Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

or

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

For the transition period from to

Commission file number 001-40502

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 ☐ No ☒

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

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

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

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

The aggregate market value of the common stock held by non-affiliates of the registrant on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $306 million based on the closing price reported for such date on The Nasdaq Global Select Market.

The registrant had 295,228,868 shares of common stock outstanding as of March 6, 2025.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2025 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, 2024.

Lyell Immunopharma, Inc.
2024 Annual Report on Form 10-K
Table of Contents

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 IMPT-314 or any other product candidates we may develop or acquire, including both nonclinical studies and clinical trials;
- the timing and costs involved in obtaining and maintaining regulatory approvals of IMPT-314 or any other product candidates we may develop or acquire, and the timing or likelihood of regulatory filings and approvals, including any expectations or plans regarding seeking special designations, such as Regenerative Medicine Advanced Therapy designation, Orphan Drug designation or Fast Track designation, for our product candidates for various diseases;
- our plans relating to the commercialization of IMPT-314 or any other product candidates we may develop or acquire, if approved, including the geographic areas of focus, and our ability to commercially differentiate such product candidates and build a sales force;
- the size of the market opportunities for IMPT-314 or any other product candidates we may develop or acquire in each of the diseases we may target;
- our reliance on third parties to conduct research activities for IMPT-314 or any other product candidates we may develop or acquire;
- the characteristics, safety, efficacy and therapeutic effects of IMPT-314 or any other product candidates we may develop or acquire;
- the advancement of our technology platforms and the effectiveness and expected benefits of any of our technologies and manufacturing processes;
- our estimates of the number of patients in the United States and worldwide who suffer from the diseases we target and the number of patients that may enroll in our clinical trials;
- the progress and focus of the 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 IMPT-314 or any other product candidates we may develop or acquire, 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 IMPT-314 or any other product candidates we may develop or acquire, including lines of therapy or 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 IMPT-314 or any other product candidates we may develop or acquire for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance, as well as the pricing and reimbursement, of IMPT-314 or any other product candidates we may develop or acquire, if approved;
- our continued reliance on third parties to assist us in conducting additional clinical trials of IMPT-314 or any other product candidates we may develop or acquire;
- the scope of protection we are able to establish and maintain for intellectual property rights, including covering IMPT-314 and other product candidates and technology platforms we may develop or acquire;
- our ability to retain the continued service of our key personnel and to identify, hire and 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 ability to realize the anticipated benefits of and potential value created by our acquisition of ImmPACT Bio USA Inc. (ImmPACT) or any other acquisition or strategic transaction and our success in commercializing any product candidates we acquire in connection therewith, including IMPT-314;
- the inherent risks, costs and uncertainties associated with integrating the businesses in the merger with ImmPACT successfully and the amount of any costs, fees, expenses, impairments and charges relating to the acquisition of ImmPACT;
- the potential impact of the reported Nasdaq notification on the listing of our common stock or the non-compliance with the Nasdaq listing rules and our intent to monitor the bid price of our common stock and implement available options, including a reverse stock split, if necessary, in order to regain compliance;
- our ability to successfully appeal a delisting determination, if a delisting notice is received, and the impact of any such delisting; and
- our anticipated use of our existing cash, cash equivalents and marketable securities.

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 a clinical-stage biopharmaceutical company that has 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 milestone, royalty and success payment obligations may result in dilution to our stockholders or may reduce the availability of our cash resources to satisfy the payment obligations, which could cause our operating results and financial condition to fluctuate significantly from quarter to quarter and year to year and may reduce the usefulness of our GAAP consolidated financial statements.
- Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which expose us to unforeseen risks and make 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.
- 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 rely on third parties to assist in conducting and monitoring our clinical trials and for some of our research and non-clinical studies 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 in rapidly changing industries, 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 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, initial clinical results in a clinical trial may not be predictive of future results in the same clinical trial and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. If clinical trials of our product candidates fail to produce positive results or demonstrate satisfactory safety and efficacy, at the appropriate dose level or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- 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.
- We recently acquired ImmPACT and may not be able to successfully integrate ImmPACT into our business, including manufacturing of IMPT-314 at our LyFE Manufacturing Center™, or realize the benefits of such acquisition or any potential future collaborations, licenses, product acquisitions or other strategic transactions.
- 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 and other third parties. If we breach any of our license agreements with these licensors, we could potentially lose the ability to continue the development and potential commercialization of one or more of our product candidates.
- We may be unable to comply with the applicable continued listing requirements of The Nasdaq Global Select Market.

PART I

Item 1. Business.

Overview

We are a clinical-stage cell therapy company expecting to enter pivotal trials in 2025 and advancing a pipeline of proprietary next-generation autologous chimeric antigen receptor (CAR) T-cell product candidates for patients with hematologic malignancies and solid tumors. We are pioneering novel approaches designed to generate T cells that drive long-lasting clinical responses. The patient's own living cells are the starting point for our investigational CAR T-cell therapies, and we enhance them with our innovative CAR constructs, technology and manufacturing protocols.

In hematologic malignancies, we are focused on advancing to pivotal trials a product candidate designed to deliver improved outcomes over first-generation CD19 CAR T-cell therapies for patients with B-cell lymphomas. Our lead program, IMPT-314, currently under evaluation for the treatment of aggressive large B-cell lymphoma, is a dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response as compared to the approved CD19-targeted CAR T-cell therapies. IMPT-314 is designed with a true 'OR' logic gate to target B cells that express either CD19 or CD20 with full potency and is manufactured with a process that enriches for CD62L+ cells to generate more naïve and central memory CAR T cells with enhanced stemlike features and antitumor activity.

To realize the potential of cell therapy for solid tumors, we are also developing next-generation CAR T-cell product candidates enhanced with our anti-exhaustion and additional arming technologies and manufactured with our proprietary protocols. These approaches are designed to endow CAR T cells with attributes needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment.

In October 2024, we acquired ImmPACT, a privately-owned clinical stage biotechnology company developing next-generation CAR T-cell product candidates, including IMPT-314.

Our pipeline of next-generation CAR T-cell product candidates target cancers with large unmet need and are summarized in Table 1 below:

Table 1: Lyell's Pipeline

Product	Target	Target Indications	Technology	Preclinical	Phase 1	Phase 2/ Pivotal	Next Expected Milestone
IMPT-314	CD19/CD20	3L+ Aggressive LBCL (Fast Track Designation)	• CD62L+	3L+ CAR T Naïve			• More mature data mid-2025 • Initiate pivotal trial mid-2025
IMPT-314	CD19/CD20	2L Aggressive LBCL	• CD62L+	2L CAR T Naïve			• Initial data mid-2025 • More mature data late-2025 • Initiate pivotal trial by early-2026
Solid Tumor Programs	Undisclosed	Undisclosed	• Anti-exhaustion • Stemness • TME functional enhancement				• First IND in 2026

CAR, chimeric antigen receptor; CD62L+, CD62L or L-selectin positive T cells; IND, Investigational new drug; LBCL, large B-cell lymphoma; TME, tumor microenvironment; 2L, second-line; 3L+, third-line plus

Our Strategy

Our goal is to realize the potential of next-generation CAR T-cell therapies for patients with cancer. We are advancing an innovative CAR T-cell therapy for hematologic malignancies designed to improve outcomes over first-generation products and are progressing the next wave of innovation of CAR T-cell therapy for solid tumors. 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. To realize the potential of cell therapy for cancer, Lyell utilizes a suite of technologies to endow CAR T cells with attributes needed to drive durable tumor cytotoxicity and achieve

consistent and long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment.

Our product candidates target carefully selected tumor antigens and are enhanced with our proprietary technologies and manufacturing protocols designed to generate potent, tumor-reactive, long-lasting and functional T cells to drive durable tumor cytotoxicity.

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

- ***Efficiently advance our clinical-stage pipeline of next-generation CAR T-cell product candidates*** — We believe our autologous T-cell therapies have the potential to deliver improved, durable clinical outcomes for patients with hematologic malignancies and solid tumors. Our most advanced wholly-owned CAR T-cell product candidate, IMPT-314, has the potential to provide meaningfully differentiated benefit in overall and complete response rates and in the duration of the responses over first-generation CD19 CAR T-cell therapies in patients with relapsed/refractory aggressive large B-cell lymphoma. IMPT-314 is currently in Phase 1/2 development, and we recently reported positive initial clinical data in patients with aggressive large B-cell lymphoma in the 3rd line or later (3rd line+) setting. We expect to initiate two pivotal clinical programs: one for patients being treated in the 3rd line+ setting in mid-2025, and another for patients in the 2nd line setting by early 2026.
- ***Advance novel targets and technologies to generate a robust pipeline of next-generation cell therapies designed to deliver durable anti-tumor activity for cancer indications with high unmet medical need and of substantial market size*** — We are committed to continuing the advancement of disruptive technologies designed to revolutionize cell therapy and its promise to improve the lives of patients with hematologic malignancies and solid tumors. In addition to developing novel CAR constructs that target undisclosed tumor antigen targets, we are advancing a suite of stackable proprietary technologies to arm T cells to overcome the barriers presented by solid tumors. Our preclinical programs under development target antigens in solid tumors with high unmet medical need in indications with substantial market size. We have previously validated our proprietary anti-exhaustion technology and intend to stack newer technologies expressing novel chimeric proteins designed to fully arm our CAR T-cell product candidates to optimize CAR T-cell killing in the hostile tumor microenvironment and enable durable anti-tumor function in the solid tumor setting. We anticipate submitting an Investigational New Drug (IND) application for a second CAR T-cell product candidate armed with multiple proprietary technologies and targeting a solid tumor indication in 2026.
- ***Maintain state-of-the-art infrastructure and expert capabilities to control and innovate cell product manufacturing*** — We have built and operate a dedicated manufacturing facility, the LyFE Manufacturing Center™ (LyFE), that produces cell product for our clinical trials. At full capacity, LyFE has the capacity to manufacture more than 1,000 CAR T-cell doses/year and therefore has the capability to support early commercial launch. We have invested in infrastructure that enables real-time monitoring of our manufacturing processes and the ability to incorporate insights into our research, manufacturing and clinical development efforts. Through our recent acquisition of ImmPACT, we acquired the cell manufacturing facility based in Los Angeles that has produced all of the IMPT-314 doses used in clinical trials to date. As we accelerate development of IMPT-314, we are supplementing our Los Angeles manufacturing capacity through a manufacturing technology transfer to LyFE. 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.
- ***Generate, secure and defend intellectual property on our differentiated technology platforms, CAR constructs and product candidates*** — We have developed and secured a robust suite of intellectual property, including know-how, through our internal research efforts, licensing agreements and collaborations. We rigorously analyze, file and protect our intellectual property in various jurisdictions around the world in an ongoing manner.
- ***Opportunistically pursue strategic opportunities to maximize the potential of our pipeline and capabilities*** – 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, tumor infiltrating lymphocyte (TIL) and T-cell receptor (TCR) therapies to improve the functionality of T cells. We will evaluate options for partnering programs, indications or geographies with pharmaceutical or biotechnology companies for the development and/or commercialization of our product candidates designed to address large patient populations. We also consider opportunities to acquire or license rights or invest in differentiated product candidates or technologies to complement our pipeline.

Our Pipeline Programs

We are advancing a pipeline of next-generation CAR T-cell product candidates, including our lead program, IMPT-314, that is in clinical development for aggressive large B-cell malignancies. Our preclinical programs target solid

tumor indications. Each of our programs target cancers with large unmet need with substantial patient populations (see Table 1).

CAR T-cell therapies have demonstrated the curative potential of genetically-engineered autologous cell therapy for cancer. CARs are synthetic receptors that link an extracellular antigen-binding moiety, usually a single chain variable fragment (scFv) derived from a monoclonal antibody, to intracellular signaling domains. CARs redirect T-cell functional activity, including cytotoxicity and cytokine secretion, toward cancer cells that share a common target without the limitation of human leukocyte antigen restriction.

IMPT-314: A next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of responses as compared to the approved CD19-targeted CAR T-cell therapies for the treatment of large B-cell lymphoma.

Our lead program, IMPT-314, is targeting patients with aggressive relapsed/refractory large B-cell non-Hodgkin lymphoma (NHL). Lymphoma is a blood cancer that begins in lymphocytes and spreads primarily in lymph nodes, but can also metastasize to the liver, kidney, brain and other organs. Lymphomas are broadly classified as either Hodgkin or non-Hodgkin lymphoma, with NHL present in multiple groups of lymph nodes whereas Hodgkin lymphoma is typically located in a single group of lymph nodes, generally in the upper body. NHL is the more common form of lymphoma, representing approximately 90% of all lymphomas.

The American Cancer Society estimates that more than 80,000 people will be diagnosed with NHL in the United States in 2025 and 545,000 will be diagnosed worldwide. NHL encompasses a diverse group of blood cancers, with over 90 distinct subtypes, generally classified based on (i) the type of lymphocytes involved (B-cell or T-cell), (ii) the lymphocytes' phenotype, defined as large cell or small cell and (iii) the disease's rate of progression, which can be characterized as either aggressive or indolent (Figure 1).

We are initially focused on developing IMPT-314 for the treatment of patients with NHL subtypes representing approximately 35% of the over 80,000 patients estimated to be diagnosed with NHL in the United States in 2025 and 545,000 patients worldwide. The NHL subtypes we intend to initially pursue include diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL), transformed follicular lymphoma (tFL) and Grade 3B follicular lymphoma (FL3B). DLBCL and PMBCL represent approximately 31% and 3% of patients diagnosed with NHL each year, respectively, while tFL and FL3B each represent approximately 1 to 2% of NHL patients diagnosed with follicular lymphoma each year. We may choose to further expand development to include additional NHL subtypes in the future.

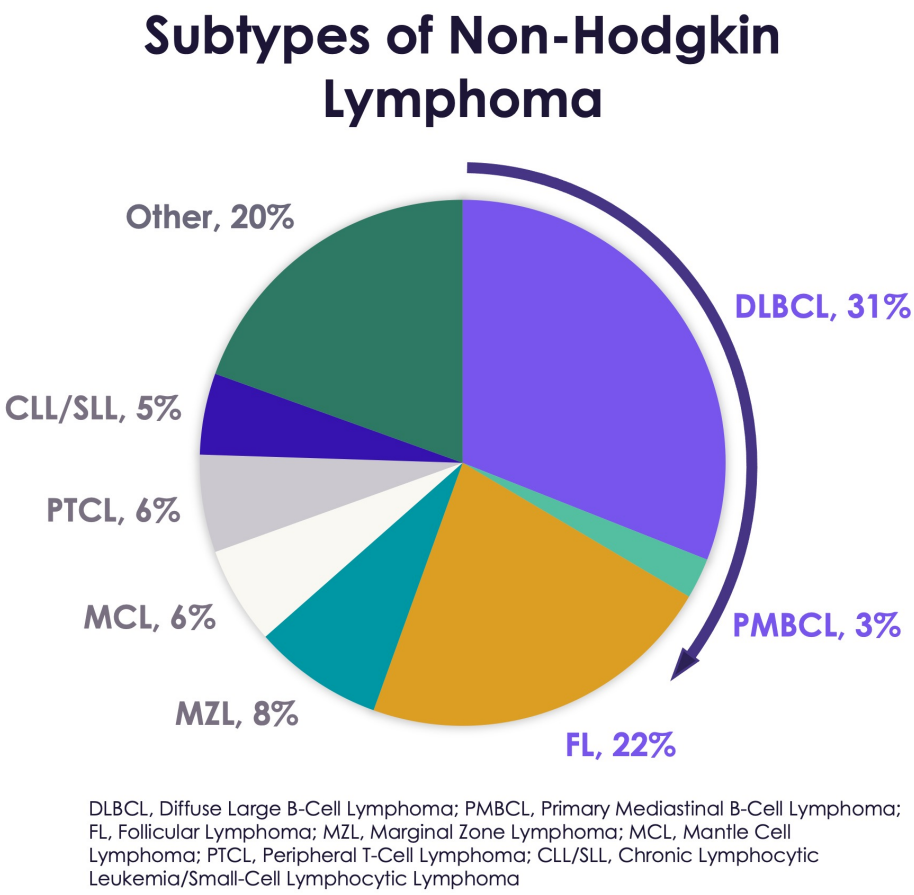


Figure 1: NHL is comprised of over 90 distinct subtypes, of which DLBCL is the most common form accounting for ~31% of all patients diagnosed with NHL. We are initially focused on developing IMPT-314 for the treatment of patients with NHL subtypes representing approximately 35% of the patients estimated to be diagnosed with NHL. The NHL subtypes we intend to initially pursue include DLBCL, transformed PMBCL, transformed FL (tFL) and Grade 3B follicular lymphoma (FL3B).

The majority of patients with NHL are successfully treated with frontline combination chemotherapy or targeted agents, but some do not stay in remission for 12 months (relapsed) and others fail to achieve a remission to therapy (refractory). Aggressive lymphomas such as DLBCL and other large B-cell lymphoma subtypes are more likely to relapse or be refractory to therapy. Approximately 40% of patients with DLBCL have refractory disease or relapse after their first line of treatment.

Prior to the approval of CD19 CAR T-cell therapies, the prognosis of patients with relapsed/refractory aggressive large B-cell lymphoma was poor, with the then current standard of care resulting in overall response rates of 26% and complete response rates of 7%. The median overall survival was 6.3 months and only 20% of patients were alive at 2 years. The three currently approved CD19 CAR T-cell therapies, axicabtagene ciloleucel (axi-cel, YESCARTA®), tisagenlecleucel (tisa-cel, KYMRIAH®), or lisocabtagene maraleucel (liso-cel, BREYANZI®) transformed the treatment landscape by improving overall response rates (72%, 50% and 73%, respectively) with complete response rates (51%, 32% and 54%, respectively) in the 3rd line+ setting.

While the first generation of CD19 CAR T-cell therapies delivered a major advance in treatment for patients with B-cell lymphoma, there remains a need for therapies that deliver more complete and durable responses. More than 40% of patients with aggressive large B-cell lymphoma treated in the 3rd line+ setting with a CD19 CAR T-cell therapy are not disease-free after treatment and 30% of patients do not respond at all. Of these patients treated with an approved CD19 CAR T-cell therapy, approximately 50% of patients progress or relapse within six months, and the overall survival at one year for patients treated with a CD19 CAR is only 50% to 60%.

IMPT-314 is an autologous dual-targeting CD19/CD20 CAR T-cell therapy designed to kill B cells expressing CD19 and/or CD20 antigens for the treatment of patients with aggressive B-cell malignancies. We acquired this product candidate through our acquisition of ImmPACT in October 2024.

A dual-targeting, or bispecific, CAR recognizes two targets. IMPT-314 is rationally designed with a true CD19/CD20 "OR" logic-gated CAR targeting either CD19 or CD20 with full potency, and the cell therapy product is enriched for naive and central memory T cells. Together, this novel construct and the cell enrichment for naïve and central memory T cells are designed to provide multiple clinical benefits over CD19 CAR T-cell therapies, including:

- Ability to target lower or heterogenous CD19 antigen density and result in a higher percentage of complete responses than with a single targeting CAR agent;
- Increase in duration of responses by preventing relapse due to CD19 antigen escape
- Better cell engraftment, persistence and reduced exhaustion to provide longer duration of responses

IMPT-314 consists of autologous T cells that are genetically modified through transduction with a lentiviral vector expressing a CAR construct composing anti-CD19 and anti-CD20 scFvs in tandem and an intracellular portion that contains the T cell signaling zeta chain (CD3-ζ) and the 4-1BB co-stimulatory domain (Figure 2). This differentiates IMPT-314 from cell therapies and other therapeutic modalities that singularly target CD19, CD20 or CD22, or bispecific CARs that target two antigens but without full potency as compared to single-targeting CARs.

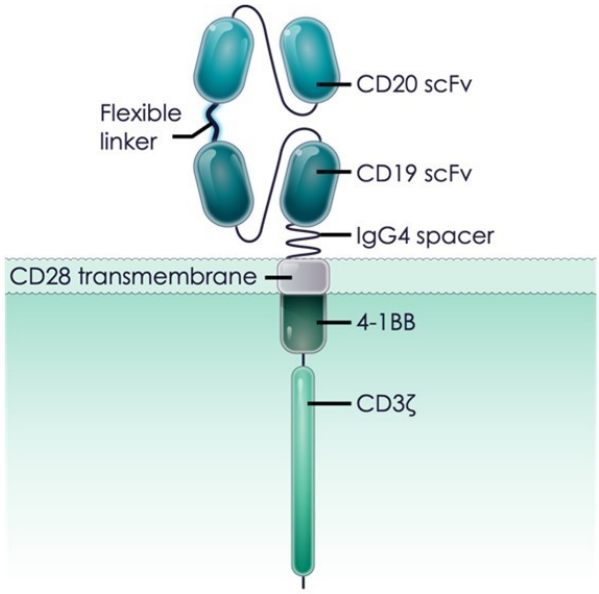


Figure 2: IMPT-314 contains separate, tandem single-chain variable fragment (scFV) antibody domains designed to target both CD19 and CD20 and is manufactured using a CAR that contains the 4-1BB costimulatory domain and is manufactured with a process to enrich for CD62-positive naïve and central memory T cells.

