31, 2021.

16. Commitments and Contingencies

Collaboration and License Agreements

The Company has entered into certain collaboration and license agreements, including those identified in Note 3, *License, Collaboration and Success Payment Agreements* above, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial milestones. The Company's obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events that could cause the discontinuance of the programs, including termination of such agreements. Due to the nature of these agreements, the future potential payments are inherently uncertain, and accordingly no amounts had been recorded for the potential future achievement of these targets as of December 31, 2023 and 2022.

17. Related-Party Transactions

In September 2021, the Company entered into a sublease with Sonoma ("Sonoma Sublease"), with whom the Company has common stockholders with board seats, whereby the Company agreed to sublease approximately 18,000 square feet of space in South San Francisco, California currently leased by the Company. Dr. Klausner, the Chair of the Company's board of directors, also serves as Board Chair of the board of directors of Sonoma. As a part of the Sonoma Sublease, a $ 4.6 million tenant improvement contribution payment was made by Sonoma, which is recognized over the term of the Sonoma Sublease. As of both December 31, 2023 and 2022, there were accrued liabilities and other current liabilities of $ 0.5 million, and as of December 31, 2023 and 2022, other non-current liabilities of $ 3.0 million and $ 3.5 million, respectively, in connection with the Sonoma Sublease. Total operating income from Sonoma and income solely attributable to the Sonoma Sublease are shown in the table below (in thousands). Total operating income includes income attributable to the sublease, as well as additional operating fees recognized in "other operating income, net" such as common area maintenance charges. See Note 9, *Leases* , for more detail on the Sonoma Sublease.

	Year Ended December 31,		
	2023	2022	2021
Sonoma other operating income, net	$ 2,592	$ 2,635	$ 1,791
Sonoma sublease income	$ 1,861	$ 1,861	$ 620

The Company was party to the GSK Agreement, who is a holder of more than 10 % of the Company's outstanding common stock. See Note 3, *License, Collaboration, and Success Payment Agreements*. Revenue recognized in connection with the GSK agreement was zero , $ 84.7 million and $ 10.5 million for the years ended December 31, 2023, 2022 and 2021, respectively. GSK terminated the GSK Agreement effective December 24, 2022. See Note 3, *License, Collaboration, and Success Payment Agreements,* for additional details regarding the termination of the GSK Agreement.

18. Workforce Reduction

In November 2023, the Company announced a reduction in its workforce to reduce operating costs and improve operating efficiency, pursuant to which the Company's workforce was reduced by approximately 25 %. The execution of the reduction in workforce was substantially completed by the end of 2023. The Company incurred approximately $ 5.5 million in expenses related to one-time severance payments and other employee-related costs as follows for the year ended December 31, 2023 (in thousands):

	Year Ended December 31, 2023
Research and development	$ 4,630
General and administrative	$ 890
Total expense	$ 5,520

The workforce reduction expenses were incurred in 2023 and cash payments were significantly completed by the end of 2023. The Company has accrued liabilities of approximately $ 1.9 million related to the workforce reduction, which were included in the Company's Consolidated Balance Sheet within Accrued Liabilities and Other Current Liabilities as of December 31, 2023.

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19. Subsequent Events

On February 28, 2024, the Company entered into a sales agreement (the "Sales Agreement") with Cowen and Company, LLC as the Company's sales agent ("Agent") with respect to an at-the-market offering program. In accordance with the terms of the Sales Agreement, the Company may offer and sell from time to time through the Agent shares of the Company's common stock having an aggregate offering amount of up to $ 150.0 million ("the Placement Shares"). Sales of the Placement Shares, if any, will be made at prevailing market prices on Nasdaq at the time of sale, or as otherwise agreed with the Agent, by any method permitted by law deemed to be an "at-the-market offering" as defined in Rule 415 of the Securities Act of 1933, as amended. The Company will pay commissions to the Agent of up to 3 % of the gross proceeds of the sale of the Placement Shares sold under the Sales Agreement and reimburse the Agent for certain expenses. Neither the Company nor the Agent are obligated to sell any shares and, to date, the Company has not made any sales under the Sales Agreement.