Antigen heterogeneity, which refers to variation in the expression levels of tumor antigens across cancer cells, can limit the effectiveness of targeted therapies, including CD19 CAR T-cell therapy. Nonclinical data demonstrated that IMPT-314's optimized tandem CAR design is capable of killing target cells that express CD19 only, CD20 only or both antigens with full potency, thus it has the potential to achieve a higher percentage of complete responses than a single targeting agent, particularly in those patients with lymphoma who may have a lower or heterogeneous CD19 antigen density.

CD19 antigen escape, a mechanism by which tumor cells evade the host immune system or targeted therapy through loss, downregulation or modification of target antigens, is a known mechanism contributing to disease relapse. CD20 expression has been shown to be more stable following single-targeted CAR T-cell treatment, as compared to CD19 and CD22. IMPT-314's dual-targeting of both CD19 and CD20 was designed to overcome CD19 antigen escape and potentially prolong the duration of responses, as well as to target those malignant B-cells that have limited or no expression of CD19 to achieve a higher overall response rate.

Additionally, IMPT-314 is manufactured to produce a CAR T-cell product with higher proportions of naïve and central memory T cells through a process that enriches for CD62L-expressing cells. This manufacturing process is

designed to generate CAR T cells with enhanced antitumor activity, which we believe could result in both increased complete response rates and more durable responses. Naïve T cells are mature T lymphocytes that have differentiated in the bone marrow and undergone central tolerance selection in the thymus, but have not interacted with their antigen. CAR T cells generated from these CD62L-positive less differentiated T cells have been associated with better engraftment, improved persistence, reduced exhaustion and lower cytokine production compared to CAR T cells generated from traditional processes. The enrichment of CD62L-expressing T cells does not increase the manufacturing time, which is similar to that of the approved CD19 CAR T-cell therapies. Data from the ZUMA-7 pivotal trial of axicabtagene ciloleucel in patients with relapsed or refractory large B-cell lymphoma demonstrated an improved overall survival in those patients with a higher median percentage of T cells with a naïve/stem memory phenotype in the administered cell product.

ImmPACT licensed its dual-targeting CD19/CD20 CAR T-cell product candidate from the University of California Los Angeles (UCLA). Interim Phase 1 data in 13 patients with relapsed/refractory aggressive NHL treated in a UCLA-sponsored single-center clinical trial were initially published and updated data were presented (Figure 3). CAR T-cell naïve patients with relapsed/refractory DLBCL or PMBCL after at least two lines of therapy or MCL, or FL were evaluated. Autologous T cells were obtained and enriched for CD62L-positive naïve or memory T cells. Two doses were to be evaluated including 50 and 200 million cells. Three patients received cell doses below 50 million cells due to manufacturing issues. The overall response rate was 92% with a complete response rate of 77% (10/13 patients). The median progression-free survival was 50.1 months, and median overall survival was not reached with a median follow-up of 32 months (range: 5.7 – not estimable). The overall survival at three years was 65%. A favorable safety profile was observed with no cases of cytokine release syndrome (CRS) above Grade 1 and no reported cases of immune effector cell-associated neurotoxicity syndrome (ICANS). Two patients in this study who achieved a complete response but experienced disease progression after approximately 18 months and four years respectively were both successfully retreated with the UCLA CD19/CD20 CAR T-cell product and both patients again achieved a complete response.

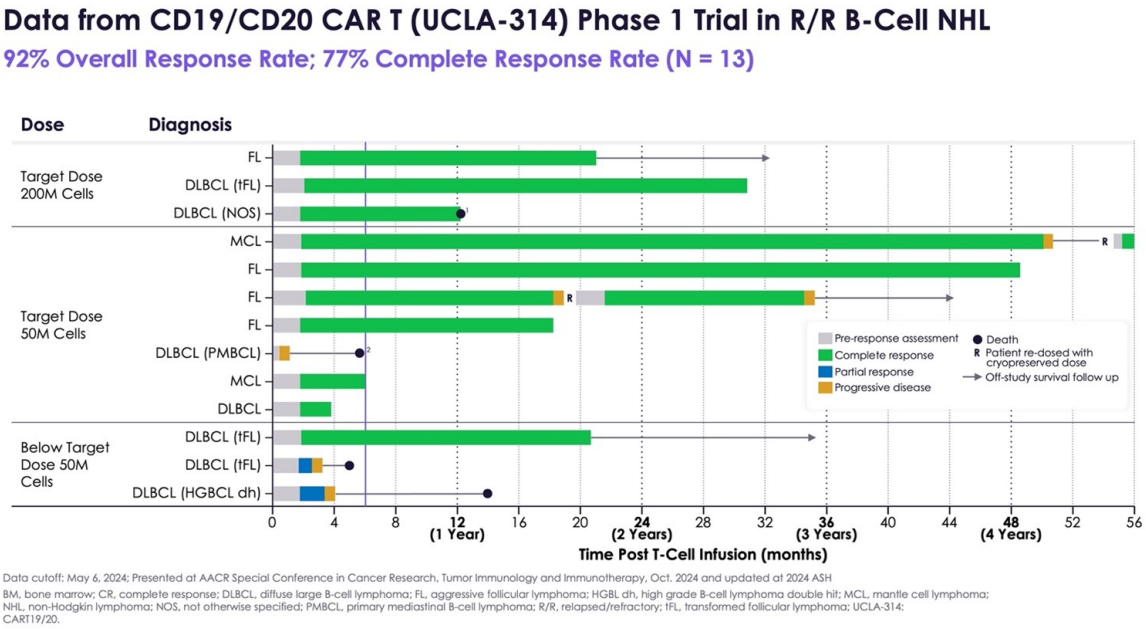


Figure 3: Interim Phase 1 data in 13 patients with relapsed/refractory aggressive NHL treated with UCLA-314 in a UCLA-sponsored clinical trial were presented at the 2024 American Association for Cancer Research Special Conference in Cancer Research: Tumor Immunology and Immunotherapy.

UCLA licensed the CD19/CD20 dual-targeting CAR construct to ImmPACT, who developed a GMP manufacturing process and initiated a Phase 1/2 clinical trial with their product candidate IMPT-314. We acquired ImmPACT in October 2024 and are continuing the development of IMPT-314.

Phase 1/2 Clinical Trial of IMPT-314

Our ongoing Phase 1/2 trial of IMPT-314 is a multi-center, open-label dose-escalation and dose-expansion clinical trial designed to evaluate the safety and clinical benefit of IMPT-314 and to determine a recommended Phase 2 dose in patients with relapsed/refractory aggressive large B-cell lymphoma. IMPT-314 has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of relapsed/refractory aggressive large B-cell lymphoma

in the 3rd line+ setting. The trial is enrolling patients with relapsed/refractory DLBCL, PMBCL, high-grade B-cell lymphoma (HGBCL), FL3B and tFL. The trial is enrolling CAR T-cell therapy naïve patients in the 3rd line+ and 2nd line settings. If successful, we may expand into other types of B-cell NHL.

Phase 1/2 Clinical Data

We reported initial data from the ongoing Phase 1/2 trial at the American Society of Hematology 2024 Annual Meeting (ASH). As of October 22, 2024 (the data cutoff date for the presentation at ASH), 23 patients with relapsed or refractory CAR T-naive large B-cell lymphoma received IMPT-314 and comprised the safety population. The efficacy evaluable population consisted of 17 patients and was defined as patients with a response assessment at Day 84 or later or an earlier scan with a complete response or progressive disease. Of the six patients not included in the efficacy evaluable population presented at ASH, two were excluded because they had T-cell histiocyte-rich lymphoma, a histologic subtype with a poor prognosis that is not included in the clinical trial moving forward, and four patients who had not yet reached their Day 84 scan.

The demographic and baseline characteristic data from the patients enrolled into the trial demonstrated a median age of 65 (range, 21 – 87) years, the majority (61%) of patients with DLBCL, and a median of three prior lines of therapy (range, 2 – 6). Approximately 50% of patients had elevated lactate dehydrogenase levels suggesting high disease burden and 53% of patients received bridging therapy.

The overall response rate for the efficacy evaluable patients was 94% (16/17 patients), with 71% (12/17 patients) achieving a complete response by three months (Table 2 and Figure 4). At the time the data were presented, three of those four patients were continuing on in the study. The median follow up was 6.3 months (range 1.2 – 12.5 months) and 71% of patients were experiencing a response when these data were reported.

CAR T-Naïve Cohort in the 3rd Line+ Setting

Best Overall Response	N = 17
Overall Responses, n (%)	**16 (94%)**
Complete Responses, n (%)	**12 (71%)**
Partial Responses, n (%)	4 (24%)
Stable Disease, n (%)	1 (6%)
Median Follow Up, months (range)	6.3 (1.2–12.5)
Median Duration of Response	Not reached

Table 2: Best overall response in CAR T-cell therapy naïve patients in the 3rd line+ cohort in the initial data presented at the 2024 American Society of Hematology annual meeting. Data cutoff October 22, 2024.

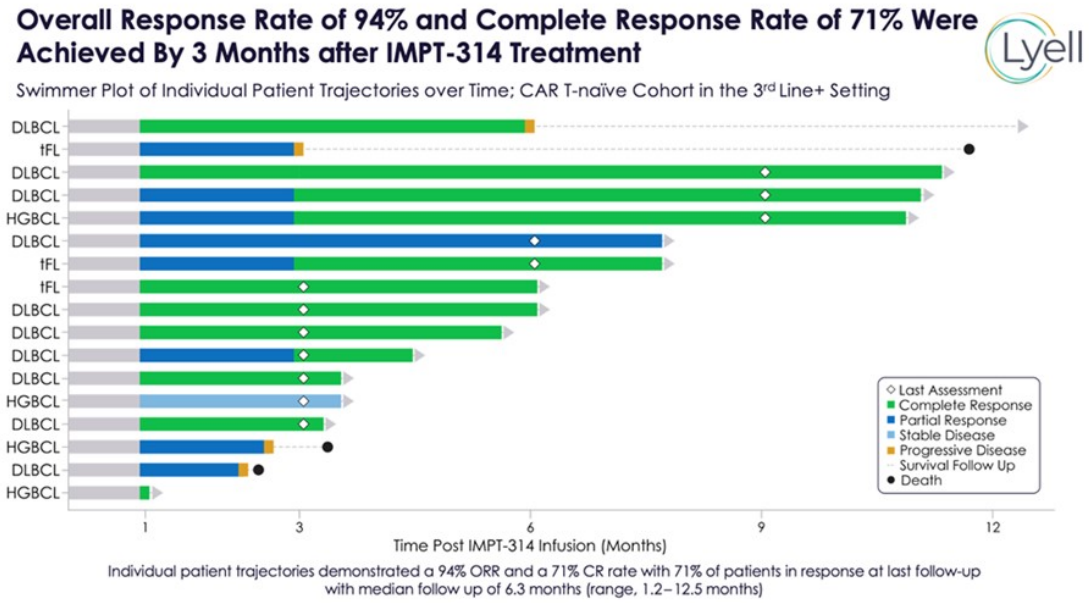


Figure 4: Initial data from the Phase 1/2 trial in patients with relapsed/refractory aggressive large B-cell lymphoma treated with IMPT-314 were presented at American Society of Hematology 2024 Annual Meeting 2024. The efficacy evaluable population consisted of 17 patients. The overall response rate was 94% (16/17 patients), with 71% (12/17 patients) achieving a CR by three months. The median follow up was 6.3 months (range 1.2 – 12.5 months) and 71% of patients were experiencing a response when these data were reported.

In the safety evaluable population of 23 patients, no Grade 3 or greater CRS was reported. Grade 3 ICANS was reported in 13% (3/23) of patients with a median time to complete ICANS resolution of five days, and rapid improvement to Grade 2 or lower with standard therapy. Four patients had Grade 3 infections including bacteremia not otherwise specified, tooth infection, urinary tract infection and a herpes zoster infection, all of which responded to treatment and resolved. Pharmacokinetic data were available from 16 of the efficacy-evaluable patients.

IMPT-314 demonstrated robust expansion and peak cell expansion occurred between Days 7 and 28 after IMPT-314 infusion (median T_{max} = 10 days). Median peak of expansion (C_{max}) was 93,723 copies/µg gDNA (range 2,338 – 555,284). IMPT-314 cells persisted multiple weeks post infusion across multiple patients with median expansion at Day 28 of 11,766 copies/µg gDNA (range 56 – 555,284). The median peak expansion of IMPT-314 is approximately four-fold higher than the median peak expansion reported for lisocabtagene maraleucel, a CD19 CAR T-cell therapy approved for patients with relapsed or refractory (R/R) large B-cell lymphoma. Greater CAR T-cell expansion has been associated with improved treatment response in patients with B-cell lymphoma. Additionally, the final drug product contained the desired naïve and central memory cell phenotype (median, 91%; range, 82 – 99%) that has been associated with improved overall survival in other CAR T-cell clinical studies.

Based on these promising initial and emerging data from the Phase 1/2 IMPT-314 clinical trial and following appropriate regulatory interactions, we intend to initiate a pivotal trial in the 3rd line+ setting in mid-2025 and a pivotal trial in the 2nd line setting by early 2026.

Target Markets

We are initially developing IMPT-314 for the treatment of aggressive large B-cell NHL. NHL is a common blood cancer in the United States and worldwide. There are more than 60 NHL subtypes that have been identified by the World Health Organization. Aggressive lymphomas grow and spread quickly and cause more severe symptoms, and these account for approximately 60% of all NHL cases. B-cell lymphoma is the most common type of NHL, comprising approximately 85% of all lymphomas in the United States. We are initially focusing on the subtypes classified as large B-cell lymphomas; of these diffuse large B-cell lymphoma (DLBCL) is the most common. Annually, it is estimated that approximately 80,000 people in the United States and 545,000 worldwide will be diagnosed with NHL. Approximately 200,000 cases of DLBCL are expected to be treated in the U.S., European Union (EU), United Kingdom (UK), China and Japan in 2025, with approximately 24,000 and 13,000 patients receiving treatment in the 2nd and 3rd line and later settings, respectively, in the U.S. and approximately 62,000 and 24,000 patients receiving treatment in the 2nd and 3rd line and later settings,

respectively, in the U.S., EU, UK, China and Japan. Today, the approved CD19 CAR T-cell therapy products have worldwide projected sales of approximately $3 billion and this is expected to nearly double by 2030.

Beyond DLBCL, other subtypes of B-cell NHL that could be evaluated in future trials of IMPT-314 include FL, MZL and MCL, where approximately 200,000, 79,000 and 38,000 patients are expected to be treated in the U.S., EU, UK, China and Japan in 2025.

Our Preclinical Programs

Cell therapy has demonstrated profound results in some patients suffering from hematologic malignancies, but there remains a need for therapies that deliver more complete and durable responses. Solid tumors are even 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. And while there has been recent progress with new cell therapies approved for solid tumors, overall response rates and the duration of response remain low.

To complement our clinical programs, we continue to invest in earlier stage cell therapy research and development utilizing our proprietary technologies. We expect to submit an IND application in 2026 for a new, armed solid tumor CAR T-cell product candidate with a new target, anti-exhaustion and durable stemness technologies, as well as a new technology designed to overcome the hostile tumor microenvironment.

Our T-cell Enhancement and Manufacturing Technologies

At Lyell, we believe that careful selection and evaluation of our CAR targets is important to ensure we are aiming for larger markets with substantial unmet medical need and to ensure that binding to normal tissues is limited and manageable for safety. Selecting an appropriate antigen target and designing a potent CAR construct, however, are necessary but insufficient for most solid tumors. Based on nonclinical evidence and clinical data, we believe there are multiple mechanisms limiting efficacy and durability of cell therapy for solid tumors. To address this need, we are advancing solid tumor CAR T-cell product candidates with new CAR targets and that are armed with a suite of proprietary anti-exhaustion and durable stemness technologies, as well as new enhancements designed to overcome the hostile tumor microenvironment.

T-cell exhaustion remains a major barrier for the development of effective CAR T-cell therapy. We have previously demonstrated Lyell's proprietary anti-exhaustion technology improves anti-tumor functions in in vitro and in vivo preclinical models. In patients with triple-negative breast cancer we have shown that our anti-exhaustion technology reduces T-cell exhaustion and improves CAR T-cell pharmacokinetics and tumor infiltration. Recently, alternative approaches that arm CAR T cells with transforming growth factor beta (TGF-β) blockade or constitutive cytokine signaling to enhance their anti-tumor functionality in the suppressive tumor microenvironment have shown promise in the solid tumor settings. In addition to developing novel CAR constructs targeting undisclosed tumor antigen targets, our research activities explore stacking these additional approaches to our proprietary anti-exhaustion technology via the expression of novel chimeric protein or polypeptide to optimize CAR T-cell killing in the hostile tumor microenvironment for application in future solid tumor product candidates.

Our technologies and manufacturing approaches designed to generate CAR T cells that can achieve potent and durable anti-tumor cytotoxicity are summarized in Table 3 described below.

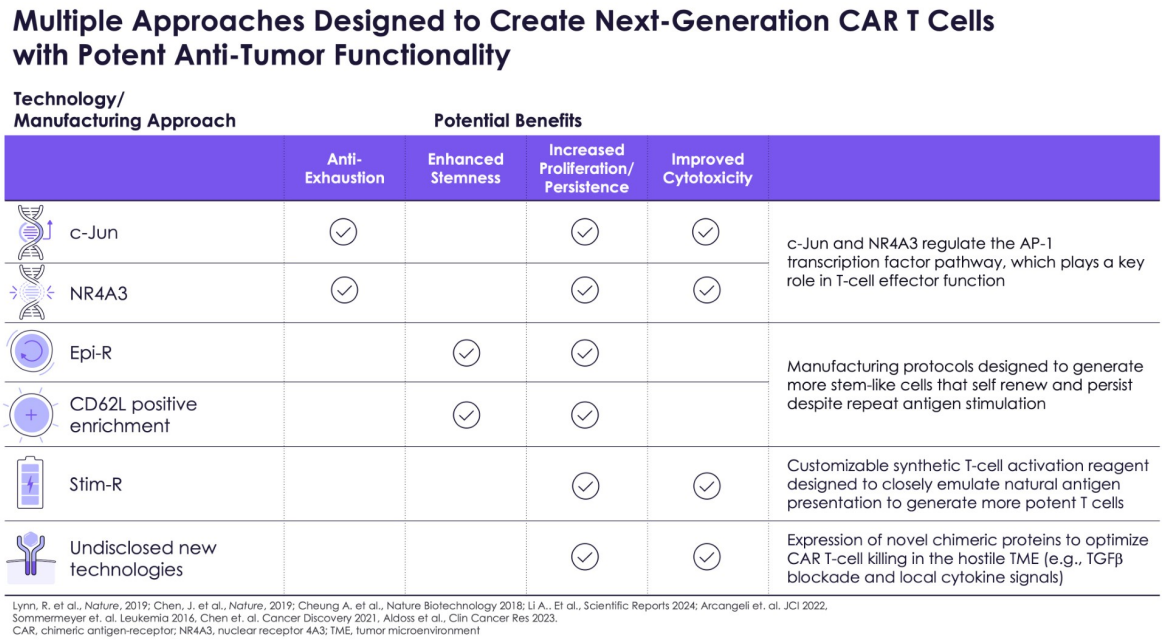


Table 3: Lyell has a suite of technologies designed to enhance the potency and durability of our CAR T-cell product candidates.

Two of our technologies, c-Jun overexpression and our Epi-R manufacturing protocol, have been clinically validated in a Phase 1 study in patients with triple-negative breast cancer, and we are advancing an additional anti-exhaustion technology, knockout of NR4A3 by gene editing, that has demonstrated even more potent anti-tumor functionality in nonclinical models. More recently, we have explored new strategies to express novel chimeric proteins to optimize CAR T-cell killing in the hostile tumor microenvironment.

c-Jun Overexpression

Overexpression of c-Jun is based on the work of our co-founder, Crystal Mackall, M.D., the Ernest and Amelia Gallo Family Professor of Pediatrics and Medicine at Stanford University (Stanford) 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. Overexpression of c-Jun was recently validated in a Phase 1 clinical study where a ROR1-targeted CAR T-cell products overexpressing c-Jun demonstrated clinical responses, improved pharmacokinetics, less CAR T-cell exhaustion and CAR T-cell tumor infiltration on histologic examination of on-study tumor biopsies. These data demonstrated improvement over the clinical data from a prior study conducted at the Fred Hutchinson Cancer Center (Fred Hutch) of a similar ROR-1 CAR T-cell product, but without c-Jun overexpression, in a similar patient population where no responses were observed after a single CAR T-cell treatment and high levels of CAR T-cell exhaustion occurred rapidly.

NR4A3 Gene Knockout

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 (Figure 5).

Epi-R Manufacturing Protocol

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. Lyell developed technology based upon the science conducted at the National Cancer Institute, 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.

CD62L Positive Enrichment

Our lead product candidate, IMPT-314 is manufactured with a process that enriches for CD62L positive cells. This manufacturing process is designed to generate CAR T cells with enhanced antitumor activity that we believe could result in both increased complete response rates and more durable responses. Naïve T cells are CD62L positive mature T lymphocytes that have differentiated in the bone marrow and undergone central tolerance selection in the thymus, but have not interacted with their antigen. CAR T cells generated from these CD62L positive less differentiated T cells have been associated with better engraftment, improved persistence, reduced exhaustion and lower cytokine production compared to CAR T cells generated from traditional processes. The enrichment of CD62L positive T cells does not increase the manufacturing time, which is similar to that of the approved CD19 CAR T-cell therapies.

Stim-R Technology

Stim-R is our 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.

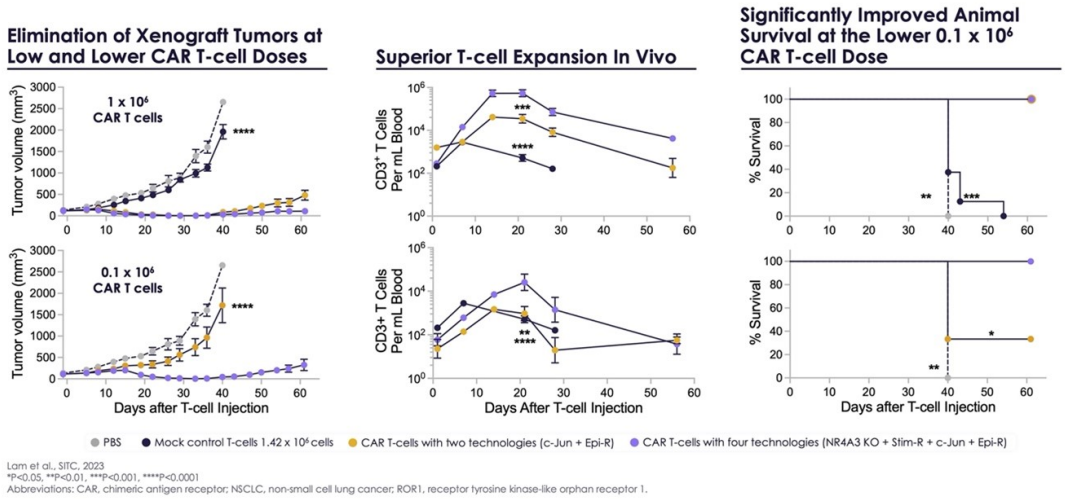


Figure 5: Nonclinical data demonstrate that CAR T cells enhanced with four technologies (c-Jun overexpression, NR4A3 knockout and manufactured with Epi-R and Stim-R) mediated anti-tumor response and enhanced survival in a murine xenograft tumor model, even at a very low CAR T-cell dose of 100,000 CAR T cells. Additionally, both in vitro and in vivo nonclinical data demonstrated that the combination of all four of these 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.

Undisclosed New Technologies

Recently, alternative approaches that arm CAR-T cells with TGF-β blockade or constitutive cytokine signaling to enhance their anti-tumor functionality in the suppressive tumor microenvironment have shown promise in the solid tumor settings. In addition to developing novel CAR constructs that target undisclosed tumor antigen targets, our research activities explore stacking our proprietary anti-exhaustion technology and these additional approaches targeting the tumor microenvironment via the expression of novel chimeric proteins or polypeptides (Table 3) to optimize more durable CAR T-cell killing for application in future solid tumor product candidates.

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. At full staffing and capacity, we expect to be able to manufacture >1,000 patient CAR T-cell products/year, able to support our clinical development needs for IMPT-314 and other pipeline programs, as well as early commercial launch if IMPT-314 is approved. LyFE was commissioned and designed to be in compliance with U.S. and EU current Good Manufacturing Practices (cGMP) standards and has a flexible and modular design enabling CAR T-cell, TIL, TCR T-cell therapies 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.

Clinical supply for our Phase 1/2 trial of IMPT-314 is currently manufactured in our manufacturing facility in Los Angeles, California, that we acquired in connection with the acquisition of ImmPACT. As we accelerate development of IMPT-314, we are supplementing our Los Angeles manufacturing capacity through a manufacturing technology transfer to LyFE. We are focused on maintaining a manufacturing strategy that is operationally efficient to maximize our capacity and avoid any disruption to clinical trial supply.

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 and clinical trials, 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.

If approved, our product IMPT-314 will need to compete against other products approved in the 2nd and 3rd line+ settings in our approved indications, including any approved CD19 CAR T-cell therapies, monoclonal antibodies targeting CD19, antibody-drug conjugates, selective inhibitors of exportin 1 and bispecific antibodies.

We are also aware of a number of companies using autologous or allogeneic CAR T-cell therapy approaches to treat hematologic malignancies and solid tumors. Some of these companies 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 operate in jurisdictions where we do not have staffing or resources.

CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors are being developed by a number of companies, including but not limited to Arcellx, Inc., Allogene Therapeutics, Inc., Arsenal Biosciences, Inc., AstraZeneca plc, Autolus Therapeutics plc, Bristol Myers Squibb Co., Caribou Biosciences, Inc., Cargo Therapeutics, Inc., Gilead Sciences Inc., Immunocore Holdings plc, Johnson & Johnson, Nanjing Legend Biotech, Novartis AG and Poseida/F. Hoffmann-La Roche AG . We are also aware that other companies are developing therapies in modalities such as bispecific antibodies for B-cell lymphomas, including AstraZeneca, F. Hoffmann-La Roche AG and Amgen Inc.

Among companies developing CAR T-cell therapies for hematologic malignancies and solid tumors, we believe we are substantially differentiated by our technologies, manufacturing protocols and capabilities, 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 scale and cost of manufacturing.

License and Collaboration Agreements

UCLA License Agreement

As a result of our acquisition of ImmPACT, we assumed its rights and obligations under a license agreement with the Regents of the University of California, acting through The Technology Development Group of UCLA, dated February 18, 2021, as amended (the UCLA License Agreement). Pursuant to the UCLA License Agreement, UCLA granted us an

exclusive, royalty-bearing license, with the right to sublicense through a specified number of tiers, under certain patent rights owned by UCLA and certain patent rights co-owned by UCLA and the Seattle Children's Hospital doing business as the Seattle Children's Research Institute (SCRI) and a non-exclusive, royalty-bearing license, with the right to sublicense through a specified number of tiers, under related technical information, in each case related to our CD19/CD20 program, for the development, use and sale of products or services associated with certain inventions made in the course of research by UCLA and SCRI in all fields of use. In accordance with the Patent and Trademark Law Amendments Act (the Bayh-Dole Act), UCLA granted the U.S. federal government a non-exclusive, non-transferable, irrevocable, paid-up license to the licensed patents.

Under the UCLA License Agreement, we are obligated to diligently develop and commercialize licensed products and to achieve certain development, regulatory and commercialization diligence milestones. If, subject to our right to extend such diligence milestones in certain circumstances, we are unable to meet our diligence obligations and do not agree with UCLA to modify such obligations, UCLA has the right and option to either terminate the license agreement or convert the granted rights to a non-exclusive license. We are also required, subject to certain exceptions, to provide UCLA with an affordable access plan within a specified time following the first commercial sale of a licensed product that is intended to support affordable access to licensed products in certain low- and middle-income countries and other countries in which we do not intend to commercialize licensed products.

UCLA and SCRI reserved, for themselves and for other nonprofit and academic research institutions, their rights to use the patent rights and technical information licensed to us for education and research purposes and to publish results arising therefrom, and for UCLA to offer and perform clinical diagnostic and prognostic services for patients in the University of California healthcare system, in each case subject to certain exclusions. Our rights under the UCLA License Agreement are also subject to certain government rights.

Under the UCLA License Agreement, ImmPACT paid UCLA a small upfront license issue fee and, upon our assumption of the agreement in connection with our acquisition of ImmPACT, we are obligated to pay a nominal, tiered annual license maintenance fee each year of the term until we make the first commercial sale of a licensed product. Upon the achievement of specified development, regulatory and commercial milestones, we are obligated to pay UCLA one-time milestone payments of up to an aggregate amount in the mid-single digit millions for each commercialized licensed product. In addition, we are obligated to pay UCLA a tiered royalty on worldwide annual net sales of any commercialized licensed products in the low- to mid-single digits percentage, subject to specified and capped reductions and a tiered minimum annual royalty payment of between a low-five figure and a low-six figure amount. ImmPACT reimbursed UCLA for all patent costs incurred prior to the effective date of the UCLA License Agreement, and we are obligated to reimburse UCLA for all patent costs incurred by them during the term of the license agreement.

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 patent 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. UCLA has the right to terminate the agreement in the event of our uncured material breach, subject to a specified notice and cure period, or upon certain insolvency events. We may terminate the agreement for convenience, subject to a specified notice period.

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 Orphan Drug designations. 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 technologies and manufacturing protocols, including but not limited to c-Jun, NR4A3, CD62L^{+} enrichment, Epi-R and Stim-R, as well as various aspects of our product candidates, including but not limited to CAR constructs. 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, 2024, our patent portfolio consists of over 50 issued patents and over 250 pending patent applications that we either own or have licensed. Our portfolio covers various aspects of our technologies and manufacturing protocols, including but not limited to c-Jun, NR4A3, CD62L^{+} enrichment, 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 and Collaboration 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, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (USPTO) in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In 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, 2024, our registered trademark portfolio contains over 135 registered trademarks and pending trademark applications, consisting of approximately one trademark registration and four pending trademark applications in the United States, and approximately 121 foreign trademark registrations and approximately 10 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 IMPT-314 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 Risk Evaluation and Mitigation Strategy (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 Fast Track 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, Breakthrough Therapy Designation, 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 Drug Designation (ODD) 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. 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 the ODD. 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 (as amended by the Health Information Technology for Economic and Clinical Health Act, 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 commercial 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.

There have been executive, judicial and Congressional challenges and amendments to certain aspects of the ACA. Further, on August 16, 2022, the Inflation Reduction Act of 2022 (the IRA) was signed 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 additional challenges in the future. It is unclear how any such additional challenges and healthcare reform measures of the second Trump 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.

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 high-expenditure, single-source biologics that have been on the market for at

least eleven years covered under Medicare (the Medicare Drug Price Negotiation Program) and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations which take effect in January 2026. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, 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) was announced. 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.

These health reform measures 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, particularly in light of the recent U.S. Presidential and Congressional elections.

Other Data Privacy and Security Laws

In the ordinary course of our business, we 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, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA), the EU's General Data Protection Regulation 2016/679 (EU GDPR), the EU GDPR as it forms part of 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 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 cell therapy company entering pivotal trials and advancing a pipeline of proprietary next-generation CAR T-cell product candidates for patients with cancer. We are pioneering novel approaches designed to generate T cells that drive long-lasting clinical response. 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 operate with 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.

In 2024, with active participation from our employees, we created behavior expectations to describe how Lyellites demonstrate our values at work. Leaders and employees attended workshops where we defined behavior statements that have been embedded in our performance management and development programs. These behaviors exemplify our values as well as principles of patient-centricity, innovation and inclusion.

Our Employees

Our people drive 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 we believe is a competitive advantage. Our organization is designed to support 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 now 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, 2024, we had 300 employees, over 83% 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. The majority of our employees are located in California and Washington, with all employees based in the United States. 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 learning 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 leaders identifying talent for promotion across all functions. Foundations of our talent management practice include career frameworks for progression and development, individual goal setting for all staff including one development goal to continue to improving skills and abilities in the current role and a compensation approach that recognizes differentiated performance and shares performance feedback regularly.

In 2024, we participated in the Great Place to Work survey for the first time and, based on employee responses to the survey, we received certification as a Great Place to Work. With 81% of employees participating in the survey, we received high ratings in multiple areas, with engagement, culture, inclusion and innovation being specific areas of strength. Employee feedback, through independent and anonymous surveys, provide us with the data on an ongoing basis that we need to ensure that our leadership, culture and people practices are supporting the talented workforce that we need to advance our mission.

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 or health savings 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 across each of our 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.

Employee feedback from our Great Place to Work survey rated the organization very high on four key questions on inclusion: (1) People here are treated fairly regardless of their sexual orientation; (2) People here are treated fairly regardless of their race; (3) People here are treated fairly regardless of their gender; and (4) People here are treated fairly

regardless of their age. We continue to evolve our workplace practices to ensure that our culture embeds fair treatment for all and is seen as a place where individuals can be their authentic selves at work. We have plans to continue to build on our early years and continue to mature our DEI strategy and practices in the years ahead working from this strong foundation.

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; we recognize differentiation in rewards, where our highest performing employees receive 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

We were incorporated in June 2018 under the laws of the state of Delaware. 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 a clinical-stage biopharmaceutical company that has 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 a clinical-stage biopharmaceutical company that does not yet have any products approved by regulatory authorities for sale, and we 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, including pivotal 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 and compliance programs;
- acquire and license technology or technology platforms;
- integrate ImmPACT and IMPT-314 into our business;
- 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 and maintaining or regaining compliance with the applicable continued listing requirements of The Nasdaq Global Select Market.

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 make 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 approvals 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 European Medicines Agency 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 any 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 availability of other competing approved or commonly used therapies in the indications for which we are approved, 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, 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 acquisition of ImmPACT, 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, 2024, we had approximately $383.5 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 milestone, royalty and success payment obligations may result in dilution to our stockholders or may reduce the availability of our cash resources to satisfy the payment obligations, which could cause our operating results and financial condition to fluctuate significantly from quarter to quarter and year to year and may reduce the usefulness of our GAAP consolidated financial statements.

In connection with the Agreement and Plan of Merger, dated as of October 24, 2024, by and among Lyell, ImmPACT, Inspire Merger Sub Inc. and WT Representative LLC, solely in its capacity as the Representative (the Merger Agreement), we agreed to issue additional shares of our common stock upon the achievement of certain IMPT-314 clinical or regulatory milestones and to make certain cash royalty payments to the pre-closing stockholders of ImmPACT based on future annual net sales of IMPT-314 in the United States. In addition, as a result of the acquisition of ImmPACT, we have assumed ImmPACT's rights and obligations under the UCLA License Agreement, pursuant to which we are obligated to pay a nominal, tiered annual license maintenance fee, one-time milestone payments for each commercialized licensed product and a tiered royalty on worldwide annual net sales of commercialized licensed products. For information related to our milestone and royalty obligations, see Note 3, *Acquisition*, in the accompanying notes to our audited consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Additionally, 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, pursuant to which we may be required to make success payments based on increases in the per share fair value of our common stock on each contractually prescribed measurement date. Our success payment obligations are recorded as liabilities on our audited 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. For information related to our success payment obligations, see Note 4, *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.

In order to satisfy our obligations to make these milestone and success payments, if and when they are triggered, we may issue equity or convertible debt securities, as applicable, that may cause dilution to our stockholders. We may also use our existing cash to satisfy the milestone, royalty or success payment obligations, if and as applicable, in the future, which may adversely affect our financial position. 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, which may reduce the usefulness of our GAAP consolidated financial statements. In addition, these success, milestone and royalty 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.

We have long-lived assets, which are assessed for impairment whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. In addition, we may never realize the full value of our long-lived assets, causing us to record material impairment charges.

Under GAAP, we assess our long-lived assets, including property and equipment and lease right-of-use assets, for possible impairment whenever events or circumstances indicate that the carrying amount of such assets may not be recoverable. For example, as a result of the sustained decline in the trading price of our Common Stock and related market capitalization, our reprioritization of certain research and development programs and our associated reductions in workforce, we performed an impairment assessment of long-lived assets for the year ended December 31, 2024 that resulted in recognition of an impairment of long-lived assets. See Note 5, *Impairment of Long-Lived Assets*, 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.

It is possible that changes in circumstances, many of which are outside of our control, or in the numerous variables associated with the assumptions and estimates used in assessing the appropriate valuation of our long-lived assets, could in the future result in an impairment to our long-lived assets, requiring us to record impairment charges, which would adversely affect our results of operations.

Risks Related to Our Business and Industry

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 currently have only one product candidate, IMPT-314, in Phase 1/2 clinical development. We have not yet demonstrated our ability to successfully complete any clinical trials (including any 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. For example, before prioritizing development of our IMPT-314 product candidate, our strategy focused on the development of our LYL797, LYL845 and LYL119 clinical programs, which we discontinued following the acquisition of IMPT-314. We have invested substantial resources in developing our technology platforms and our product candidates, conducting nonclinical studies, commencing and conducting 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 in profitable indications and markets. The success of our efforts to identify, develop, manufacture and commercialize 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 materials 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;
- developments relating to our competitors and our industry, including any existing or future competing product candidates or therapies, and our ability to effectively compete with other marketed therapies;
- 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 expose us to unforeseen risks and make 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 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 is both preliminary and limited. Additionally, although IMPT-314 is in Phase 1/2 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. Although ImmPACT had licensed the dual-targeting CD19/CD20 CAR T-cell product candidate (IMPT-314) from UCLA, which had presented at a conference interim Phase 1 data in 13 patients with relapsed/refractory aggressive NHL treated in its clinical trial, our IMPT-314 Phase 1/2 clinical trials may not generate similar results or otherwise provide adequate data to demonstrate the efficacy and safety of our product candidate.

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 foreign 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 sufficient 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, including our highly skilled and trained personnel at our manufacturing facilities, 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, Bothell and Los Angeles 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 awards that vest over time and, for certain key employees, equity awards that vest subject to certain performance conditions. The value to employees of equity incentives 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, there have been departures of executive officers in the past. 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, we implemented reductions in workforce in the fourth quarters of 2023 and 2024 and the first quarter of 2025, respectively. These reductions in workforce 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.

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 successes 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. Prior reductions in workforce may adversely impact our culture. Alternatively, as the organization again starts to grow, such as would be expected to support commercialization, and we 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.

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.

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, quality 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 actual or perceived changes in interest rates and economic inflation), which included severely diminished liquidity and credit availability, declines in consumer confidence, slower 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 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, and other actions taken, 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 a 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.

The U.S. government has indicated its intent to alter its approach to international trade policy and in some cases to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries. In addition, the U.S. government has initiated or is considering imposing tariffs on certain foreign goods. Related to this action, certain foreign governments, including China, have instituted or are considering imposing tariffs on certain U.S. goods. It remains unclear what the U.S. administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers and/or the United States or global economy or certain sectors thereof and, thus, could adversely impact our businesses.

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. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented 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, Silvergate Capital Corp and First Republic Bank, 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 U.S. 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. As part of the acquisition of ImmPACT, we own and operate a manufacturing facility in Los Angeles, California. If we fail to adequately technology transfer IMPT-314 to LyFE or fail to qualify LyFE for additional production, our business and financial condition may be significantly harmed, and we may incur significant additional costs and delays related to the development of IMPT-314.

In addition, our manufacturing facilities 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 facilities. Without further investment, advances in manufacturing techniques may render our facilities 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 cell 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 cell 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, for which there is significant competition. The loss of such manufacturing personnel, including at our newly acquired manufacturing facility in Los Angeles, California, may result in the loss of institutional knowledge and expertise and delays in our manufacturing processes, which may harm our business and financial condition. We may also incur additional costs and expenses related to the recruitment of replacement 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 or fires 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 clinical manufacturing facility in Bothell, Washington, or recently acquired manufacturing facility in Los Angeles, California, 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 manufacturing facility in Bothell, Washington, and recently acquired a manufacturing facility in Los Angeles, California in connection with the acquisition of ImmPACT and may rely on potential third-party contract manufacturing organizations to meet our current and future manufacturing needs. If our manufacturing facilities 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 properties 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 facilities 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 as part of an overall CAR T-cell manufacturing strategy to build scale and reduce cost. Utilizing a third-party cGMP 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 rely on third parties to assist in conducting and monitoring our clinical trials and for some of our research and non-clinical studies 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 rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to help 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 IMPT-314 Phase 1/2 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 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.