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

As of December 31, 2023, management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2023, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Inherent Limitations on Controls and Procedures

Our management, including the principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures and our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well designed and operated, can only provide reasonable assurances that the objectives of the control system are met. The design of a control system reflects resource constraints; the benefits of controls must be considered relative to their costs. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, for our company have been or will be detected. As these inherent limitations are known features of the disclosure and financial reporting processes, it is possible to design into the processes safeguards to reduce, though not eliminate, these risks. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events. While our disclosure controls and procedures and our internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives, there can be no assurance that any design will succeed in achieving its stated goals under all future conditions. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with the policies or procedures. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) for our company. Our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework set forth in "Internal Control—Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). Based on an evaluation under that framework, our management concluded that our internal control over financial reporting was effective at the reasonable assurance level as of December 31, 2023.

The effectiveness of our internal control over financial reporting as of December 31, 2023 has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their report in Part II, Item 8 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Lyell Immunopharma, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Lyell Immunopharma, Inc.'s internal control over financial reporting as of December 31, 2023, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Lyell Immunopharma, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholder's equity (deficit) and cash flows for each of the three years in the period ended December 31, 2023, and the related notes and our report dated February 28, 2024 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Mateo, California

February 28, 2024

Item 9B. Other Information.

During the quarter ended December 31, 2023, none of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement as defined in Item 408(a) and (c) of Regulation S-K, respectively.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Our Board of Directors adopted a Code of Business Conduct and Ethics, which applies to all of our employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics may be viewed at the investors relations portion of our website at https://ir.lyell.com, in the section entitled "Governance Highlights" under "Corporate Governance." We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at the website address and location specified above.

The remainder of the information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

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

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to our Proxy Statement for the 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2023.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a) The following documents are being filed as part of this report:

(1) The following financial statements and the Report of Independent Registered Public Accounting Firm are included in Part II, Item 8:

(2) All financial statement schedules are omitted because the information is inapplicable or presented in the Notes to Consolidated Financial Statements.

(3) The following Exhibits are filed as part of this report.

		Incorporation by Reference				
Exhibit Number	Exhibit Description	Form	File Number	Exhibit/ Appendix Reference	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation.	S-8	333-257249	4.1	6/21/2021	
3.2	Amended and Restated Bylaws.	10-Q	001-40502	3.2	11/07/2023	
4.1	Form of Common Stock Certificate.	S-1/A	333-256470	4.1	6/9/2021	
4.2	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated March 5, 2020.	S-1	333-256470	4.2	5/25/2021	
4.3	Description of Securities	10-K	001-40502	4.3	2/28/2023	
10.1	Lyell Immunopharma, Inc. 2018 Equity Incentive Plan, as amended.	S-1	333-256470	10.1	5/25/2021	
10.2	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise and Restricted Stock Award Agreement under the Lyell Immunopharma, Inc. 2018 Equity Incentive Plan.	S-1	333-256470	10.2	5/25/2021	
10.3	Lyell Immunopharma, Inc. 2021 Equity Incentive Plan.	S-8	333-257249	99.3	6/21/2021	
10.4	Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan.	S-1/A	333-256470	10.4	6/9/2021	
10.5	Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan.	S-1/A	333-256470	10.5	6/9/2021	
10.6	Lyell Immunopharma, Inc. 2021 Employee Stock Purchase Plan.	S-8	333-257249	99.6	6/21/2021	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.7	Lyell Immunopharma, Inc. Non-Employee Director Compensation Policy.	10-Q	001-40502	10.2	11/7/2023	
10.8	Lyell Immunopharma, Inc. Officer Severance Plan.	10-K	001-40502	10.8	3/29/2022	
10.9	Form of Indemnification Agreement by and between the Registrant and its directors and executive officers.	S-1	333-256470	10.9	5/25/2021	
10.10	Amended Offer Letter by and between the Registrant and Richard Klausner, dated July 23, 2020.	S-1	333-256470	10.10	5/25/2021	
10.11	Offer Letter, by and between the Registrant and Lynn Seely, dated December 14, 2022	8-K	001-40502	10.2	12/16/2022	
10.12	Offer Letter by and between the Registrant and Charles Newton, dated February 3, 2021.	S-1	333-256470	10.12	5/25/2021	
10.13	Release and Separation Agreement, by and between the Registrant and Rahsaan Thompson, effective June 24, 2023.	10-Q	001-40502	10.1	8/8/2023	
10.14	Offer Letter by and between the Registrant and Stephen Hill, dated May 9, 2019.	S-1	333-256470	10.14	5/25/2021	
10.15	Offer Letter by and between the Registrant and Matthew Lang, dated May 12, 2023.	10-Q	001-40502	10.1	11/07/2023	
10.16	Offer Letter by and between the Registrant and Gary Lee, dated November 24, 2021.					X
10.17	Severance Waiver by and between the Registrant and Stephen Hill, dated April 19, 2022.	10-Q	001-40502	10.1	5/10/2022	
10.18	Separation, Transition and General Release Agreement, by and between Elizabeth Homans and Lyell Immunopharma, Inc., dated December 15, 2022	8-K	001-40502	10.1	12/16/2022	
10.19	License Agreement by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated January 29, 2019.	S-1	333-256470	10.16	5/25/2021	
10.20	Success Payment Agreement, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University, dated October 1, 2020.	S-1	333-256470	10.17	5/25/2021	
10.21	Success Payment Agreement, by and between the Registrant and Fred Hutchinson Cancer Research Center, dated December 19, 2018.	S-1	333-256470	10.18	5/25/2021	
10.22	Standard Office Lease for Building C by and between the Registrant and Bre Wa Office Owner LLC, dated August 28, 2019.	S-1	333-256470	10.19	5/25/2021	
10.23	Standard Office Lease for Building E by and between the Registrant and Bre Wa Office Owner LLC, dated August 28, 2019.	S-1	333-256470	10.20	5/25/2021	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.24	Lease by and between the Registrant and BMR-500 Fairview Avenue LLC, dated November 27, 2018, as amended.	S-1	333-256470	10.21	5/25/2021	
10.25	Lease Agreement by and between the Registrant and ARE-San Francisco No. 65, LLC, dated August 15, 2019, as amended.	S-1	333-256470	10.22	5/25/2021	
23.1	Consent of independent registered public accounting firm.					X
24.1	Power of Attorney (included on signature page).					X
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a).					X
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a).					X
32.1+	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.					X
97.1	Incentive Compensation Recoupment Policy dated September 6, 2023.					X
101.INS	XBRL Instance Document.	The XBRL instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File.	Formatted as Inline XBRL and contained in Exhibit 101.				

*Portions of this exhibit (indicated by [*]) have been omitted because the registrant has determined that the information is both not material and is the type that the registrant treats as private or confidential.

+ The certifications attached as Exhibit 32.1 accompanying this Annual Report on Form 10-K are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Act of 1934, the Registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of South San Francisco, State of California on February 28, 2024.

LYELL IMMUNOPHARMA, INC.

By:	/s/ LYNN SEELY
Name:	**Lynn Seely, M.D.**
Title:	President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Lynn Seely, Charles Newton and Matthew Lang, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, 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, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this Annual Report on Form 10-K has been signed by the following persons on behalf of the Registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ LYNN SEELY **Lynn Seely, M.D.**	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 28, 2024
/s/ CHARLES NEWTON **Charles Newton**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	February 28, 2024
/s/ RICHARD D. KLAUSNER **Richard D. Klausner, M.D.**	Chair of the Board of Directors	February 28, 2024
/s/ HANS BISHOP **Hans Bishop**	Director	February 28, 2024
/s/ OTIS BRAWLEY **Otis Brawley, M.D.**	Director	February 28, 2024
/s/ CATHERINE FRIEDMAN **Catherine Friedman**	Director	February 28, 2024
/s/ ELIZABETH NABEL **Elizabeth Nabel, M.D.**	Director	February 28, 2024
/s/ ROBERT NELSEN **Robert Nelsen**	Director	February 28, 2024
/s/ WILLIAM RIEFLIN **William Rieflin**	Director	February 28, 2024

Exhibit 10.16

November 24, 2021

Gary Lee Electronic delivery

Re: Offer of Employment by Lyell Immunopharma, Inc.

Dear Gary:

I am very pleased to confirm our offer to you of employment with Lyell Immunopharma, Inc. (the "**Company**"). The opportunity to work with you to build one of the world's great companies whose goal is nothing less than to develop curative therapies for solid tumors is one I am thrilled to have and know that your contributions will help ensure that we will achieve our ambitions.