We have a CRO located in China. International tension or conflict between the United States and China could result in a disruption in our contractual relationship with this CRO or any other CROs we may engage in China, which could delay or otherwise negatively impact progress in our IMPT-314 clinical programs. For example, the tensions between the United States and China have led to a series of tariffs and sanctions being imposed by the United States on imports from China, as well as other business restrictions.

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 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 clinical trial investigators and study teams and outside scientists who conduct the research and development upon which portions of our product candidate regulatory submissions depend 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 institutions. Such investigators, study staff, 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 U.S. regulatory 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 clinical investigators and study staff or 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 or other reasons, 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 recently acquired ImmPACT and may not realize the benefits of such acquisition or any potential future collaborations, licenses, product acquisitions or other strategic transactions.

We recently acquired ImmPACT, a privately-owned clinical stage biotechnology company developing next-generation CAR T-cell product candidates, 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 may not be able to successfully integrate ImmPACT into our business, including manufacturing of IMPT-314 at LyFE, or to realize the anticipated benefits of the acquisition.

Combining our company and ImmPACT may be more difficult, costly or time consuming than expected, and we and ImmPACT may fail to successfully integrate the two businesses or to realize the anticipated benefits of the acquisition. The success of the acquisition will depend, in part, on the ability to realize the anticipated cost savings from integrating

ImmPACT's operations with ours, including our plans to technology transfer IMPT-314 to LyFE. This integration will depend substantially on our and ImmPACT's ability to consolidate operations, corporate cultures, systems and procedures and to eliminate redundancies and costs. We may not be able to combine our business with that of ImmPACT without encountering difficulties that could adversely affect the ability to maintain relationships with existing partners and employees, such as:

- the loss of key employees, including our manufacturing personnel, and associated costs;
- the disruption of operations and business;
- inability to maintain and increase competitive presence;
- possible inconsistencies in standards, control procedures and policies;
- inability to complete trials in a manner previously planned or announced;
- additional costs or unexpected problems with manufacturing IMPT-314 at LyFE, executing clinical trials, loss of key personnel or with the licensed technology; and/or
- potential unknown liabilities associated with the ImmPACT acquisition.

Additionally, general market and economic conditions or governmental actions generally may inhibit our successful integration of ImmPACT.

Further, we acquired ImmPACT with the expectation that this acquisition will result in various benefits including, among other things, benefits relating to a strengthened market position for the combined company, cost savings and operating efficiencies. Achieving the anticipated benefits of this acquisition is subject to a number of uncertainties, including whether we integrate ImmPACT in an efficient and effective manner, and general competitive factors in the marketplace. Failure to achieve these anticipated benefits on the anticipated timeframe, or at all, including manufacturing IMPT-314 at LyFE, could result in a reduction in the market price of our securities as well as in increased costs, decreases in the amount of expected revenues and diversion of management's time and energy and could materially and adversely affect our business, financial condition and operating results. Additionally, we will or have made fair value estimates of certain assets and liabilities in recording the ImmPACT acquisition. Actual values of these assets and liabilities could differ from our estimates, which could result in our not achieving the anticipated benefits of the acquisition. ImmPACT may have liabilities that we failed or were unable to discover in the course of performing due diligence investigations, or we may not have correctly assessed the significance of certain liabilities of ImmPACT identified in the course of our due diligence. Any such liabilities, individually or in the aggregate, could have an adverse effect on our business, financial condition and results of operations. Finally, any cost savings that are realized may be offset by losses in revenues or other charges to earnings.

Failure to successfully address these and other issues related to the acquisition could have a material adverse effect on our financial condition and results of operations and could adversely affect our ability to successfully implement our business strategy.

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 study participants. 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. There are also currently a number of companies with approved CAR T-cell therapies in our therapeutic areas, which could further limit the number of potential patients available to us. We may also encounter additional challenges and slower than anticipated enrollment in our clinical trials if more 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. 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 in rapidly changing industries, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is substantially dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. We face and will continue to face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions, many of whom have market presence, engineering, technical and marketing capabilities and financial, personnel and other resources substantially greater than ours. These organizations may conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources, including intellectual property that may be necessary or useful for the development and commercialization of our product candidates, being concentrated in our competitors and becoming unavailable to us on commercially reasonable terms or at all. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

There are currently a number of companies using autologous and allogeneic CAR T-cell therapy, as well as bi- and tri-specific T-cell engager approaches to treat hematologic malignancies and solid tumors. Some of the approved or commonly used drugs and therapies for our current or future target diseases, including large B-cell lymphoma, are established and are widely accepted by physicians, patients and third party payors, and insurers and other third party payors may encourage the use of these products. Our product and our product candidates, if approved, may be priced at a significant premium over competitive products. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our product candidates continue in clinical development.

Our ability to enroll clinical trials and/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. In addition, our potential future collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, which could have a material adverse effect on our future business, financial condition and results of operations.

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 and any product candidates we acquire.

We currently have no products approved for commercial sale, and we are in the first phase of clinical development of our product candidates, with IMPT-314 currently in Phase 1/2 clinical development. The future success of our business is substantially dependent on our ability to obtain regulatory approval for our product candidates, and any product candidates we acquire, 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 well-controlled clinical trials, 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 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 of product candidates, in particular. Because some of 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 cell 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, clinical trials such as those that evaluate T cells expressing a synthetic CAR 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 patients 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, initial clinical results in a clinical trial may not be predictive of future results in the same clinical trial and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. If clinical trials of our product candidates fail to produce positive results or demonstrate satisfactory safety and efficacy, at the appropriate dose level or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. 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. Clinical trials may show that one or more of our product candidates are not safe or effective, in which event we may need to abandon development of such product candidates. In fact, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in early- and 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, nonclinical activities or early clinical results appear positive, we do not know whether the current Phase 1/2 clinical trial for IMPT-314 or subsequent clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any product candidates. Although ImmPACT had licensed the dual-targeting CD19/CD20 CAR T-cell product candidate (IMPT-314) from UCLA, which had presented at a conference interim Phase 1 data in 13 patients with relapsed/refractory aggressive non-Hodgkin lymphoma treated in its single-center clinical trial, such results may not be predictive of future results in our IMPT-314 Phase 1/2 multi-center clinical trials in patients with aggressive large B-cell lymphoma.

Moreover, final study results may not be consistent with interim study results, and results in one indication may not be predictive of results for the same product candidate in another indication. 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. Additionally, even if clinical trials show promising early results, clinical trials of the same product candidate in another indication may fail to show similar results, and market acceptance of our product candidate, if approved, may be limited.

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, with IMPT-314 in Phase 1/2 clinical development. The risk of failure of our product candidates, or any product candidates we acquire, is high. The clinical trials and manufacturing of our product candidates, or any product candidates we acquire, are, and the manufacturing and marketing of such product candidates, 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 submissions 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 patients on time, will need to be redesigned, will achieve expected enrollment rates or will be completed on schedule, if at all. Our inability to successfully manufacture cell product candidates for enrolled patients or to obtain sufficient amounts of specific reagents and raw materials to manufacture product candidates 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;
- change in our strategy, such as our recent prioritization of the IMPT-314 product candidate and discontinuation of our LYL797, LYL845 and LYL119 programs;
- 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 candidates 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 independent 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 independent 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 CRS and immune effector cell-associated neurotoxicity syndrome, and approved CAR T products carry a boxed warning concerning the risk of developing secondary T-cell malignancies. A prior Phase 1 clinical trial of LYL797, a ROR1-targeted CAR T-cell product candidate was discontinued due to a narrow therapeutic window and safety reports of pneumonitis. Adverse events may also be associated with the lymphodepletion utilized with cellular therapies. If additional adverse events or other side effects are observed in any of our clinical trials that are atypical of, or more severe than, the known side effects of similar cell therapies, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of any of our product candidates, which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities.

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 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 from our or related third party 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. For example, although ImmPACT had licensed the dual-targeting CD19/CD20 CAR T-cell product candidate (IMPT-314) from UCLA, our IMPT-314 Phase 1/2 clinical trials may not generate similar results or otherwise provide adequate data to demonstrate the efficacy and safety of our product candidate. 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 that have obtained, or may obtain in the future, FDA approval before us in the same therapeutic areas as our product candidates. 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. Further, the U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the United States or abroad.

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

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

Because we have limited financial and management resources, we have chosen to prioritize our pipeline to focus on our most differentiated product candidates. As such, we are currently primarily focused on the clinical development of our recently acquired product candidate IMPT-314 and pre-clinical research into novel CAR T-cell product candidates with new targets that are fully-armed with multiple technologies, each designed to address different barriers to effective cell therapies, including T-cell exhaustion, lack of durable stemness, as well as immune suppression within the hostile tumor microenvironment. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially-viable products. For example, before prioritizing development of our IMPT-314 product candidate, our strategy focused primarily on the development of LYL797, LYL845 and LYL119, which we discontinued following the acquisition of IMPT-314. Further, if we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, in connection with our discontinuation of LYL797, LYL845 and LYL119, we may incur additional costs associated with termination of agreements associated with these programs, including winding down our agreements

with third-party providers and CROs conducting our clinical trials. Termination of these agreements may result in disputes with these service providers that may result in additional costs and liabilities and divert management's attention and resources, which could harm our business, reputation, overall financial condition and operating results.

IMPT-314 has received Fast Track designation from the FDA, but receipt of such designation or any other designation, such as Regenerative Medicine Advanced Therapy designation, may not actually lead to a faster development, regulatory review or approval process, and does not assure ultimate FDA approval.

The FDA has granted Fast Track designation to investigate IMPT-314 for the treatment of relapsed/refractory aggressive B-cell lymphoma in the 3rd line and later settings, and we may seek additional Fast Track designations for our product candidates or for IMPT-314 in other indications or seek other designations, such as Regenerative Medicine Advanced Therapy (RMAT) designation, for our product candidates.

The FDA has broad discretion whether or not to grant such special designations, so even if we believe a particular product candidate is eligible or meets the criteria for a particular special designation, we cannot assure you that the FDA would decide to grant it. Even though we have received Fast Track designation to develop IMPT-314 for the treatment of relapsed/refractory aggressive B-cell lymphoma in the 3rd line and later settings, and even if we receive Fast Track or RMAT designation for other product candidates or indications, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and such designation does not assure ultimate approval by the FDA. In addition, the FDA may withdraw Fast Track or RMAT designations if it believes that the designation is no longer supported by data from our clinical development program. Many product candidates that have received special FDA designations have ultimately failed to obtain approval.

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 HIPAA; 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.

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 the section entitled "Other Healthcare Laws" in Part I, Item 1 of this Annual Report on Form 10-K.

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 and amendments 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. Further, the Inflation Reduction Act of 2022 (the IRA), signed into law on August 16, 2022, among other things, 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.

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, the IRA, among other things: (i) directs HHS to negotiate the price of certain high-expenditure, single source biologics that have been on the market for at least eleven years 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 (the Medicare Drug Price Negotiation Program), and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions began to take effect progressively in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon reimbursement prices of the first ten drugs that were subject to price negotiations, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. Further, on December 7, 2023, 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) was announced. 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections, 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 the section entitled "Healthcare Reform" in Part I, Item 1 of this Annual Report on Form 10-K.

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 our cost containment, see the section entitled "Healthcare Reform" in Part I, Item 1 of this Annual Report on Form 10-K. 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 caused by funding shortages, policy changes, workforce reductions or other reasons 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 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, workforce reductions, the authority's ability to hire, train 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, such as the recent large-scale government workforce reductions, 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. Additionally, 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 the FDA or other regulatory authorities are prevented from conducting their regular inspections, reviews or other regulatory activities for any reason, including due to workforce reductions, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are subject to U.S. and certain foreign anti-corruption laws and regulations, export and import controls, sanctions and embargoes. We could face liability and other serious consequences for violations which can harm our business.

We are subject to anti-corruption laws and regulations, including the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act and other state and national anti-bribery laws in the countries in which we may conduct activities in the future. Anti-corruption laws are interpreted broadly and generally prohibit companies and their employees, agents, contractors and other third-party collaborators from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly through third parties, to any person in the public or private sector to obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. We may engage third parties to develop or commercialize our product candidates or to obtain necessary permits, licenses, patent registrations and other regulatory approvals outside the United States. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Any violation of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We are also subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic

sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions.

There is no certainty that all of our employees, agents, partners, vendors, contractors or collaborators, or those of our affiliates, will comply with all applicable anti-corruption, export and import control, and sanctions laws and regulations. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to develop or commercialize our product candidates in one or more countries as well as difficulties in manufacturing or continuing to develop our product candidates, and could materially damage our reputation, any international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

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 action 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 de-identified 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 privacy and security laws, regulations, guidance and industry standards and are or may become 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 data, including information of our employees. For example, HIPAA 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 data secure may constitute a violation of the Federal Trade Commission Act and other similar laws (e.g., wiretapping laws).

Numerous U.S. states 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 include the right to access, correct or delete certain personal data and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. 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 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 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 data 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 to achieve compliance and restrict our ability to process certain sensitive and personal data.

Outside the United States, an increasing number of laws, regulations and industry standards may govern data privacy and security. For example, the EU GDPR and the 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 privacy and security, including those governing various aspects of clinical research in the EU and the UK.

In addition to data privacy and security laws, we are or may become contractually subject to industry standards adopted by industry groups. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Our employees and personnel use generative artificial intelligence (AI) technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various data privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Data privacy and security laws are quickly evolving, becoming increasingly stringent, and creating uncertainty. Additionally, these laws may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. 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 or our partners or vendors could fail or be perceived to have failed to comply with such obligations, 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 action 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 the 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 foreign, 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.

International expansion of our business would expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

As part of our long-term business strategy, we may pursue international expansion, including partnering with academic and commercial testing laboratories and introducing our technology outside the United States. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of IMPT-314 or any other product candidates we may develop or acquire in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing government payor systems, multiple payor-reimbursement regimes or self-pay systems;
- logistics and regulations associated with shipping blood samples, including infrastructure conditions and transportation delays;

- limits on our ability to penetrate international markets if our current products or any other product candidates we may develop or acquire cannot be processed by an appropriately qualified local laboratory;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights, or lack of them in certain jurisdictions, forcing more reliance on our trade secrets, if available;
- natural disasters, political and economic instability, including wars, invasions, other military actions, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the FCPA, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales activities and distributors' activities.

Any of these risks, if encountered, could significantly harm our international expansion and operations and, consequently, could have a material adverse effect on our financial condition and results of operations and could adversely affect our ability to successfully implement our business strategy.

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 lifespans 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 and other third parties. If we breach any of our license agreements with these licensors, 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 and other third parties. Our discovery and development technology platforms are built, in part, around intellectual property rights in-licensed from these licensors. Under our existing license agreements, such as the UCLA License Agreement related to our CD19/CD20 program that we assumed in connection with our acquisition of ImmPACT, 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 licensors 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 or other licensor, 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 and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

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 and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties. 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. 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. 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. 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 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.

As of December 31, 2024, we are a non-accelerated filer. For so long as we remain a non-accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

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. We recently received a letter from The Nasdaq Stock Market advising us of our non-compliance with the minimum share price required for continued listing on Nasdaq, and that we could be subject to delisting if our common stock does not regain compliance. 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:

- prioritization of our product candidates;
- 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, licenses, product acquisitions or other strategic transactions relating to our product development and research programs;
- the failure to successfully integrate ImmPACT into our business;
- any future acquisitions, strategic investments, partnerships or alliances and the related financial terms and obligations;
- 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 and tensions, social unrest, war, armed conflicts and turmoil, 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, the interest rate environment, labor shortages and supply chain constraints, instability in the banking industry 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.

We may be unable to comply with the applicable continued listing requirements of The Nasdaq Global Select Market.

Our common stock is currently listed on The Nasdaq Global Select Market (Nasdaq). In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our common stock of $1.00 per share. In January 2025, we received a letter from The Nasdaq Stock Market advising us that for 33 consecutive trading days preceding the date of the letter, the bid price of our common stock had closed below the $1.00 per share minimum price required for continued listing on Nasdaq, and therefore we could become subject to delisting if our common stock does not meet the $1.00 minimum bid price for 10 consecutive trading days within the 180-day period following the date of the letter. We intend to actively monitor the closing bid price of our common stock and will evaluate potential actions to regain compliance with the continued listing requirements of Nasdaq, including by effecting a reverse stock split, if necessary. There can be no assurance that we will be able to regain compliance with the $1.00 minimum bid price requirement or comply with Nasdaq's other continued listing standards.

If we are ultimately not able to maintain or timely regain compliance with Nasdaq's continued listing requirements, our common stock will be subject to delisting. In the event that our common stock is delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. A delisting could also adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws, materially adversely affect our ability to obtain financing on acceptable terms, if at all, and may result in the potential loss of confidence by investors, suppliers, partners and employees and fewer business development opportunities.

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, 2024, we have approximately 294,876,000 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. For example, in connection with the acquisition of ImmPACT, we issued 37.5

million shares of our common stock at closing and have agreed to issue 12.5 million additional shares of our common stock upon the achievement of certain clinical or regulatory milestones to certain pre-closing stockholders of ImmPACT. Holders of such shares of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares for public sale within certain timeframes following the closing of the acquisition and the achievement of milestones, as applicable. 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. Pursuant to the Merger Agreement, we have also agreed to issue additional shares of our common stock to pre-closing ImmPACT stockholders upon the achievement of certain clinical or regulatory milestones. Any such future issuance of capital stock will result in further dilution of your ownership.

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 recently acquired ImmPACT and reprioritized our pipeline of product candidates. In the future, we may seek to acquire or invest in additional 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. Once we acquire additional businesses, we may not be able to integrate them effectively following the acquisition, including our most recent acquisition of ImmPACT. Acquisitions could also result in the incurrence of debt or dilutive issuances of equity securities, as we had done in connection with the acquisition of ImmPACT, 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 rules and regulations of the Securities and Exchange Commission, the listing requirements and rules of The Nasdaq Stock Market LLC 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 recently acquired ImmPACT, a privately-owned clinical stage biotechnology company that was not previously subject to these requirements. In connection with our efforts to comply with the requirements of being a public company, our management and our accounting, finance and other personnel will continue to need to devote a substantial amount of time towards maintaining compliance with these requirements as well as establishing and enhancing related processes, procedures and controls as we integrate ImmPACT into our business. 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, including those that are applied adversely to us or our customers, may have a material adverse effect on our business, cash flow, financial condition, results of operations, effective tax rate or compliance costs.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time (including in connection with reforms under consideration or being implemented at an international level by the Organisation for Economic Co-Operation and Development (the OECD)), 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, and tax authorities may disagree with tax positions that we have taken, which could, in each case, result in increased tax liabilities. 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 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 previously 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 (whether at the initiative of the U.S. government or international bodies such as the OECD), could have a material adverse effect on our business, cash flow, financial condition, results of operations, effective tax rate or compliance costs.

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 with whom we work, 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 with whom we work face a variety of evolving threats that could cause security incidents, including but not limited to social-engineering attacks (including through deep fakes, which are 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, including those of ImmPACT we are in the process of integrating, 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. Furthermore, we may not be successful in our integration of ImmPACT's information technology systems with ours, and any disruptions to our operations or other similar challenges may increase our vulnerability to cybersecurity threats.

Our reliance on 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 and 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 material 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, 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, we have been the target of unsuccessful phishing attempts in the past and expect such attempts will continue in the future. If any of the events referenced 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 data), 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 data, including personal data regarding our clinical trial patients 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 data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems. However, we may not detect and remediate all such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident, and we may need to expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against any security incidents.

Additionally, certain data privacy and security obligations 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.

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 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 with whom we work, 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.

In connection with our acquisition of ImmPACT, we acquired a lease for office and laboratory space in Los Angeles, California. We lease approximately 26,000 square feet of manufacturing, office and laboratory space in Los Angeles, California, pursuant to a lease agreement that we acquired in October 2024 and expires in January 2028.