1. **Position.** I am delighted to offer you a position as Chief Scientific Officer (CSO). Your proposed start date is January 31, 2022. You will be responsible for overseeing the research organization and will initially report to Elizabeth Homans, CEO. Your role is categorized as a Traveler and you will be authorized to be onsite up to 3 days per week depending on Company requirements. You will be based out of our South San Francisco, California office. The Company may change your position, duties, and work location from time to time in its discretion.

2. **Cash Compensation.**

(a) Starting Salary. Your starting salary will be $480,000 per year, less payroll deductions and withholdings, paid on the Company's normal payroll schedule. As a full- time exempt salaried employee, you will be expected to work the Company's normal business hours as well as additional hours as required by the nature of your work assignments, and you will not be entitled to overtime compensation. Your salary will be subject to annual review and may or may not be adjusted in the Company's sole discretion.

(b) Sign-on Bonus Advance. The Company will pay you a sign-on bonus advance of $350,000, less applicable tax and other withholding within thirty (30) days after your start date (the "Sign-On Bonus Advance"). You will earn 50% of the Sign-On Bonus Advance if you remain continuously employed with the Company through the one year anniversary of your Start Date and you will earn the remaining 50% of the Sign-On Bonus Advance if you remain continuously employed with the Company through the second anniversary of your Start Date. If your employment with the Company terminates for any reason other than for Good Reason (as defined in the Officer Severance Benefit Plan) or without Cause, you authorize the Company to consider any unearned portion of the Sign-On Bonus Advance as a payroll advance and to deduct it from any amounts owed to you by the Company, including, without limitation, any accrued but unpaid salary and any unreimbursed business expenses. You agree to repay, within thirty (30) days of your last day of employment with the Company, any unearned portion of the Sign-On Bonus Advance previously paid to you by the Company in advance of becoming earned. If your employment terminates for Good Reason or based on a termination without Cause, the entire Sign-On Bonus Advance will be earned and will not need to be repaid by you. "Cause" as used herein,

and as applicable to any severance benefits for which you are eligible under the Officer Severance Benefit Plan, will mean the definition of Cause in the Officer Severance Benefit Plan.

(c) Target Annual Bonus. In addition, you will be eligible to earn an annual incentive bonus of up to 50 % of your base salary for the fiscal year of the Company (which runs from January 1st to December 31st) during which you commence employment, based on the achievement of performance objectives to be determined by the Company's Board of Directors (the "**Board**") or the Compensation Committee of the Board (the "**Committee**") in the its sole discretion. Any bonus for the fiscal year in which your employment begins will be prorated, based on the number of days you are employed by the Company during that fiscal year. Thereafter, you will be eligible to receive an annual bonus in such amount and upon such terms as shall be determined by the Board or the Committee, in its sole discretion. If you remain on the same standard work hours and have a change to your base salary during the fiscal year, any bonus earned will be calculated based on your target bonus and base salary as of December 31 of that fiscal year. Any bonus for a fiscal year will be paid within 3 months after the close of that fiscal year, and you must be employed on the day that your bonus (if any) is paid in order to earn the bonus. Therefore, if your employment is terminated either by you or the Company for any reason prior to the bonus being paid, you will not have earned the bonus and no partial or prorated bonus will be paid. The determinations of the Board or the Committee with respect to your bonus will be final and binding.

3. **Benefits.** In addition, you will be eligible to participate in regular health insurance, bonus and other employee benefit plans established by the Company for its employees from time to time. The Company reserves the right to change or otherwise modify, in its sole discretion, the preceding terms of employment.

4. **Equity.** We will recommend to the Board of Directors of the Company that you be granted an option to purchase up to 800,000 shares of Common Stock of the Company (the "**Option**"). The Option will be granted under the Company's 2021 Equity Incentive Plan, as amended (the "**Plan**") and associated form of stock option agreement, and will have an exercise price equal to the fair market value of the Company's Common Stock on the date such grant is approved by the Committee. The Option will be subject to the terms and conditions of the Plan and your grant agreement. The Option will vest at the rate of twenty five percent (25%) of the shares at the end of your first anniversary with the Company, and an additional 1/48th of the total shares subject to the Option per month thereafter, so long as you remain employed by the Company. However, the grant of such option by the Company is subject to the Committee's approval and this promise to recommend such approval is not a promise of compensation and is not intended to create any obligation on the part of the Company. Further details on the Plan and any specific option grant to you will be provided upon approval of such grant by the Committee.

5. **Severance Payments/COBRA**. Your employment relationship with the Company is at will, as described below. You will be eligible to receive severance benefits as set forth in that certain Officer Severance Benefit Plan, while in effect and as amended from time to time by the Board or the Committee. You will be considered a Tier 1 employee under the Officer Severance Benefit Plan at all times during your Company employment.

6. **Company Policies**. You will be expected to abide by Company rules and policies (including but not limited to the Company's Code of Business Conduct and Ethics, Insider Trading

Policy, Whistleblower and Complaint Policy and Lyell Workplace Policies), as adopted or modified by the Company from time to time.

7. **Confidentiality.** As an employee of the Company, you will have access to certain confidential information of the Company and you may, during the course of your employment, develop certain information or inventions that will be the property of the Company. To protect the interests of the Company, you will need to sign the Company's standard "Employee Invention Assignment and Confidentiality Agreement" as a condition of your employment. We wish to impress upon you that we do not want you to, and we hereby direct you not to, bring with you any confidential or proprietary material of any former employer or to violate any other obligations you may have to any former employer. Rather, you will be expected to use only that information which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company. You agree that you will not bring onto Company premises, or upload onto any Company systems, any unpublished documents, information or property belonging to any former employer or other person to whom you have an obligation of confidentiality.

8. **No Breach of Obligations to Prior Employers.** You represent that your signing of this offer letter, agreement(s) concerning stock options granted to you, if any, under the Plan (as defined above), and the Company's Employee Invention Assignment and Confidentiality Agreement and your commencement of employment with the Company will not violate any agreement currently in place between yourself and current or past employers. You hereby represent that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company.

9. **Conflicting Obligations**. During the period that you render services to the Company, you agree to not engage in any employment, business or activity that is in any way competitive with the business or proposed business of the Company. You will disclose to the Company in writing any other gainful employment, business or activity that you are currently associated with or participate in that competes with the Company. You will not assist any other person or organization in competing with the Company or in preparing to engage in competition with the business or proposed business of the Company.

10. **At Will Employment**. While we look forward to a long and profitable relationship, should you decide to accept our offer, you will be an at-will employee of the Company, which means the employment relationship can be terminated by either of us for any reason, at any time, with or without prior notice, and with or without cause. Any statements or representations to the contrary (and, indeed, any statements contradicting any provision in this letter) should be regarded by you as ineffective. Further, your participation in any stock option or benefit program is not to be regarded as assuring you of continuing employment for any particular period of time. Any modification or change in your at will employment status may only occur by way of a written employment agreement signed by you and the Chief Executive Officer of the Company.

11. **Background Check.** This offer is contingent upon satisfactory verification of criminal, education, driving and/or employment background and reference checks. This offer can be rescinded based upon data received in this verification.

12. **Work Authorization.** Please note that because of employer regulations adopted in the Immigration Reform and Control Act of 1986, within three (3) business days of starting your new position you will need to present documentation demonstrating that you have authorization to work in the United States.

13. **COVID-19 Vaccination.** This position requires you to work onsite at the Company's facilities and the Company requires that all employees working in its facilities (including attending in-person meetings and events) be fully vaccinated against Covid-19 (except as required by applicable law). Therefore, this offer is contingent upon satisfactory proof that you are fully vaccinated from COVID-19, subject to reasonable accommodations for medical or religious reasons, and/or as otherwise required by applicable law. The Company considers you fully vaccinated once 14 days have passed since you received either the second dose in a two-dose COVID-19 vaccine series or a single-dose COVID-19 vaccine. Acceptance of this offer of employment is contingent on you maintaining a fully vaccinated status (including any vaccine boosters) against COVID-19 and providing vaccination attestation in our Human Resources Information System (UltiPro/UKG). The vaccine (including any vaccine booster) must have been FDA approved, have emergency use authorization from the FDA, or, for persons fully vaccinated outside of the U.S., be listed as approved by the World Health Organization or for emergency use by the World Health Organization.