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

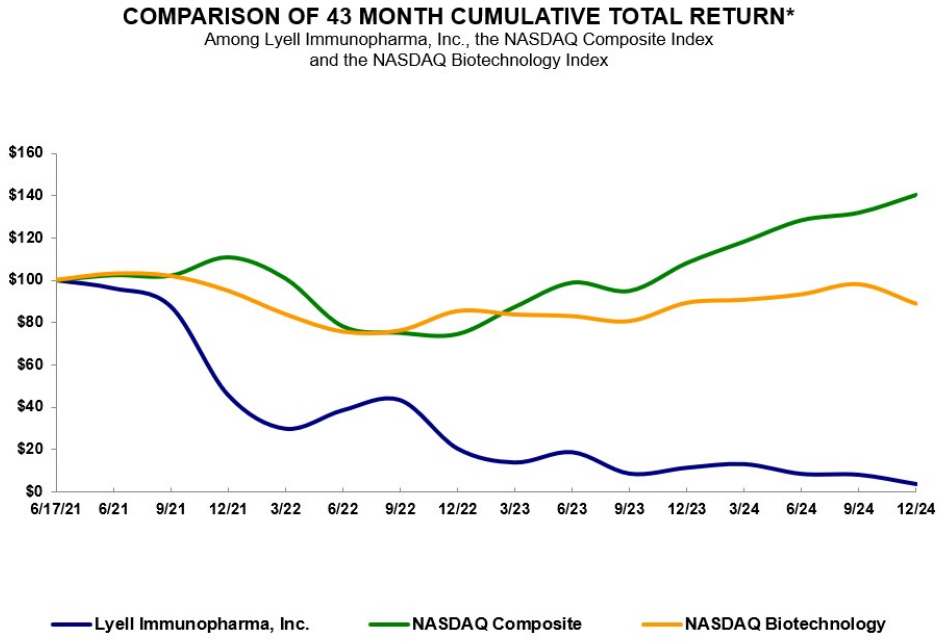
On March 6, 2025, there were 73 holders of record of our common stock. The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in "street names" or persons, partnerships, associations, corporations or other entities 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, 2024. 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.



*$100 invested on June 17, 2021 in stock or index, including reinvestment of dividends.
Fiscal year ending December 31, 2024.

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 Financial Condition and Results of Operations generally discusses 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 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, 2023.

Overview

We are a clinical-stage cell therapy company expecting to enter pivotal trials in 2025 and advancing a pipeline of proprietary next-generation autologous CAR T-cell product candidates for patients with hematologic malignancies and solid tumors. We are pioneering novel approaches designed to generate T cells that drive long-lasting clinical responses. The patient's own living cells are the starting point for our investigational CAR T-cell therapies, and we enhance them with our innovative CAR constructs, technology and manufacturing protocols.

In hematologic malignancies, we are focused on advancing to pivotal trials a product candidate designed to deliver improved outcomes over first-generation CD19 CAR T-cell therapies for patients with aggressive large B-cell lymphoma. Our lead program, IMPT-314, is a dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response as compared to the approved CD19-targeted CAR T-cell therapies. IMPT-314 is designed with a true 'OR' logic gate to target B cells that express either CD19 or CD20 with full potency and is manufactured with a process that enriches for CD62L+ cells to generate cell products with more naïve and central memory CAR T cells with enhanced stemlike features and antitumor activity.

To realize the potential of cell therapy for solid tumors, Lyell is also developing next-generation CAR T-cell product candidates enhanced with our anti-exhaustion and additional arming technologies and manufactured with our proprietary protocols. These approaches are designed to endow CAR T cells with attributes needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment.

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 a pipeline of next-generation CAR T-cell product candidates. Our lead program, IMPT-314, is in Phase 1/2 clinical development for relapsed or refractory aggressive large B-cell lymphoma and our preclinical programs target solid tumor indications. Each of our programs target cancers with large unmet need with substantial patient populations (see Table 1).

IMPT-314: A next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response as compared to the approved CD19-targeted CAR T-cell therapies for the treatment of large B-cell lymphoma.

- A Phase 1/2 clinical trial is ongoing and currently enrolling patients in the 3rd line+ and 2nd line settings who have not previously received CAR T-cell therapy. IMPT-314 has received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of relapsed/refractory aggressive large B-cell lymphoma in the 3rd line+ setting.

- Initial data from the Phase 1/2 trial was presented at the ASH 2024 Annual Meeting on December 9, 2024. Data from 23 patients with R/R, CAR T-naive large B-cell lymphoma who received IMPT-314 were reported. The efficacy evaluable population consisted of 17 patients. The overall response rate was 94% (16/17 patients), with 71% (12/17 patients) achieving a complete response by three months. The median follow up was 6.3 months (range 1.2 – 12.5 months) and 71% of patients were experiencing a response at last follow-up. In the safety evaluable population of 23 patients, no Grade 3+ CRS was reported. Grade 3 ICANS was reported in 13% (3/23) of patients with a median time to complete ICANS resolution of 5 days, and rapid improvement to Grade 2 or lower with standard therapy.
- More mature data from the ongoing Phase 1/2 trial in the 3rd line+ setting and initial data from patients in the 2nd line setting are expected to be presented in mid-2025.
- We expect to initiate a pivotal trial in mid-2025 in patients with relapsed/refractory large B-cell lymphoma in the 3rd line+ setting who have not yet received CAR T-cell therapy.
- We expect to initiate a pivotal trial by early 2026 in patients with relapsed/refractory large B-cell lymphoma in the 2nd line setting who have not yet received CAR T-cell therapy.

Preclinical Pipeline, Technologies and Manufacturing Protocols

- The first IND for a fully-armed CAR T-cell product candidate with an undisclosed target for solid tumors is expected in 2026. Lyell is advancing next-generation fully-armed CAR T-cell product candidates, meaning they are armed with multiple technologies, each designed to address different barriers to effective cell therapies, including T-cell exhaustion, lack of durable stemness, as well as immune suppression within the hostile tumor microenvironment.
- During the past year, we presented nonclinical and clinical data from our suite of anti-exhaustion and manufacturing technologies demonstrating their potential to improve T-cell function in solid tumors.
- We presented data at the Society for Immunotherapy of Cancer (SITC) 2024 from a validated nonclinical xenograft model of non-small cell lung cancer, demonstrating that combining c-Jun overexpression and NR4A3 knockout achieves tumor control and prolonged survival even at very low doses (100,000 CAR T cells/dose) compared to c-Jun overexpression alone (1,000,000 CAR T cells/dose). The study presented potential molecular mechanisms underlying the functional reduction of T-cell exhaustion and enhancement of memory-related characteristics of CAR T cells enhanced with c-Jun overexpression and NR4A3 knockout after antigen encounter in vitro and in vivo.
- We presented translational clinical data at SITC 2024 from an in-human Phase 1 trial of CAR T-cells enhanced with c-Jun overexpression and manufactured with Epi-R, showing reduced T-cell exhaustion and enhanced stemness of CAR T cells, resulting in CAR T-cell tumor infiltration with histological evidence of T-cell mediated tumor lysis in patients with ROR1 positive triple-negative breast cancer and non-small cell lung cancer. ROR1 CAR T cells enhanced with c-Jun overexpression demonstrated lower exhaustion and maintenance of stem- and memory-like phenotypes in the peripheral blood post-infusion, suggesting c-Jun overexpression can delay CAR T-cell exhaustion in patients.
- We delivered an oral presentation at SITC 2024 demonstrating successful incorporation of an anti-TGF-β scFv domain into a novel bispecific CAR designed to mediate TGF-β blockade and overcome the suppressive solid tumor microenvironment. In nonclinical models, these bispecific CAR T-cells demonstrated long term maintenance of effector function with resistance towards both exhaustion and the conversion of regulatory T cells in repeated antigen stimulation challenges, as well as effective tumor infiltration and anti-tumor function in vivo.
- We presented data at SITC 2024 suggesting Stim-R is a viable replacement for feeder cells in TIL manufacturing and has the potential to overcome limitations that may arise in feeder cell-mediated TIL expansion. Stim-R™ is our customizable and degradable biomimetic emulating physiologic, cell-like presentation of signal molecules.

Corporate Updates

- To accelerate the pivotal trials of IMPT-314 and focus resources on next-generation solid tumor CAR T-cell programs in preclinical development, we have streamlined expenses and focused our development on IMPT-314 and preclinical solid tumor CAR T-cell programs. Our net cash use in 2025 is expected to be between $175 million and $185 million.

Additional Pipeline and Business Updates

Acquisition of ImmPACT

Pursuant to the Agreement and Plan of Merger (the Merger Agreement) by and among us, ImmPACT, Inspire Merger Sub Inc., a Delaware corporation and our indirect, wholly-owned subsidiary, and WT Representative LLC, a Delaware limited liability company, solely in its capacity as the representative, agent and attorney-in-fact of ImmPACT securityholders, dated October 24, 2024, we acquired all of the outstanding equity interests of ImmPACT in exchange for an upfront payment of $30.0 million in cash (in addition to approximately $11.9 million for ImmPACT's existing cash balance) and the issuance of 37.5 million shares of our common stock at closing. Contingent consideration following the closing includes (a) additional equity consideration of 12.5 million shares of our common stock upon the achievement of the earlier to occur of (i) the demonstration of certain clinical milestones or (ii) the receipt of certain regulatory approvals and (b) a low single-digit royalty on future net sales of IMPT-314 in the United States. Contingent consideration payable in our Consolidated Balance Sheet as of December 31, 2024 consists of the additional equity consideration of 12.5 million shares of our common stock.

As a result of the acquisition of ImmPACT, we assumed its rights and obligations under its license agreement with the Regents of the University of California, acting through The Technology Development Group of UCLA, dated February 18, 2021 (the UCLA License Agreement). Pursuant to the UCLA License Agreement, we are obligated to pay a nominal, tiered annual license maintenance fee each year of the term of the UCLA License Agreement until we make the first commercial sale of a licensed product and, upon the achievement of specified development, regulatory and commercial milestones, we are obligated to pay UCLA one-time milestone payments of up to an aggregate amount in the mid-single digit millions for each commercialized licensed product. In addition, we are obligated to pay UCLA a tiered royalty on worldwide annual net sales of any commercialized licensed products in the low- to mid-single digits percentage, subject to specified and capped reductions and a tiered minimum annual royalty payment of between a low-five figure and a low-six figure amount.

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, armed conflicts and turmoil in the Middle East, tensions in U.S.-China relations, inflationary pressures, fluctuations in the interest rate environment, disruption between the U.S. and its trading partners due to tariffs or other policies, instability in the banking industry, supply constraints and overall market volatility. Economic uncertainty may persist into the remainder of 2025, and the market dynamics discussed above and similar adverse 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.

License and Collaboration Agreements

For a detailed description of our license and collaboration agreements, see the section titled "*Business—License and Collaboration Agreements*" in Part I, Item 1 of this Annual Report on Form 10-K and Notes 2 and 4 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 4, *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 November 2023 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 was recognized in other income, net, as the requisite service obligation had been met. As of September 30, 2024, Stanford had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. For the last three months of the year ended December 31, 2024 and future periods, the change in the Stanford success payment liability fair value was recognized in other income, net, as the requisite service obligation had been met. See Note 4, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to our Consolidated Financial Statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information. 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.

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 the retirement of property and equipment.

Acquired In-Process Research and Development

Acquired in-process research and development (IPR&D) consists primarily of the expense of the acquired IPR&D asset recognized as part of the acquisition of ImmPACT in October 2024, which was determined to have no alternative future use. See Note 3, *Acquisition*, 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.

Impairment of Long-Lived Assets

Impairment of long-lived assets consists primarily of the expense associated with our 2024 annual impairment assessment, with the impairment loss measured as the amount by which the carrying value of our asset group exceeded its fair value. The impairment loss was allocated on a pro rata basis to our lease right-of-use assets and associated leasehold improvements. See Note 5, *Impairment of Long-Lived Assets*, 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.

Interest Income, Net

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

Other Income, Net

Other income, net for the year ended December 31, 2024 consists primarily of the change in fair value associated with our contingent consideration payable related to the ImmPACT acquisition and changes in the fair value of our success payment liabilities. Other income, net for the year ended December 31, 2023 consists primarily of changes in the fair value of our success payment liabilities to Fred Hutch. Other income, net for the year ended December 31, 2022 consists primarily of a gain to record the PACT Series D convertible preferred shares and changes in the fair value of an equity warrant investment for the year ended December 31, 2022.

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, 2024, 2023 and 2022

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

	Year Ended December 31,			Change	
	2024	2023	2022	2024 vs 2023	2023 vs 2022
Revenue	$ 61	$ 130	$ 84,683	$ (69)	$ (84,553)
Operating expenses:					
Research and development	171,603	182,945	159,188	(11,342)	23,757
General and administrative	52,041	66,983	117,307	(14,942)	(50,324)
Other operating income, net	(3,309)	(2,790)	(4,754)	(519)	1,964
Acquired in-process research and development	87,184	—	—	87,184	—
Impairment of long-lived assets	51,297	—	—	51,297	—
Total operating expenses	358,816	247,138	271,741	111,678	(24,603)
Loss from operations	(358,755)	(247,008)	(187,058)	(111,747)	(59,950)
Interest income, net	24,068	23,453	7,053	615	16,400
Other income, net	4,694	1,846	1,887	2,848	(41)
Impairment of other investments	(13,001)	(12,923)	(5,000)	(78)	(7,923)
Total other income, net	15,761	12,376	3,940	3,385	8,436
Net loss	$ (342,994)	$ (234,632)	$ (183,118)	$ (108,362)	$ (51,514)

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	
	2024	2023	2022	2024 vs 2023	2023 vs 2022
Personnel	$ 67,693	$ 81,717	$ 70,483	$ (14,024)	$ 11,234
Research activities, collaborations and outside services	53,654	50,470	41,682	3,184	8,788
Facilities, technology and depreciation	50,564	51,688	52,153	(1,124)	(465)
Success payments	(308)	(930)	(5,130)	622	4,200
Total research and development expenses	$ 171,603	$ 182,945	$ 159,188	$ (11,342)	$ 23,757

Research and development expenses were $171.6 million and $182.9 million for the years ended December 31, 2024 and 2023, respectively. The decrease of $11.3 million was primarily due to a decrease of $14.0 million in personnel-related expenses and a decrease of $1.1 million in facilities, technology and depreciation expenses mainly due to the decrease in headcount associated with the Company's November 2023 reduction in workforce and lower software implementation costs. These decreases were offset by an increase of $3.2 million in research activities, collaborations and outside services primarily driven by clinical trial activity and a change of $0.6 million in success payment expense primarily driven by the change in our stock price.

General and Administrative Expenses

General and administrative expenses were $52.0 million and $67.0 million for the years ended December 31, 2024 and 2023, respectively. The decrease of $14.9 million was primarily due to a $13.0 million reduction in personnel costs, including a $10.3 million decrease in stock-based compensation expense, primarily related to significant awards being fully expensed in previous periods and a decrease of $2.7 million in personnel-related expenses mainly due to a decrease in headcount associated with the Company's November 2023 reduction in workforce.

Other Operating Income, Net

Other operating income, net was $3.3 million and $2.8 million for the years ended December 31, 2024 and 2023, respectively. The increase of $0.5 million was due to an increase in sublease income due to the addition of a new sublessee at the Company's headquarters in South San Francisco, California in September 2024.

Acquired In-Process Research and Development

Acquired IPR&D was $87.2 million and zero for the years ended December 31, 2024 and 2023, respectively. Acquired IPR&D consists primarily of the expense of the acquired IPR&D asset recognized as part of the acquisition of ImmPACT Bio USA Inc. in October 2024 as the asset was determined to have no alternative future use. See Note 3, *Acquisition*, 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.

Impairment of Long-Lived Assets

Impairment of long-lived assets was $51.3 million and zero for the years ended December 31, 2024 and 2023, respectively. Impairment of long-lived assets expense of $51.3 million consists of $12.6 million of impairment expense of our lease right-of-use assets and $38.7 million of impairment expense for the associated leasehold improvements. See Note 5, *Impairment of Long-Lived Assets*, 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.

Interest Income, Net

Interest income, net was $24.1 million and $23.5 million for the years ended December 31, 2024 and 2023, respectively. The increase of $0.6 million was primarily driven by higher interest rates in 2024.

Other Income, Net

Other income, net was $4.7 million and $1.8 million for the years ended December 31, 2024 and 2023, respectively. Other income, net of $4.7 million for the year ended December 31, 2024 was primarily driven by a $3.8 million gain resulting from the change in the fair value of our contingent consideration payable related to the ImmPACT acquisition and changes in the fair value of our success payment liabilities.

Impairment of Other Investments

For the year ended December 31, 2024, the $13.0 million impairment consisted of the full impairment of one of our 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. See Note 7, *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, 2024, we had $383.5 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 may never generate revenue from sales of any product candidates. We had an accumulated deficit of $1.3 billion as of December 31, 2024. From June 29, 2018 (inception) through December 31, 2024, 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, integration of ImmPACT into our business, 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 for at least the next 12 months. 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;
- the extent to which we acquire or invest in businesses, products and technology platforms; and
- integration of businesses, products and technology platforms, such as ImmPACT, into our business.

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, 2024, 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 collaboration and license agreements and the Merger Agreement. See Note 4, *License, Collaboration and Success Payment Agreements*, Note 11, *Leases*, and Note 3, *Acquisition*, 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,		
	2024	2023	2022
Net cash (used in) provided by:			
Operating activities	$ (162,394)	$ (163,694)	$ (169,555)
Investing activities	122,424	184,048	(11,540)
Financing activities	1,326	1,743	10,635
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (38,644)	$ 22,097	$ (170,460)

Operating Activities

During the year ended December 31, 2024, net cash used in operating activities was $162.4 million, primarily reflecting our net loss of $343.0 million, partially offset by non-cash items primarily related to acquired IPR&D expense of $87.2 million, impairment of long-lived assets expense of $51.3 million, stock-based compensation expense of $33.1 million, depreciation and amortization expense of $19.6 million and impairment of other investments of $13.0 million. Non-cash net amortization and accretion on marketable securities of $14.7 million also contributed to net cash used in 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 mainly 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.

Investing Activities

During the year ended December 31, 2024, cash provided by investing activities was $122.4 million, consisting of net maturities and purchases of marketable securities of $154.2 million, partially offset by the $31.3 million acquisition of ImmPACT net of cash acquired. During the year ended December 31, 2023, cash used in investing activities was $184.0 million, consisting of net maturities and purchases of marketable securities of $186.7 million, partially offset by purchases of property and equipment of $2.7 million.

Financing Activities

During the year ended December 31, 2024, cash provided by financing activities was $1.3 million, consisting of $1.2 million in proceeds from our employee stock purchase plan and $0.2 million in proceeds from the exercise of stock options, partially offset by $0.1 million in taxes paid related to the net share settlement of equity awards. 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.

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 liabilities at the date of our 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.

Acquisitions

We evaluate acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not we have acquired inputs and processes that have the ability to create outputs which would meet the requirements of a business in which case the transaction is accounted for using the acquisition method of accounting, which requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired intangibles be recorded on the balance sheet. Any excess of the purchase price over the assigned fair values of the net assets acquired is recorded as goodwill. If we determine an acquisition does not meet the definition of a business combination under the acquisition method of accounting, the transaction is accounted for as an asset acquisition.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition, with cost allocated to acquired assets on a relative fair value basis. Direct transaction costs are recognized as part of the cost of an asset acquisition. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. In an asset acquisition, upfront payments allocated to IPR&D are recorded in research and development expense if we determine that there is no alternative future use, and subsequent milestone payments are recorded in research and development expense when achieved for technology that has not yet met product feasibility.

Contingent Consideration

Contingent consideration relates to the potential payments to the pre-acquisition stockholders of ImmPACT for meeting certain clinical and/or regulatory milestones. For transactions accounted for as asset acquisitions, we record contingent consideration at fair value at the date of the acquisition when deemed probable. Liabilities for contingent consideration are remeasured each reporting period and subsequent changes in fair value are recognized within other income, net in our Consolidated Statements of Operations and Comprehensive Loss. The assumptions utilized in the calculation of the fair values include the probability of success and our stock price. Contingent consideration involves certain assumptions requiring significant judgment and actual results may differ from estimated amounts.

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.

Stock-based Compensation

Under ASC 718, the Company measures and recognizes expense for restricted stock awards (RSAs), restricted stock units (RSUs), performance-based restricted stock units (PSUs), 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. 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. For RSAs, RSUs and certain PSUs, the fair value of the Company's common stock is used to determine the resulting stock-based compensation expense. The fair value of stock options is estimated on the date of grant using a Black-Scholes option pricing model which requires management to apply judgment and make estimates, using inputs including:

- Fair Value of Common Stock—The fair value of common stock is based on the closing price as reported on The Nasdaq Global Select Market on the date of grant.
- Expected Term—The expected term represents the period that a stock-based award is expected to be outstanding. The Company generally uses the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the 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.
- Expected Volatility—The expected volatility of stock options is based on the historical volatility of the stock of similar entities within the Company's industry over a period commensurate with the Company's expected term assumption.
- Risk-Free Interest Rate—The risk-free interest rate is based 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 Company's expected term assumption.
- Expected Dividend—The Company has not historically paid, and does not expect for the foreseeable future to pay, a dividend. Therefore, the Company used an expected dividend yield of zero.