14. **Governing Law and Arbitration**. This Agreement shall be governed by the law of the State of California. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California. To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this letter Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the

applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

15. **Entire Agreement.** This letter, together with your Employee Invention Assignment and Confidentiality Agreement, constitutes the entire agreement between you and the Company with respect to the subject matter hereof and supersedes all prior offers, negotiations and agreements, if any, whether written or oral, relating to such subject matter. Modifications or amendments to this agreement, other than those changes expressly reserved to the Company's discretion in this letter, must be made in a written agreement signed by you and an officer of the Company. If any provision of this offer letter agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this offer letter agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. You acknowledge that neither the Company nor its agents have made any promise, representation or warranty whatsoever, either express or implied, written or oral, which is not contained in this agreement for the purpose of inducing you to execute the agreement, and you acknowledge that you have executed this agreement in reliance only upon such promises, representations and warranties as are contained herein.

16. **Acceptance.** This offer will remain open until November 29, 2021. If you decide to accept our offer, and I hope you will, please sign the enclosed copy of this letter in the space indicated and return to the People team. We also ask that you sign and return to the People team the Employee Invention Assignment and Confidentiality Agreement that is enclosed. Your signature will acknowledge that you have read and understood and agreed to the terms and conditions of this offer letter and the attached documents, if any. Should you have anything else that you wish to discuss, please do not hesitate to call me.

We look forward to the opportunity to welcome you to the Company.

Very truly yours,

DocuSigned by:
Elizabeth Homans
01FE96764C1C4D5...

Elizabeth Homans, Chief Executive Officer

I have read and understood this offer letter and hereby acknowledge, accept and agree to the terms as set forth above and further acknowledge that no other commitments were made to me as part of my employment offer except as specifically set forth herein.

DocuSigned by:
Gary Lee
B4934DB85ED548D...

Gary Lee

Date signed: 11/24/2021

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

1. Registration Statement (Form S-8 No. 333-257249) pertaining to the Lyell Immunopharma, Inc. 2018 Equity Incentive Plan, the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan and the Lyell Immunopharma, Inc. 2021 Employee Stock Purchase Plan,
2. Registration Statement (Form S-8 No. 333-263952) pertaining to the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan and the Lyell Immunopharma, Inc. 2021 Employee Stock Purchase Plan, and
3. Registration Statement (Form S-8 No. 333-270145) pertaining to the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan ;

of our reports dated February 28, 2024, with respect to the consolidated financial statements of Lyell Immunopharma, Inc., and the effectiveness of internal control over financial reporting of Lyell Immunopharma, Inc., included in this Annual Report (Form 10-K) of Lyell Immunopharma, Inc. for the year ended December 31, 2023.

/s/ Ernst & Young LLP
San Mateo, California
February 28, 2024

Exhibit 31.1

CERTIFICATION PURSUANT TO

RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,

AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lynn Seely, certify that:

1. I have reviewed this annual report on Form 10-K of Lyell Immunopharma, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2024 By: /s/ LYNN SEELY

Lynn Seely, M.D.

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles Newton, certify that:

1. I have reviewed this annual report on Form 10-K of Lyell Immunopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2024 By: /s/ CHARLES NEWTON

Charles Newton

Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), each of the undersigned hereby certifies in her or his capacity as an officer of Lyell Immunopharma, Inc, Inc. (the "Company"), that, to the best of her or his knowledge:

(1) the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, to which this Certification is attached as Exhibit 32.1 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ LYNN SEELY

Lynn Seely, M.D.

President and Chief Executive Officer
(Principal Executive Officer)

Date: February 28, 2024

By: /s/ CHARLES NEWTON

Charles Newton

Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: February 28, 2024

Exhibit 97.1

Lyell Immunopharma, Inc.

Incentive Compensation Recoupment Policy

Adopted by the Compensation Committee
of the Board of Directors: September 9, 2023

1. Introduction

The Compensation Committee (the "***Compensation Committee***") of the Board of Directors (the "***Board***") of Lyell Immunopharma, Inc., a Delaware corporation (the "***Company***"), has determined that it is in the best interests of the Company and its stockholders to adopt this Incentive Compensation Recoupment Policy (this "***Policy***") providing for the Company's recoupment of Recoverable Incentive Compensation that is received by Covered Officers of the Company under certain circumstances. Certain capitalized terms used in this Policy have the meanings given to such terms in Section 3 below.

This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, Rule 10D-1 promulgated thereunder ("***Rule 10D-1***") and Nasdaq Listing Rule 5608 (the "***Listing Standards***").

2. Effective Date

This Policy shall apply to all Incentive Compensation that is received by a Covered Officer on or after October 2, 2023 (the "***Effective Date***"). Incentive Compensation is deemed "***received***" in the Company's fiscal period in which the Financial Reporting Measure specified in the Incentive Compensation award is attained, even if the payment or grant of such Incentive Compensation occurs after the end of that period.

3. Definitions

"***Accounting Restatement***" means an accounting restatement that the Company is required to prepare due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

"***Accounting Restatement Date***" means the earlier to occur of (a) the date that the Board, a committee of the Board authorized to take such action, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement, or (b) the date that a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement.

"***Administrator***" means the Compensation Committee or, in the absence of such committee, the Board.

"***Code***" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

"***Covered Officer***" means each current and former Executive Officer.

"***Exchange***" means the Nasdaq Stock Market.

"***Exchange Act***" means the U.S. Securities Exchange Act of 1934, as amended.

"***Executive Officer***" means the Company's chief executive officer, president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales,

administration, or finance), any other officer who performs a policy-making function, or any other person who performs similar policy-making functions for the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed executive officers of the Company if they perform such policy-making functions for the Company. Policy-making function is not intended to include policy-making functions that are not significant. Identification of an executive officer for purposes of this Policy would include at a minimum executive officers identified pursuant to Item 401(b) of Regulation S-K promulgated under the Exchange Act.

"***Financial Reporting Measures***" means measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures derived wholly or in part from such measures, including Company stock price and total stockholder return ("***TSR***"). A measure need not be presented in the Company's financial statements or included in a filing with the SEC in order to be a Financial Reporting Measure.

"***Incentive Compensation***" means any compensation that is granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure.

"***Lookback Period***" means the three completed fiscal years immediately preceding the Accounting Restatement Date, as well as any transition period (resulting from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period of at least nine months shall count as a completed fiscal year). Notwithstanding the foregoing, the Lookback Period shall not include fiscal years completed prior to the Effective Date.

"***Recoverable Incentive Compensation***" means Incentive Compensation received by a Covered Officer during the Lookback Period that exceeds the amount of Incentive Compensation that would have been received had such amount been determined based on the Accounting Restatement, computed without regard to any taxes paid (*i.e.*, on a gross basis without regard to tax withholdings and other deductions). For any compensation plans or programs that take into account Incentive Compensation, the amount of Recoverable Incentive Compensation for purposes of this Policy shall include, without limitation, the amount contributed to any notional account based on Recoverable Incentive Compensation and any earnings to date on that notional amount. For any Incentive Compensation that is based on stock price or TSR, where the Recoverable Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the Administrator will determine the amount of Recoverable Incentive Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or TSR upon which the Incentive Compensation was received. The Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange in accordance with the Listing Standards.

"***SEC***" means the U.S. Securities and Exchange Commission.

4. Recoupment

(a) Applicability of Policy. This Policy applies to Incentive Compensation received by a Covered Officer (i) after beginning services as an Executive Officer, (ii) who served as an Executive Officer at any time during the performance period for such Incentive Compensation, (iii) while the Company had a class of securities listed on a national securities exchange or a national securities association, and (iv) during the Lookback Period.

(b) Recoupment Generally. Pursuant to the provisions of this Policy, if there is an Accounting Restatement, the Company must reasonably promptly recoup the full amount of the Recoverable Incentive Compensation, unless the conditions of one or more subsections of Section 4(c) of this Policy are met and the Compensation Committee, or, if such committee does not consist solely of independent directors, a majority of the independent directors serving on the Board, has made a determination that recoupment would be impracticable. Recoupment is required regardless of whether the Covered Officer engaged in any misconduct and regardless of fault, and the Company's obligation to recoup Recoverable Incentive Compensation is not dependent on whether or when any restated financial statements are filed.

(c) Impracticability of Recovery. Recoupment may be determined to be impracticable if, and only if:

(i) the direct expense paid to a third party to assist in enforcing this Policy would exceed the amount of the applicable Recoverable Incentive Compensation; provided that, before concluding that it would be impracticable to recover any amount of Recoverable Incentive Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Recoverable Incentive Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange in accordance with the Listing Standards; or

(ii) recoupment of the applicable Recoverable Incentive Compensation would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of Code Section 401(a)(13) or Code Section 411(a) and regulations thereunder.