For awards with performance conditions that vest upon a performance condition being met, compensation expense is recognized for the number of shares expected to be earned after assessing the probability that a certain performance condition will be met and the targeted payout level associated with the performance condition expected to be achieved. At each reporting date, the Company is required to evaluate whether achievement of a performance condition is probable. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled. If performance conditions are not met or not expected to be met, any compensation expense previously recognized associated with the awards will be reversed.

The fair values of the Company's PSUs that have market-based metrics are estimated using Monte Carlo simulations. The Company applies an accelerated attribution method to recognize stock-based compensation expense over the applicable service period for these awards. The number of shares expected to be earned is considered in the grant date valuation; therefore, the expense is not subsequently adjusted to reflect the actual shares ultimately earned.

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.

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, 2024, 2023 and 2022. 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 $13.0 million for one investment the year ended December 31, 2024, $12.9 million for two investments for the year ended December 31, 2023 and $5.0 million for one investment for the year ended December 31, 2022. The impairment expenses were recorded within impairment of other investments on our Consolidated Statements of Operations and Comprehensive Loss and as a reduction of the other investments on our Consolidated Balance Sheets.

Valuation of Long-Lived Assets

Long-lived assets, including property and equipment and lease right-of-use assets, are reviewed for possible impairment whenever events or circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of these assets is measured by a comparison of the carrying amounts of the future undiscounted cash flows the assets are expected to generate from their use and eventual disposition over the remaining useful life of the primary asset of the asset group. The primary asset is the principal long-lived tangible asset being depreciated or intangible asset being amortized that is the most significant component asset from which the asset group derives its cash-flow-generating capacity. If such review indicates the carrying amount of the long-lived assets is not recoverable, the carrying amount of such assets is reduced to fair value. We have recorded impairment of long-lived assets of $51.3 million during the year ended December 31, 2024. See Note 5, *Impairment of Long-Lived Assets*, 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.

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 $80.6 million as of December 31, 2024, 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 $277.9 million as of December 31, 2024. 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, 2024.

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, 2024, 2023 and 2022

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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

The critical audit matters communicated below are matters 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 critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Accrued clinical expenses

Description of the Matter	During 2024, the Company incurred $171.6 million of research and development expenses and accrued $9.4 million for research and development expenses as of December 31, 2024, which includes clinical expenses. As described in Notes 2 and 10 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	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.

Impairment of long-lived assets

Description of the Matter	As discussed in Notes 2 and 5 to the consolidated financial statements, the Company's long-lived assets are assessed for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. 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 for the amount by which the carrying amount of the asset group exceeds the fair value of the asset group. The Company concluded that the carrying value of the asset group was not recoverable as it exceeded the future undiscounted cash flows the assets are expected to generate from their use and eventual disposition over the remaining useful life of the Company's primary asset. The Company applied a discounted cash flow method to estimate the fair values of their asset group. As a result, the Company recorded an impairment charge of $51.3 million relating to their right-of-use assets and related leasehold improvements as of December 31, 2024. Auditing the Company's impairment model was challenging due to the subjective assumptions of market rental rates used as an input in determining the fair value of the right-of-use assets and related leasehold improvements.
How We Addressed the Matter in Our Audit	To test the Company's accounting for the impairment of the asset group, our audit procedures included, among others, utilizing our valuation specialists to assist in evaluating the reasonableness of the Company's valuation methodology and the market rental rate assumptions, performing an evaluation of market rental rates by benchmarking to other properties of similar type and within the geographic areas, and testing the completeness and accuracy of the inputs within the model.

/s/ Ernst & Young LLP

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

San Mateo, California

March 11, 2025

Lyell Immunopharma, Inc.

Consolidated Balance Sheets

(in thousands, except per share amounts)

	As of December 31,	
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,597	$ 145,647
Marketable securities	264,930	400,576
Prepaid expenses and other current assets	9,067	8,463
Total current assets	379,594	554,686
Restricted cash	1,690	284
Marketable securities, non-current	13,014	16,506
Other investments	19,000	32,001
Property and equipment, net	48,200	102,654
Operating lease right-of-use assets	24,739	39,663
Other non-current assets	4,622	4,235
Total assets	$ 490,859	$ 750,029
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,366	$ 4,817
Accrued liabilities and other current liabilities	40,411	28,126
Success payment liabilities	411	1,576
Contingent consideration payable	7,600	—
Total current liabilities	53,788	34,519
Operating lease liabilities, non-current	50,994	56,894
Other non-current liabilities	3,253	3,664
Total liabilities	108,035	95,077
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000 shares authorized at December 31, 2024 and 2023, respectively; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.0001 par value; 500,000 shares authorized at December 31, 2024 and 2023, respectively; 294,876 and 253,958 shares issued and outstanding at December 31, 2024 and 2023, respectively	29	25
Additional paid-in capital	1,727,610	1,657,133
Accumulated other comprehensive income (loss)	291	(94)
Accumulated deficit	(1,345,106)	(1,002,112)
Total stockholders' equity	382,824	654,952
Total liabilities and stockholders' equity	$ 490,859	$ 750,029

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,		
	2024	2023	2022
Revenue[1]	$ 61	$ 130	$ 84,683
Operating expenses:			
Research and development	171,603	182,945	159,188
General and administrative	52,041	66,983	117,307
Other operating income, net	(3,309)	(2,790)	(4,754)
Acquired in-process research and development	87,184	—	—
Impairment of long-lived assets	51,297	—	—
Total operating expenses	358,816	247,138	271,741
Loss from operations	(358,755)	(247,008)	(187,058)
Interest income, net	24,068	23,453	7,053
Other income, net	4,694	1,846	1,887
Impairment of other investments	(13,001)	(12,923)	(5,000)
Total other income, net	15,761	12,376	3,940
Net loss	(342,994)	(234,632)	(183,118)
Other comprehensive loss:			
Net unrealized gain (loss) on marketable securities	385	7,505	(5,976)
Comprehensive loss	$ (342,609)	$ (227,127)	$ (189,094)
Net loss per common share, basic and diluted	$ (1.31)	$ (0.93)	$ (0.74)
Weighted-average shares used to compute net loss per common share, basic and diluted	261,480	250,983	247,080

(1) Includes related-party revenue of zero for both the years ended December 31, 2024 and 2023 and $84,653 for the year ended December 31, 2022.

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

Lyell Immunopharma, Inc.

Consolidated Statements of Stockholders' Equity

(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
Balance as of December 31, 2021	242,738	$ 24	$ 1,515,748	$ (1,623)	$ (584,362)	$ 929,787
Stock-based compensation	2,600	—	81,924	—	—	81,924
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)
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
Stock-based compensation	—	—	47,084	—	—	47,084
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)
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
Stock-based compensation	—	—	33,144	—	—	33,144
Issuance of common stock upon exercise of stock options	1,246	—	154	—	—	154
Issuance of common stock under employee stock purchase plan	955	—	1,248	—	—	1,248
Issuance of common stock in connection with restricted stock units, net of tax	1,217	—	(76)	—	—	(76)
Issuance of common stock as payment for acquisition of IPR&D asset	37,500	4	36,007	—	—	36,011
Other comprehensive income	—	—	—	385	—	385
Net loss	—	—	—	—	(342,994)	(342,994)
Balance as of December 31, 2024	294,876	$ 29	$ 1,727,610	$ 291	$ (1,345,106)	$ 382,824

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,		
	2024	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (342,994)	$ (234,632)	$ (183,118)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired IPR&D expense	87,184	—	—
Impairment of long-lived assets	51,297	—	—
Stock-based compensation expense	33,144	47,084	81,924
Depreciation and amortization expense	19,631	20,250	18,020
Net amortization and accretion on marketable securities	(14,681)	(9,596)	(930)
Impairment of other investments	13,001	12,923	5,000
Change in fair value of contingent consideration payable	(3,804)	—	—
Non-cash lease income	(2,198)	(1,873)	(1,553)
Loss on property and equipment disposals, net	1,341	1,509	103
Change in fair value of success payment liabilities	(1,165)	(2,780)	(5,130)
Gain on marketable equity security	(30)	—	—
Change in fair value of equity warrant	—	—	1,067
Gain on other investments	—	—	(2,923)
Changes in operating assets and liabilities:			
Prepaid expenses, other current assets and other assets	1,775	3,125	(1,968)
Accounts payable	(3,234)	1,464	667
Accrued liabilities and other current liabilities	(1,250)	(719)	(463)
Deferred revenue	—	—	(84,653)
Operating lease liabilities, non-current	—	—	4,855
Other non-current liabilities	(411)	(449)	(453)
Net cash used in operating activities	(162,394)	(163,694)	(169,555)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property and equipment	(464)	(2,686)	(24,276)
Purchases of marketable securities	(394,707)	(476,880)	(406,316)
Maturities of marketable securities	548,941	663,614	419,052
Acquisition of assets, net of cash acquired	(31,346)	—	—
Net cash provided by (used in) investing activities	122,424	184,048	(11,540)
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from exercise of stock options	154	306	9,577
Proceeds from employee stock purchase plan	1,248	1,894	1,519
Taxes paid related to net share settlement of equity awards	(76)	(457)	(461)
Net cash provided by financing activities	1,326	1,743	10,635
Net (decrease) increase in cash, cash equivalents and restricted cash	(38,644)	22,097	(170,460)
Cash, cash equivalents and restricted cash at beginning of period	145,931	123,834	294,294
Cash, cash equivalents and restricted cash at end of period	$ 107,287	$ 145,931	$ 123,834
Represented by:			
Cash and cash equivalents	$ 105,597	$ 145,647	$ 123,554
Restricted cash	1,690	284	280
Total	$ 107,287	$ 145,931	$ 123,834
SUPPLEMENTAL CASH FLOW INFORMATION			
Cash paid for amounts included in the measurement of lease liabilities	$ 11,467	$ 10,845	$ 10,870
Cash received for amounts related to tenant improvement allowances	$ —	$ —	$ 4,761
Non-cash investing and financing activities:			
Issuance of common stock related to the purchase of the IPR&D asset on Closing Date (Note 3)	$ 36,011	$ —	$ —
Contingent consideration payable related to the purchase of the IPR&D asset on Closing Date (Note 3 & 8)	$ 11,404	$ —	$ —
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 144	$ 29	$ 1,325
Acquisition of PACT Series D convertible preferred shares	$ —	$ —	$ 2,923
Remeasurement of operating lease right-of-use asset for lease modification	$ —	$ —	$ 31

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 proprietary next-generation chimeric antigen receptor ("CAR") T-cell product candidates for patients with hematologic malignancies and solid tumors. The Company's primary activities since incorporation have been to develop T-cell therapies, conduct research and development, acquire technology and product candidates, 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.

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 subsidiaries. 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, 2024 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 long-lived and acquired assets, other investments 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, 2024, 2023 and 2022, 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 investment grade fixed income securities 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 as well as collateral for a letter of credit in favor of one of the Company's landlords.

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, 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, net.

Valuation of Other Investments

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 7, *Other Investments*, for details related to investment impairments recognized during the years ended December 31, 2024, 2023 and 2022.

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 and, if applicable, impairment charges. 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 group. Any impairment loss is allocated to the long-lived assets of the group on a pro rata basis using the relative carrying amounts of those assets, except that the carrying amount of an individual asset shall not be reduced below its fair value. The Company recognized impairment of long-lived assets expense of $51.3 million for the year ended December 31, 2024 and zero for both the years ended December 31, 2023 and 2022.

Factors that may indicate potential impairment and trigger an impairment test include, but are not limited to, general macroeconomic conditions, conditions specific to the industry and market, business climate or operational performance of the business and sustained decline in the stock price and market capitalization compared to net book value.

Calculating the fair value of a reporting unit, an asset group and an individual asset involves significant estimates and assumptions. These estimates and assumptions include, among others, projected future cash flows, risk-adjusted discount rates, future economic and market conditions, and the determination of appropriate market comparisons. Changes in these factors and assumptions used can materially affect the amount of impairment loss recognized in the period the asset or asset group was considered impaired.

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, 2024 and 2023, 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.

The Company evaluates lease arrangements for impairment whenever events or changes in circumstances indicate that the carrying amounts of the right-of-use asset may not be fully recoverable. To the extent an impairment of the right-of-use asset is identified, the Company recognizes a lease impairment and subsequently amortizes the remaining lease asset on a straight-line basis (unless another systematic basis is more representative of the pattern in which the Company expects to consume the future economic benefits from the asset) from the date of impairment to the earlier of the right-of-use asset's useful life or the end of the lease term.

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 8, *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 7, *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.

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.

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 as well as collateral for a letter of credit in favor of one of the Company's landlords. 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.

Stock-based Compensation

Under ASC 718, the Company measures and recognizes expense for restricted stock awards ("RSAs"), restricted stock units ("RSUs"), performance-based restricted stock units ("PSUs"), 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. 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. For RSAs, RSUs and certain PSUs, the fair value of the Company's common stock is used to determine the resulting stock-based compensation expense. The fair value of stock options is estimated on the date of grant using a Black-Scholes option pricing model, which requires management to apply judgment and make estimates using inputs including:

- Fair Value of Common Stock—The fair value of common stock is based on the closing price as reported on The Nasdaq Global Select Market on the date of grant.
- Expected Term—The expected term represents the period that a stock-based award is expected to be outstanding. The Company generally uses the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the 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.
- Expected Volatility—The expected volatility of stock options is based on the historical volatility of the stock of similar entities within the Company's industry over a period commensurate with the Company's expected term assumption.
- Risk-Free Interest Rate—The risk-free interest rate is based 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 Company's expected term assumption.

- Expected Dividend—The Company has not historically paid, and does not expect for the foreseeable future to pay a dividend. Therefore, the Company used an expected dividend yield of zero.

For awards with performance conditions that vest upon a performance condition being met, compensation expense is recognized for the number of shares expected to be earned after assessing the probability that a certain performance condition will be met and the targeted payout level associated with the performance condition expected to be achieved. At each reporting date, the Company is required to evaluate whether achievement of a performance condition is probable. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled. If performance conditions are not met or not expected to be met, any compensation expense previously recognized associated with the awards will be reversed.

The fair values of the Company's PSUs that have market-based metrics are estimated using Monte Carlo simulations. The Company applies an accelerated attribution method to recognize stock-based compensation expense over the applicable service period for these awards. The number of shares expected to be earned is considered in the grant date valuation; therefore, the expense is not subsequently adjusted to reflect the actual shares ultimately earned.

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.

Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen is met, the transaction is accounted for as an asset acquisition. If the screen is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs which would meet the requirements of a business in which case the transaction is accounted for using the acquisition method of accounting, which requires, among other things, that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date, and that the fair value of acquired intangibles be recorded on the balance sheet. Any excess of the purchase price over the assigned fair values of the net assets acquired is recorded as goodwill. If the Company determines an acquisition does not meet the definition of a business combination under the acquisition method of accounting, the transaction is accounted for as an asset acquisition.

For asset acquisitions, a cost accumulation model is used to determine the cost of an asset acquisition, with cost allocated to acquired assets on a relative fair value basis. Direct transaction costs are recognized as part of the cost of an asset acquisition. The cost of an asset acquisition, including transaction costs, is allocated to identifiable assets acquired and liabilities assumed based on a relative fair value basis. Goodwill is not recognized in an asset acquisition. In an asset acquisition, upfront payments allocated to in-process research and development ("IPR&D") are recorded in research and development expense if it is determined that there is no alternative future use, and subsequent milestone payments are recorded in research and development expense when achieved for technology that has not yet met product feasibility.

Contingent Consideration

Contingent consideration relates to the potential payments for achieving certain clinical and/or regulatory milestones. For transactions accounted for as asset acquisitions, the Company records contingent consideration at fair value at the date of the acquisition when deemed probable. Liabilities for contingent consideration are remeasured each reporting period and subsequent changes in fair value are recognized within other income, net in the Consolidated Statements of

Operations and Comprehensive Loss. The assumptions utilized in the calculation of the fair values include the probability of success and the Company's stock price. Contingent consideration involves certain assumptions requiring significant judgment and actual results may differ from estimated amounts.

Recently Adopted 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 Company adopted the annual requirements under ASU 2023-07 on January 1, 2024 on a retrospective basis and adopted interim requirements under ASU 2023-07 on January 1, 2025. There was no impact on the Company's reportable segments identified and additional required disclosures have been included in Note 20, *Segment*.

Recently Issued Accounting Pronouncements

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 currently evaluating the impact of ASU 2023-09 on its consolidated financial statements.

Income Statement Expense Disaggregation

In November 2024, the FASB issued ASU 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures*, to require more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of ASU 2024-03 on its consolidated financial statements.

3. Acquisition

On October 31, 2024 (the "Closing Date"), the Company completed its previously announced acquisition of ImmPACT Bio USA Inc., a Delaware corporation ("ImmPACT"), pursuant to the Agreement and Plan of Merger (the "Merger Agreement"), dated as of October 24, 2024, by and among the Company, ImmPACT, Inspire Merger Sub Inc., a Delaware corporation and an indirect, wholly owned subsidiary of the Company ("Merger Sub"), and an attorney-in-fact of ImmPACT securityholders (the "Representative").

Pursuant to the terms of the Merger Agreement, on the Closing Date, the Company acquired all of the outstanding equity interests of ImmPACT in exchange for an upfront payment of $30.0 million in cash (in addition to approximately $11.9 million for ImmPACT's existing cash balance, net of certain of ImmPACT's unpaid transaction expenses) and 37.5 million shares of Company common stock. The acquisition was effected via a merger whereby Merger Sub merged with and into ImmPACT (the "Merger"), with ImmPACT surviving the merger as an indirect, wholly-owned subsidiary of the Company. Contingent consideration following the Closing Date includes (a) additional equity consideration of 12.5 million shares of Company Common Stock ("contingent consideration payable") that may be earned upon the achievement of the earlier to occur of (i) the demonstration of certain clinical milestones or (ii) the receipt of certain regulatory approvals and (b) a low single-digit royalty on future net sales of the dual-targeting CD19/20 CAR T-cell product in the United States. Contingent consideration payable in the Company's Consolidated Balance Sheet as of December 31, 2024 consists of the additional equity consideration of 12.5 million shares of Company common stock.

The total consideration paid for the Merger consisted of the following (in thousands):

Fair value of components of purchase price consideration at closing:	As of Closing Date
Cash (including $11.9 million for existing cash balances)	$ 41,913
Common Stock	36,011
Representative holdback	200
Contingent consideration payable	11,404
Company’s capitalizable transaction expenses	4,215
Total consideration paid	$ 93,743

The fair value of the common stock consideration transferred for the acquisition of ImmPACT was calculated based on the closing stock price of the Company’s common stock on October 31, 2024, which was $0.9603 per share. The fair value of the contingent consideration payable was derived based on certain valuation inputs, including the closing share price of Lyell common stock on October 31, 2024 and the probability of meeting the milestone, as further discussed in Note 8, *Fair Value Measurements*. Pursuant to the terms of the Merger Agreement, the Company has a right to offset and cause the sellers to forfeit shares underlying the contingent consideration payable against certain indemnification claims and indemnifiable losses. As a result of this provision, the number of shares underlying the contingent consideration payable is contingently subject to adjustments and the Company has concluded that the arrangement is not indexed to the Company’s equity pursuant to guidance in Accounting Standards Codification (“ASC”) 815-40. Accordingly, the contingent consideration payable is classified as a liability, subject to be remeasured at fair value at each reporting date with changes in fair value reported in earnings until the liability is settled in accordance with the terms of the Merger Agreement.

The Company determined that the contingent consideration for the royalty payments is not subject to derivative accounting under ASC 815, *Derivatives and Hedging*, as its settlement is contingent upon future net sales of the Company's dual-targeting CD19/20 CAR T-cell product in the United States. Therefore, the Company did not record an associated contingent consideration liability on the acquisition date for the royalty payments. The Company will recognize any future contingent consideration payments in the period in which the royalty payments become due and payable. The Company has not made or accrued for contingent payments relating to the royalty payments as these have not become due and payable.

The estimated fair value of the net acquired at Closing Date are as follows (in thousands):

Assets acquired:	As of Closing Date
Cash and cash equivalents	$ 14,982
Prepaid expenses and other current assets	1,211
Property and equipment, net	4,446
Long-term deposits	459
Operating lease right-of-use assets	1,816
Assembled workforce intangible asset	1,315
IPR&D asset	87,184
Total assets	$ 111,413
Liabilities Assumed:	
Accounts payable and other current liabilities	$ 16,090
Operating lease liability, long-term	1,580
Total liabilities assumed	17,670
Total net assets acquired	$ 93,743

The Company concluded that the arrangement met the definition of an asset acquisition rather than a business combination, as substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset,

IPR&D of product candidate IMPT-314. The $87.2 million fair value of the IPR&D acquired was charged to acquired IPR&D expense during the year ended December 31, 2024 as it had no alternative future use at the time of the Closing Date.