(d) Sources of Recoupment. To the extent permitted by applicable law, the Administrator shall, in its sole discretion, determine the timing and method for recouping Recoverable Incentive Compensation hereunder, provided that such recoupment is undertaken reasonably promptly. The Administrator may, in its discretion, seek recoupment from a Covered Officer from any of the following sources or a combination thereof, whether the applicable compensation was approved, awarded, granted, payable or paid to the Covered Officer prior to, on or after the Effective Date: (i) direct repayment of Recoverable Incentive Compensation previously paid to the Covered Officer; (ii) cancelling prior cash or equity-based awards (whether vested or unvested and whether paid or unpaid); (iii) cancelling or offsetting against any planned future cash or equity-based awards; (iv) forfeiture of deferred compensation, subject to compliance with Code Section 409A; and (v) any other method authorized by applicable law or contract. Subject to compliance with any applicable law, the Administrator may effectuate recoupment under this Policy from any amount otherwise payable to the Covered Officer, including amounts payable to such individual under any otherwise applicable Company plan or program, *e.g.*, base salary, bonuses or commissions and compensation previously deferred by the Covered Officer. The Administrator need not utilize the same method of recovery for all Covered Officers or with respect to all types of Recoverable Incentive Compensation.

(e) No Indemnification of Covered Officers. Notwithstanding any indemnification agreement, applicable insurance policy or any other agreement or provision of the Company's certificate of incorporation or bylaws to the contrary, no Covered Officer shall be entitled to indemnification or advancement of expenses in connection with any enforcement of this Policy by the Company, including paying or reimbursing such Covered Officer for insurance premiums to cover potential obligations to the Company under this Policy.

(f) Indemnification of Administrator. Any members of the Administrator, and any other members of the Board who assist in the administration of this Policy, shall not be personally liable for any action, determination or interpretation made with respect to this Policy and shall be indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board under applicable law or Company policy.

(g) No "Good Reason" for Covered Officers. Any action by the Company to recoup or any recoupment of Recoverable Incentive Compensation under this Policy from a Covered Officer shall not be deemed (i) "good reason" for resignation or to serve as a basis for a claim of constructive termination under any benefits or compensation arrangement applicable to such Covered Officer, or (ii) to constitute a breach of a contract or other arrangement to which such Covered Officer is party.

5. Administration

Except as specifically set forth herein, this Policy shall be administered by the Administrator. The Administrator shall have full and final authority to make any and all determinations required under this Policy. Any determination by the Administrator with respect to this Policy shall be final, conclusive and binding on all interested parties and need not be uniform with respect to each individual covered by this

Policy. In carrying out the administration of this Policy, the Administrator is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to applicable law, the Administrator may authorize and empower any officer or employee of the Company to take any and all actions that the Administrator, in its sole discretion, deems necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

6. Severability

If any provision of this Policy or the application of any such provision to a Covered Officer shall be adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

7. No Impairment of Other Remedies

Nothing contained in this Policy, and no recoupment or recovery as contemplated herein, shall limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Covered Officer arising out of or resulting from any actions or omissions by the Covered Officer. This Policy does not preclude the Company from taking any other action to enforce a Covered Officer's obligations to the Company, including, without limitation, termination of employment and/or institution of civil proceedings. This Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 ("***SOX 304***") that are applicable to the Company's Chief Executive Officer and Chief Financial Officer and to any other compensation recoupment policy and/or similar provisions in any employment, equity plan, equity award, or other individual agreement, to which the Company is a party or which the Company has adopted or may adopt and maintain from time to time; provided, however, that compensation recouped pursuant to this Policy shall not be duplicative of compensation recouped pursuant to SOX 304 or any such compensation recoupment policy and/or similar provisions in any such employment, equity plan, equity award, or other individual agreement except as may be required by law..

8. Amendment; Termination

The Administrator may amend, terminate or replace this Policy or any portion of this Policy at any time and from time to time in its sole discretion. The Administrator shall amend this Policy as it deems necessary to comply with applicable law or any Listing Standard.

9. Successors

This Policy shall be binding and enforceable against all Covered Officers and, to the extent required by Rule 10D-1 and/or the applicable Listing Standards, their beneficiaries, heirs, executors, administrators or other legal representatives.

10. Required Filings

The Company shall make any disclosures and filings with respect to this Policy that are required by law, including as required by the SEC.

* * * * *