4. License, Collaboration and Success Payment Agreements

Fred Hutch

License Agreement - In 2018, the Company entered into a license agreement with Fred Hutchinson Cancer Center ("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 utilizing chimeric antigen receptors ("CARs") and/or T-cell receptors ("TCRs"), subject to certain exceptions.

Collaboration and Success Payments - In 2018, the Company entered into a research and collaboration agreement with Fred Hutch ("Fred Hutch Collaboration Agreement"), pursuant to which it granted Fred Hutch rights to certain success payments. The potential payments for the Fred Hutch success payments are based on multiples of increased value ranging from 10 times to 50 times 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 initial public offering ("IPO"). The aggregate success payments to Fred Hutch are not to exceed $200.0 million, which would only occur upon a 50 times increase in value relative to the original $1.83 per share issuance price of the Company's Series A convertible preferred stock. 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. 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	10x	20x	30x	40x	50x
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, 2024, 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, net. The success payment liability was $0.1 million and $0.7 million as of December 31, 2024 and 2023, respectively. With respect to the Fred Hutch Collaboration Agreement success payment obligations, the Company recognized success payment expense reversals of $0.5 million, $1.9 million and $3.9 million for the years ended December 31, 2024, 2023 and 2022, respectively .

Stanford

License Agreement - In 2019, the Company entered into a license agreement with The Board of Trustees of the Leland Stanford Junior University ("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.

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 funded aggregate research performed by Stanford of $12.0 million under the Stanford Collaboration Agreement, with the research conducted in accordance with a research plan and budget approved by the parties. The Company incurred $2.3 million in expense in connection with the Stanford Collaboration Agreement for the year ended December 31, 2024 and $3.0 million in expense for both the years ended December 31, 2023 and 2022.

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 times to 50 times 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 relative to the original $1.83 per share issuance price of the Company's Series A convertible preferred stock. 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. 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	10x	20x	30x	40x	50x
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, 2024, 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 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 through September 2024. As of October 2024, the Company's associated success payment liability was fully accreted to fair value as Stanford had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. For the year ended December 31, 2024 and future periods, the change in the Stanford success payment liability fair value is recognized in other income, net. The success payment liability was $0.3 million and $0.9 million as of December 31, 2024 and 2023, respectively. With respect to the Stanford Collaboration Agreement success payment obligations, the Company recognized success expense payment reversals of $0.6 million, $0.9 million and $1.2 million for the years ended December 31, 2024 and 2023 and 2022, respectively.

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. 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, zero and $84.7 million for the years ended December 31, 2024, 2023 and 2022 respectively. As of December 31, 2024, 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 7, *Other Investments*, for additional details regarding the PACT investment impairment.

5. Impairment of Long-Lived Assets

As a result of the sustained decline in the Company's stock price and related market capitalization, deferral and reprioritization of certain research and development programs and associated reduction in force, the Company performed an impairment assessment of long-lived assets for the year ended December 31, 2024.

The Company operates as a single reporting unit based on its business and reporting structure. The Company determined all of its long-lived assets represent one asset group for the purposes of the long-lived asset impairment assessment. The Company concluded that the carrying value of the asset group was not recoverable as it exceeded the future undiscounted cash flows the assets are expected to generate from their use and eventual disposition over the remaining useful life of the Company's primary asset; approximately six years remain on the initial term of the Company's operating lease in South San Francisco, California, which expires in March 2031. To allocate and recognize the impairment loss, the Company determined individual fair values of its long-lived assets. The Company applied a discounted cash flow method to estimate the fair values of its leasehold improvements and right-of-use assets. These represented level 3 nonrecurring fair value measurements. The remaining property and equipment, net was determined to not be impaired. Based on this analysis, the Company recognized long-lived asset impairment charges of $12.6 million on the lease right-of-use assets and $38.7 million on the related leasehold improvements during the year ended December 31, 2024. No impairment was recognized on the remaining long-lived assets as their carrying values were not in excess of their fair values.

6. Cash Equivalents and Marketable Securities

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

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 73,975	$ —	$ —	$ 73,975
U.S. Treasury securities	226,049	262	(40)	226,271
U.S. government agency securities	36,765	51	(1)	36,815
Corporate debt securities	21,473	20	(1)	21,492
Total cash equivalents and marketable securities	$ 358,262	$ 333	$ (42)	$ 358,553

Classified as:	Fair Value
Cash equivalents	$ 80,639
Marketable securities	264,900
Marketable securities, non-current	13,014
Total cash equivalents and marketable securities	$ 358,553

	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

The fair values of money market and fixed income marketable securities held by the Company in an unrealized loss position for less than 12 months were $31.7 million and $117.8 million, as of December 31, 2024 and 2023, respectively. The fair values of money market and fixed income marketable securities held by the Company in an unrealized loss position for greater than 12 months were zero and $43.6 million as of December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, all of the Company's money market and fixed income 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, 2024 and 2023. 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, 2024 and 2023 and as a result, amounts reclassified out of accumulated other comprehensive loss for the years ended December 31, 2024 and 2023 were also *de minimis*. See Note 8, *Fair Value Measurements*, for additional information regarding cash equivalents and fixed income marketable securities.

7. Other Investments

In prior years, the Company made minority ownership strategic investments. As of December 31, 2024 and 2023, the aggregate carrying amount of the Company's strategic investments in non-publicly traded companies was $19.0 million and $32.0 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, 2024 and 2023 were $23.0 million and $15.0 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. As of both December 31, 2024 and 2023, the Company held an interest in one entity that was concluded to be a variable interest for which the Company was not the primary beneficiary as the Company did not have the power to direct the activities that most significantly impact the economic performance of the variable interest entity. As of December 31, 2024 and 2023, the carrying value and maximum exposure to loss of the Company's variable interests were zero and $13.0 million, respectively, which are recorded in other investments in the Company's Consolidated Balance Sheets.

During the years ended December 31, 2024, 2023 and 2022, the Company performed qualitative assessments of potential indicators of impairment and determined that indicators existed for certain of its other investments with carrying amounts of $13.0 million, $12.9 million and $5.0 million, respectively. During the year ended December 31, 2024, the anticipated funding for one of its other investments was not secured within the expected timeframe. While no single event or factor was solely responsible for the impairments in each year, 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 $13.0 million for one investment for the year ended December 31, 2024, $12.9 million for two investments for the year ended December 31, 2023 and $5.0 million for one investment for the year ended December 31, 2022. 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.

8. 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, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 73,975	$ —	$ —	$ 73,975
U.S. Treasury securities	—	226,271	—	226,271
U.S. government agency securities	—	36,815	—	36,815
Corporate debt securities	—	21,492	—	21,492
Marketable equity security	30	—	—	30
Total financial assets	$ 74,005	$ 284,578	$ —	$ 358,583
Financial liabilities:				
Contingent consideration payable	$ —	$ —	$ 7,600	$ 7,600
Success payment liabilities	$ —	$ —	$ 411	$ 411
Total financial liabilities	$ —	$ —	$ 8,011	$ 8,011

	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

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Company measures the fair value of marketable equity securities traded in active markets based on quoted prices of identical assets. The Level 2 marketable securities include U.S. Treasury securities, U.S. government agency securities and corporate debt securities, which 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 contingent consideration payable is classified as a Level 3 financial instrument. The contingent consideration payable valuation was estimated using the Company's common stock price and management's assessment of the likelihood of achieving either (i) specified clinical milestones or (ii) certain regulatory approvals, which was determined to be approximately 95%.

The Company's success payment liabilities are Level 3 financial instruments, which were estimated using Monte Carlo simulations through December 31, 2023. 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 Monte Carlo simulation to determine 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. As of December 31, 2024, success payment liabilities were estimated by management using its historical experience of the correlation of success payment fair values relative to the Company's stock price.

The following assumptions were incorporated into the calculation of the estimated fair value of the Fred Hutch and Stanford success payment liabilities as of December 31, 2023:

	Fred Hutch	Stanford
Fair value of common stock	$ 1.94	$ 1.94
Risk-free interest rate	3.51% - 5.19%	3.51% - 5.19%
Expected volatility	80.0 %	80.0 %
Expected term (in years)	0.46 - 3.97	0.46 - 5.75

The Company utilizes estimates and assumptions in determining the estimated contingent consideration payable and 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 contingent consideration payable and success payment liabilities and associated changes in fair value. Additionally, a small change in Management's assessment of the likelihood of achieving either (i) specified clinical milestones or (ii) certain regulatory approvals related to the estimated valuation of the contingent consideration payable may have a relatively large change in its estimated fair value.

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

	Contingent Consideration Payable	Success Payment Liabilities
Balance at December 31, 2022	$ —	$ 4,356
Change in fair value [1]	—	(2,780)
Balance at December 31, 2023	—	1,576
Issuance	11,404	—
Change in fair value [1]	(3,804)	(1,165)
Balance at December 31, 2024	$ 7,600	$ 411

(1) The change in fair value of the contingent consideration payable subsequent to Closing Date is recorded in other income, net for the year ended December 31, 2024. Changes in the fair value of Fred Hutch and Stanford success payment liabilities are recorded as either other income, net or research and development expenses, depending on the period. (See Note 4, License, Collaboration, and Success Payment Agreements.)

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 4, *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 7, *Other Investments*, for additional details regarding the PACT investment impairment.

9. Property and Equipment, Net

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

	December 31,	
	2024	2023
Leasehold improvements	$ 79,613	$ 118,319
Laboratory equipment	36,106	33,368
Computer equipment and software	1,805	1,672
Furniture and fixtures	1,114	814
Construction in progress	241	128
Property and equipment, at cost	118,879	154,301
Less: Accumulated depreciation and amortization	(70,679)	(51,647)
Total property and equipment, net	$ 48,200	$ 102,654

Depreciation and amortization expense was $19.4 million, $20.2 million and $18.0 million for the years ended December 31, 2024, 2023 and 2022, respectively.

During the year ended December 31, 2024, the Company recorded impairment losses of $38.7 million for leasehold improvements. The Company did not record any impairment losses in 2023 and 2022. See Note 5, *Impairment of Long-Lived Assets*, for further information.

10. Accrued Liabilities and Other Current Liabilities

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

	December 31,	
	2024	2023
Accrued compensation and related benefits	$ 19,235	$ 14,634
Current lease liabilities	7,974	6,273
Accrued research and development expenses	9,439	5,331
Other	3,071	1,493
Accrued legal	692	395
Total accrued liabilities and other current liabilities	$ 40,411	$ 28,126

11. Leases

The Company's lease portfolio is comprised of operating leases for laboratory, office and manufacturing facilities located in South San Francisco and Los Angeles, California, and Seattle and Bothell, Washington with contractual periods expiring between January 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.

On the acquisition Closing Date, the Company acquired an operating lease agreement for approximately 26,000 square feet of office and laboratory space located in Los Angeles, California, with an initial lease term expiring in January 2028. See Note 3, *Acquisition*, for further information regarding the acquisition. The Company has one five-year option to extend the lease, which is not reasonably assured.

The following table summarizes the Company's future minimum operating lease commitments, including expected lease incentives to be received, as of December 31, 2024 (in thousands):

Year Ending December 31:		
2025	$	12,587
2026		12,959
2027		13,341
2028		13,005
2029		10,398
Thereafter		12,188
Total undiscounted lease payments		74,478
Less: imputed interest		(15,510)
Total operating lease liabilities	$	58,968
Reported as of December 31, 2024:		
Short-term portion of lease liabilities (included in accrued liabilities and other current liabilities)	$	7,974
Operating lease liabilities, non-current		50,994
Total	$	58,968

The operating lease costs for all operating leases were $9.2 million, $9.0 million and $9.3 million for the years ended December 31, 2024, 2023 and 2022, respectively. The operating lease costs and total commitments for short-term leases were *de minimis* for the years ended December 31, 2024, 2023 and 2022. Variable lease costs for operating leases were $7.1 million, $5.4 million and $5.1 million for the years ended December 31, 2024, 2023 and 2022, respectively. The weighted-average remaining lease terms for operating leases were 5.7 years and 6.8 years as of December 31, 2024 and 2023, respectively. The weighted-average discount rates for operating leases were 8.5% as of both December 31, 2024 and 2023.

The Company entered into subleases in May 2021 and September 2024, whereby the Company agreed to sublease approximately 11,000 and 12,150 square feet, respectively, of its currently leased space in South San Francisco, California currently leased by the Company. These subleases are classified as operating leases and will expire in March 2031 and July 2026, respectively. The Company recognized sublease income for these subleases of $1.1 million for the year ended December 31, 2024 and $0.8 million for both the years ended December 31, 2023 and 2022.

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 19, *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 if the approximate five-year renewal term is exercised. The Company recognized Sonoma sublease income of $1.9 million for each of the years ended December 31, 2024, 2023 and 2022.

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

During the year ended December 31, 2024, the Company recorded impairment losses of $12.6 million for lease right-of-use assets. The Company did not record any impairment losses for lease right-of-use assets in 2023 and 2022. See Note 5, *Impairment of Long-Lived Assets*, for further information.

12. Convertible Preferred Stock

As of December 31, 2024, no shares of convertible preferred stock were outstanding.

13. 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, 2024 and 2023, 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, 2024 and 2023, there were 294,875,546 shares and 253,957,709 shares of the Company's common stock outstanding, respectively.

On February 28, 2024, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") acting as the Company's sales agent (the "Sales Agreement"), pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to $150.0 million from time to time in a series of one or more at-the-market equity offerings. The Company will pay Cowen commissions of up to 3% of the gross proceeds of the sale, and reimbursement of certain expenses, under this agreement. Neither the Company nor Cowen is obligated to sell any shares and, to date, the Company has not made any sales under the Sales Agreement.

14. 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, 2024, the Company reserved an additional 12,697,885 shares of common stock for issuance under the 2021 Plan representing 5% of the total common shares outstanding as of December 31, 2023. 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, 2024, 41,180,525 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. On January 1, 2024, the Company reserved an additional 2,539,577 shares of common stock for issuance under the 2021 ESPP representing 1% of the total common shares outstanding as of December 31, 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, 954,761, 986,391 and 475,363 shares have been issued for the years ended December 31, 2024, 2023 and 2022, respectively.

As of December 31, 2024, 5,046,445 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,		
	2024	2023	2022
Research and development	$ 14,577	$ 18,207	$ 16,721
General and administrative	18,567	28,877	65,203
Total stock-based compensation expense	$ 33,144	$ 47,084	$ 81,924

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 were required to 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.

At December 31, 2024, total stock-based compensation cost related to unvested awards not yet recognized was $44.7 million, which is expected to be recognized over a remaining weighted-average period of 2.3 years.

Performance-Based Restricted Stock Units

During the year ended December 31, 2024, the Company granted PSU awards to certain key employees. PSUs awarded to employees have a three-year performance period and vest based upon the Company's performance against a two and three-year relative total shareholder return ("rTSR") metric, as well as upon the achievement of certain clinical development milestones. Certain of the clinical development milestones were determined to be probable of achievement as of December 31, 2024, representing 1.5 million shares. For the portion of PSUs subject to certain clinical development milestones (other than the bonus clinical development milestone), 50% vest upon the achievement of the applicable milestone, and the remaining 50% vest upon the earlier of (a) one year of service from the date of such achievement and (b) the end of the three-year performance period. The vesting of all PSU awards granted is also subject to the respective employee's continued employment. The Company valued the portion of PSUs subject to the rTSR metric using a Monte Carlo simulation. The number of PSUs granted subject to the rTSR metrics represents the target number of units that are eligible to be earned based on the achievement of the metrics established at the beginning of the performance period, which ends on December 31st of the three-year performance period. For the portion of PSUs subject to the rTSR metrics, employees may ultimately earn between zero and 200% of the target number of PSUs granted based on the degree of achievement of the applicable rTSR metric. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned. Stock-based compensation expense recognized for the PSU awards was approximately $1.9 million for the year ended December 31, 2024 and zero for both the years ended December 31, 2023 and 2022.

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

	Performance-Based Restricted Stock Units Outstanding	Weighted-Average Value at Grant Date Per Share
Unvested PSUs as of December 31, 2023	—	$ —
PSUs granted[1]	2,703,400	$ 1.88
PSUs vested	—	$ —
PSUs forfeited or canceled	—	$ —
Unvested PSUs as of December 31, 2024	2,703,400	$ 1.88

(1) PSU grants reflect the target number of shares eligible to be earned at the time of grant.

As of December 31, 2024, none of the PSU metrics have been met, resulting in no shares vesting.

Restricted Stock Awards

The Company had no unvested RSAs as of both December 31, 2024 and 2023. The fair value of RSAs vested during the years ended December 31, 2024, 2023 and 2022 was zero, zero and $15.2 million, respectively.

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, 2023	2,072,855	$ 2.96
RSUs granted	5,762,499	$ 1.54
RSUs vested	(1,259,344)	$ 2.55
RSUs forfeited or canceled	(952,191)	$ 2.19
Unvested RSUs as of December 31, 2024	5,623,819	$ 1.72

The fair value of RSUs vested during the years ended December 31, 2024, 2023 and 2022 was $2.0 million, $1.4 million and $1.5 million, respectively.

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, 2023	55,596,831	$ 4.75	6.89	$ 7,368
Granted	3,665,500	$ 1.90		
Exercised	(1,245,836)	$ 0.12		
Canceled or forfeited	(13,229,412)	$ 6.18		
Options outstanding as of December 31, 2024	44,787,083	$ 2.49	6.62	$ 1,479
Options exercisable as of December 31, 2024	30,273,806	$ 2.74	5.88	$ 1,479

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,		
	2024	2023	2022
Risk-free interest rate	4.17 %	4.13 %	2.93 %
Expected volatility	75.9 %	88.0 %	87.3 %
Expected term (in years)	5.89	6.06	6.03
Expected dividend yield	0 %	0 %	0 %

The weighted-average grant date fair value of options granted for the years ended December 31, 2024, 2023 and 2022 was $1.30 per share, $1.69 per share and $3.60 per share, respectively. The intrinsic value of options exercised during the years ended December 31, 2024, 2023 and 2022 was $2.9 million, $6.5 million and $13.9 million, respectively.

15. Income Taxes

The Company has reported pre-tax operating losses for all periods presented. The Company generated losses in the U.S. and had a minimal amount of income in Israel. 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, 2024 and 2023, the Company had U.S. federal net operating loss ("NOL") carryforwards of approximately $599.2 million and $455.2 million, respectively, which were available to reduce future taxable income and do not expire. The Company also had U.S. state NOL carryforwards of $702.9 million that begin to expire in 2038 and foreign carryforwards of $5.8 million that do not expire. The Company had gross U.S. federal and state tax credits of $43.6 million and $24.2 million as of December 31, 2024 and 2023, 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, 2024, the Company had a capital loss carryforward of $52.5 million, which will expire in 2028.

Lyell Immunopharma, Inc.

Notes to Consolidated Financial Statements—(Continued)

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

	Year Ended December 31,		
	2024	2023	2022
Federal statutory tax	21.00 %	21.00 %	21.00 %
State tax, net of federal benefit	4.61	7.45	5.10
Valuation allowance	(20.39)	(29.10)	(28.89)
Stock-based compensation	(2.17)	(2.25)	(6.11)
Tax credits	2.23	2.96	2.33
IPR&D	(5.34)	—	—
Other	0.06	(0.06)	(0.15)
Collaboration revenue	—	—	6.72
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,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforward	$ 176,298	$ 133,141
Tax credit carryforward	37,611	22,409
Capital loss carryforward	14,705	14,368
Accrued liabilities and allowances	3,818	3,143
Deferred revenue	936	793
Property and equipment	10,551	—
Amortization	5,582	5,243
Capitalized research and development	82,389	51,159
Investment basis difference	7,820	4,104
Lease liability	16,486	17,284
Stock-based compensation	10,036	11,244
Other	125	470
Gross deferred tax assets	366,357	263,358
Valuation allowance	(359,440)	(248,420)
Deferred tax assets, net of valuation allowance	6,917	14,938
Deferred tax liabilities:		
Operating lease right-of-use assets	(6,917)	(10,853)
Property and equipment	—	(4,085)
Deferred tax liabilities	(6,917)	(14,938)
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 $82.4 million as of December 31, 2024.

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.

In connection with the October 2024 acquisition of ImmPACT stock, the Company recorded U.S. deferred tax assets of $39.6 million, which are mainly related to capitalized research costs and tax attribute carryforwards. The deferred tax assets are considered not more likely than not to be realized and therefore are fully offset by a valuation allowance of $39.6 million.

ImmPACT has an Israeli subsidiary with deferred tax assets of $1.4 million, which are mainly related to tax attribute carryforwards. These deferred tax assets are also fully offset by a valuation allowance of $1.4 million.

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 $111.0 million and $68.3 million for the years ended December 31, 2024 and 2023, 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, 2024 and 2023, 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 authorities 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,	
	2024	2023
Beginning balance	$ 400	$ 400
Additions based on tax position related to the current year	1,625	—
Adjustments based on prior year tax positions	1,634	—
Ending balance	$ 3,659	$ 400

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

16. 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, unvested PSUs 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, unvested RSUs and unvested PSUs were all excluded from consideration in the calculation of diluted net loss per share in all periods presented due to their anti-dilutive effects.

17. 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 $1.0 million, $1.2 million and $1.0 million for the years ended December 31, 2024, 2023 and 2022, respectively.

18. Commitments and Contingencies

Collaboration and License Agreements

The Company has entered into certain collaboration and license agreements, including those identified in Note 4, *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, 2024 and 2023.

19. 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, 2024 and 2023, there were accrued liabilities and other current liabilities of $0.5 million, and as of December 31, 2024 and 2023, other non-current liabilities of $2.5 million and $3.0 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 11, *Leases*, for more detail on the Sonoma Sublease.

	Year Ended December 31,		
	2024	2023	2022
Sonoma other operating income, net	$ 2,838	$ 2,592	$ 2,635
Sonoma sublease income	$ 1,861	$ 1,861	$ 1,861

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 4, *License, Collaboration, and Success Payment Agreements*. Revenue recognized in connection with the GSK agreement was zero for both the years ended December 31, 2024 and 2023, and $84.7 million for the year ended December 31, 2022. GSK terminated the GSK Agreement effective December 24, 2022. See Note 4, *License, Collaboration, and Success Payment Agreements,* for additional details regarding the termination of the GSK Agreement.

20. Segment

The Company reports segment information in accordance with the management approach, which reflects the internal reporting utilized by the Chief Operating Decision Maker ("CODM"), the Company's President and Chief Executive Officer. Based on the information used by the CODM to allocate resources and assess the Company's performance, the Company has determined it operates in one segment. The CODM reviews financial information presented on a consolidated basis for purposes of making operating decisions and assessing financial performance.

The CODM evaluates the performance of the Company's sole reportable segment based on net income or loss that also is reported on the Consolidated Statements of Operations and Comprehensive Loss as net income or loss. The measure of segment assets is reported on the Consolidated Balance Sheets as total assets. The Company's sole reportable segment generates revenue by providing research and development services.

Lyell Immunopharma, Inc.

Notes to Consolidated Financial Statements—(Continued)

	Year Ended December 31,		
	2024	2023	2022
Revenue	$ 61	$ 130	$ 84,683
Operating expenses:			
Research and development			
Technical operations	63,419	64,393	55,412
Clinical operations	39,783	31,802	19,191
Research activities	37,772	53,567	57,328
Facilities and technology	26,342	25,636	25,081
Operations management	4,287	7,547	2,176
Total research and development expenses	171,603	182,945	159,188
General and administrative			
Business support	33,973	47,428	84,500
Corporate expenses and outside services	14,450	15,575	27,717
Facilities and technology	3,618	3,980	5,090
Total general and administrative expenses	52,041	66,983	117,307
Other operating income, net	(3,309)	(2,790)	(4,754)
Acquired in-process research and development	87,184	—	—
Impairment of long-lived assets	51,297	—	—
Total operating expenses	358,816	247,138	271,741
Loss from operations	(358,755)	(247,008)	(187,058)
Interest income, net	24,068	23,453	7,053
Other income, net	4,694	1,846	1,887
Impairment of other investments	(13,001)	(12,923)	(5,000)
Total other income, net	15,761	12,376	3,940
Net loss	$ (342,994)	$ (234,632)	$ (183,118)

Total expenditures for additions to the Company's property and equipment, net were $0.6 million, $1.4 million and $21.0 million for the years ended December 31, 2024, 2023 and 2022, respectively.

For the year ended December 31, 2024, approximately 73% of revenue is attributable to a single customer headquartered in the United States and approximately 27% of revenue is attributable to a single customer headquartered in China. The Company's revenues for the year ended December 31, 2023 are attributed to a single customer headquartered in the United States. For the year ended December 31, 2022, approximately 100% of the Company's revenues were attributable to a single customer headquartered in the United Kingdom.

The Company's long-lived assets as of December 31, 2024 and 2023 are located in the United States.

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, 2024, 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, 2024, 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, 2024. In accordance with SEC staff guidance, which allows companies to exclude certain acquisitions from management's report on internal control over financial reporting, our assessment of, and conclusion on, the effectiveness of internal control over financial reporting did not include the internal controls of ImmPACT Bio USA Inc., which was acquired during October 2024. Total assets and operating expenses attributable to the acquisition of ImmPACT Bio USA Inc., represented approximately 3% of our consolidated assets as of December 31, 2024 and 4% of our total operating expenses for the year ended December 31, 2024.

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, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the quarter ended December 31, 2024, 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.

Code of Ethics

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 investor 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.

Insider Trading Policy

Our Board of Directors adopted an insider trading policy governing the purchase and sale of, and/or other transactions in, the Company's securities by our directors, officers, employees and designated consultants that we believe is reasonably designed to promote compliance with insider trading laws, rules and regulations, and the exchange listing standards applicable to us.

Directors, officers, employees and designated consultants may not buy, sell or engage in other transactions in our common stock while aware of material non-public information or engage in hedging or the use of margin accounts involving the Company's securities; buy or sell securities of other companies while aware of material non-public information about those companies that they became aware of as a result of business dealings between the Company and those companies; or disclose material non-public information to any unauthorized persons outside of the Company.

The remainder of the information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

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 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

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 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

Item 14. Principal Accountant Fees and Services.

The information required by this item is incorporated by reference to our Proxy Statement for the 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits 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
2.1*	Agreement and Plan of Merger, dated as of October 24, 2024, by and among the Registrant, ImmPACT Bio USA Inc., Inspire Merger Sub Inc. and WT Representative LLC, solely in its capacity as the Representative.	8-K	001-40502	2.1	10/24/2024	
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	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
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	
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#	Offer Letter by and between the Registrant and Stephen Hill, dated May 9, 2019.	S-1	333-256470	10.14	5/25/2021	
10.14#	Offer Letter by and between the Registrant and Matthew Lang, dated May 12, 2023.	10-Q	001-40502	10.1	11/07/2023	
10.15#	Offer Letter by and between the Registrant and Gary Lee, dated November 24, 2021.	10-K	001-40502	10.16	2/28/2024	
10.16#	Severance Waiver by and between the Registrant and Stephen Hill, dated April 19, 2022.	10-Q	001-40502	10.1	5/10/2022	
10.17	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	
10.18	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	
10.19	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	
10.20	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	
10.21	Registration Rights Agreement, dated as of October 31, 2024, by and among Lyell Immunopharma, Inc., each of the Sellers Party thereto and WT Representative LLC, solely in its capacity as the Representative of the Sellers.	8-K	001-40502	10.1	10/31/2024	

Exhibit Number	Exhibit Description	Incorporation by Reference				Filed Herewith
		Form	File Number	Exhibit/ Appendix Reference	Filing Date	
10.22	Exclusive License Agreement by and between Kalthera, Inc., a subsidiary of the Registrant, and the Regents of the University of California, acting through The Technology Development Group of the University of California, Los Angeles (UCLA), dated February 18, 2021, as amended.					X
19.1	Lyell Immunopharma, Inc. Insider Trading Policy.					X
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.	10-K	001-40502	97.1	2/28/2024	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.

# Indicates management contract or compensatory plan or arrangement.

+ 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 March 11, 2025.

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)*	March 11, 2025
/s/ CHARLES NEWTON **Charles Newton**	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 11, 2025
/s/ RICHARD D. KLAUSNER **Richard D. Klausner, M.D.**	Chair of the Board of Directors	March 11, 2025
/s/ OTIS BRAWLEY **Otis Brawley, M.D.**	Director	March 11, 2025
/s/ CATHERINE FRIEDMAN **Catherine Friedman**	Director	March 11, 2025
/s/ ELIZABETH NABEL **Elizabeth Nabel, M.D.**	Director	March 11, 2025
/s/ ROBERT NELSEN **Robert Nelsen**	Director	March 11, 2025
/s/ SUMANT RAMACHANDRA **Sumant Ramachandra, M.D., Ph.D.**	Director	March 11, 2025
/s/ WILLIAM RIEFLIN **William Rieflin**	Director	March 11, 2025

CERTAIN INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [*], HAS BEEN OMITTED BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

EXCLUSIVE LICENSE AGREEMENT

This exclusive license agreement ("**Agreement**") is made effective **February 18, 2021** ("**Effective Date**"), by and between **The Regents of the University of California**, a California public corporation, having its statewide administrative offices at 1111 Franklin Street, 12th Floor, Oakland, CA 94607-5200 ("**The Regents**"), acting through The Technology Development Group of the University of California, Los Angeles ("**UCLA**"), located at **10889 Wilshire Boulevard, Suite 920, Los Angeles, CA 90095-7191**, and **Kalthera, Inc.** ("**Licensee**"), a Delaware corporation having a principal place of business at **2629 Townsgate Rd., Suite 235, Westlake Village, CA 91361**.

RECITALS

WHEREAS, The Regents own certain rights in the Patent Rights which claim, and Associated Technology which pertains to, invention(s) arising out of the laboratory of Yvonne Chen in the course of research at UCLA;

WHEREAS, UCLA Case No. [*] is co-owned with Seattle Children's Hospital d/b/a Seattle Children's Research Institute ("**SCRI**"), and The Regents and SCRI have entered into an Inter-Institutional Agreement giving The Regents the exclusive right and final authority to negotiate, execute, and administer licenses to SCRI's interest in the Patent Rights;

WHEREAS, Licensee is a "small entity" as defined in 37 CFR 1.27(a)(2) for the purposes of determining whether The Regents is eligible for reduced patent fees;

WHEREAS, as part of its public mission to bring products to the marketplace, The Regents uses good faith efforts to enable underserved communities, which have limited access to adequate quantities of medical innovations arising from UCLA's laboratories, to have affordable access to these innovative products;

WHEREAS, The Regents and Licensee previously entered into the following agreements: [*]; and

WHEREAS, Licensee desires a license to the Patent Rights and Associated Technology and The Regents is willing to grant such license pursuant to the provisions herein below.

NOW, THEREFORE, in consideration of the mutual promises contained herein and for other good and sufficient consideration, the receipt and adequacy of which is hereby acknowledged, the parties agree as follows:

1. DEFINITIONS

As used in this Agreement, the following terms, whether used in the singular or plural, will have the following meanings:

1.1 "**Affiliate**" means any entity which, directly or indirectly, Controls Licensee, is Controlled by Licensee, or is under common Control with Licensee. "**Control**" means (i) having the actual, present capacity to elect a majority of the directors, or the power to direct greater than fifty percent (50%) of the voting rights entitled to elect directors, of such entity; or (ii) in any country where the local law will not permit foreign equity participation of a majority, the ownership or control (directly or indirectly) of the maximum percentage of such outstanding stock or voting rights permitted by local law. For clarity, an entity will be deemed an Affiliate of Licensee solely for the term during which it satisfies the foregoing definition.

1.2 "**Associated Technology**" means The Regents' interest in technical information, copyrightable works, processes, procedures, compositions, devices, tangible materials, methods, formulas, protocols, techniques, software, designs, drawings and/or data that satisfies all of the following: (i) it exists as of the Effective Date of this Agreement, (ii) it was created by the inventors of the Patent Rights, and (iii) it is expressly identified in **Appendix F**

of this Agreement. For the avoidance of doubt, Associated Technology (a) need not be, and The Regents will have no obligation to keep Associated Technology, confidential or as a trade secret, and (b) will not include anything that is created after the Effective Date unless and until the parties enter into a written amendment to this Agreement to add such Associated Technology to **Appendix F** (such as for example results from a sponsored research agreement).

1.3 "**BLA**" means a Biologics License Application (as more fully described in 21 CFR §601, *et seq.*, or its successor regulation) filed with the FDA, or any successor application thereto.

1.4 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.5 "**Field of Use**" means all fields of use.

1.6 "**First Commercial Sale**" or "**FCS**" means the first sale of any Licensed Product by Licensee or a Sublicensee that would be included in the calculation of Net Sales and thereby trigger an Earned Royalty obligation to The Regents, following approval of its marketing by the appropriate governmental agency for the country in which the sale is to be made. When governmental approval is not required, "First Commercial Sale" means the first sale of any Licensed Product by Licensee or a Sublicensee that would be included in the calculation of Net Sales pursuant to this Agreement and thereby trigger an Earned Royalty obligation to The Regents. For clarity, no sale or other disposition of a Licensed Product by Licensee or a Sublicensee that, by the terms of the definition of Net Sales in Section 1.11, would be excluded from the calculation of Net Sales shall constitute a "First Commercial Sale" for purposes of this Agreement.

1.7 "**IND**" means an Investigational New Drug application filed with the FDA pursuant to 21 C.F.R. §312, or any successor application thereto.

1.8 "**Licensed Product**" means any product or service: (i) the manufacture, use, sale, offer for sale, importation, lease, disposition or provision of which would, absent the license granted hereunder, constitute infringement (including direct, contributory or inducement) of, or is covered by, any Valid Claim of the Patent Rights (a "**Patent Rights Product**"); and/or (ii) that is developed, made or provided through the use of Associated Technology (an "**Associated Technology Product**"). For clarity:

(a) if, at the time of First Commercial Sale of a Licensed Product, such Licensed Product is both a Patent Rights Product and an Associated Technology Product (and for so long thereafter as such Licensed Product is both a Patent Rights Product and an Associated Technology Product), then Licensee shall pay an Earned Royalty on such Licensed Product only at the rate(s) applicable to Patent Rights Products set forth in Section 4.3(i), and no Earned Royalty shall be payable on such Licensed Product as an Associated Technology Product under Section 4.3(ii) during such period;

(b) at such time as a Licensed Product that was both a Patent Rights Product and an Associated Technology Product at the time of First Commercial Sale of such Licensed Product in a country ceases to be a Patent Rights Product in such country, then, *if (and only if)* less than ten (10) years has elapsed since the First Commercial Sale of such Licensed Product in such country, Licensee shall pay an Earned Royalty on such Licensed Product at the rate applicable to Associated Technology Products under Section 4.3(ii) from the date such Licensed Product ceased to be a Patent Rights Product in such country until the expiration of the Royalty Term for such Associated Technology Product in such country; and

(c) a Licensed Product that is a Patent Rights Product at the time of First Commercial Sale in a country but is also not an Associated Technology Product at the time of such First Commercial Sale shall never become an Associated Technology Product, and no Earned Royalty shall ever be payable on such Licensed Product under Section 4.3(ii), *provided* that such Licensed Product may become subject to Section 4.3.C to the extent expressly set forth in such paragraph.

Licensee acknowledges that Patent Rights Products and Associated Technology Products are the sole Licensed Products contemplated as of the Effective Date to be commercialized pursuant to this Agreement; if Licensee or a Sublicensee desires to commercialize any Licensed Product that is neither a Patent Rights Products and Associated Technology Product, the parties will confer and amend this Agreement to specify additional milestones, if any, and the royalty percentage to apply to such other Licensed Product.

1.9 "**Licensed Territory**" means (i) with respect to Patent Rights, all territories where Patent Rights exist or may come to exist, and (ii) with respect to Associated Technology, the entire world.

1.10 "**NDA**" means a New Drug Application (as more fully defined in 21 CFR 314.5, *et seq.*) filed with the FDA, or any successor application thereto.

1.11 "**Net Sales**" means the gross amounts amount invoiced or otherwise charged (including fair market value of any non- cash consideration) by Licensee and Sublicensees (in each case, a "**Selling Party**") for sales or other dispositions of Licensed Products to Third Parties, less the following amounts to the extent specifically attributable to Licensed Products and actually granted, allowed, taken or incurred (if not previously deducted from the amount invoiced): [*].

The deductible items listed in subparagraphs [*] above shall be either included as line items on the invoice or otherwise documented as being specifically attributable to sales of Licensed Products. No particular amount identified above shall be deducted more than once in calculating Net Sales (*i.e.*, no "double counting" of deductions).

Sale or other disposition of Licensed Product by a Selling Party to another Selling Party for resale by such other Selling Party to a Third Party (other than a Selling Party) shall not be deemed a sale for purposes of this definition of "**Net Sales**," provided that the subsequent resale is included in the computation of Net Sales, and *provided further* that if such subsequent resale does not occur within [*] of the initial sale or disposition of the Licensed Product, then Net Sales will be calculated as the total amount invoiced or otherwise charged (including fair market value of any non-cash consideration) for such initial sale or disposition. In the event of any sale or other disposition of Licensed Product (1) for any consideration other than exclusively monetary consideration on *bona fide* arm's-length terms, or (2) between any of Licensee, Sublicensees, or their respective affiliates for end use or consumption by Licensee or such Sublicensees or affiliates, then in each case the Net Sales for such Licensed Product shall be deemed to be equal to the average amount invoiced or otherwise charged to customers in arm's length transactions (for cash only) for such Licensed Products over the preceding [*].

Notwithstanding the foregoing, [*] shall be disregarded in determining Net Sales.

1.12 "**Patent Action**" means the preparation, filing, prosecution and maintenance of patent applications and patents in the Patent Rights, including reexaminations, interferences, oppositions, inventorship related matters, and any other ex parte or inter partes matters (e.g., inter partes review petitions) originating or conducted in a patent office.

1.13 "**Patent Rights**" means The Regents' (and SCRI's with respect to UCLA Case No. [*]) interest in: (i) the patents and patent applications expressly identified in **Appendix A**; (ii) any patent applications claiming priority to any of those identified in subpart (i) such as utility filings, divisionals, substitution applications, continuations and continuations-in-part (but, in the case of continuations-in-part, solely to the extent of those claims that are both entirely supported by the specification and entitled to the priority date of any patent application or patent identified in subpart (i) above); (iii) any patents issuing from any patent application identified in subparts (i) and (ii) above, including reissues, reexaminations, renewals and substitutions, as well as any applicable patent extensions or term adjustments, and supplementary protection certificates; and (iv) any foreign counterparts of any patent application or patent identified in subparts (i)-(iii) above.

1.14 "**Phase 1 Clinical Trial**" means a human clinical trial that would satisfy the requirements for a Phase 1 study as defined in 21 CFR § 312.21(a), regardless of where such clinical trial is conducted.

1.15 "**Phase 2 Clinical Trial**" means a human clinical trial that would satisfy the requirements for a Phase 2 study as defined in 21 CFR § 312.21(b), regardless of where such clinical trial is conducted.

1.16 "**Phase 3 Clinical Trial**" means a human clinical trial that would satisfy the requirements for a Phase 3 study as defined in 21 CFR § 312.21(c), regardless of where such clinical trial is conducted.

1.17 "**Royalty Term**" has the meaning provided in Section 4.3.

1.18 "**Selling Party**" has the meaning provided in Section 1.11.

1.19 "**Sublicense**" has the meaning provided in Section 3.1.

1.20 "**Sublicensee**" has the meaning provided in Section 3.1.

1.21 "**Sublicensing Income**" means any consideration (including, without limitation, any licensing or optioning fees, or license maintenance fees, or milestone payments, and fair market value of any non-cash consideration) received by, or payable to, Licensee from any Sublicensee, in consideration for the grant of a Sublicense; *provided, however*, that if Licensee receives any milestone payment for the achievement by a Sublicensee of a milestone event for which Licensee is obligated to pay The Regents a Milestone Payment under Section 4.7, then only the amount by which the milestone payment received by Licensee from the Sublicensee exceeds the Milestone Payment payable (and paid) by Licensee to The Regents for such Sublicensee's achievement of such milestone event shall be considered Sublicensing Income (so long as Licensee also pays such Milestone Payment to The Regents); and *provided, further*, that Sublicensing Income excludes:

(a) [*] ;

(b) [*];

(c) [*]; and

(d) [*].

1.22 "**Third Party**" means any entity other than The Regents, SCRI, and their affiliated entities, and Licensee and its Affiliates.

1.23 "**Third Party Licenses**" has the meaning provided in Section 4.3.

1.24 "**Valid Claim**" means any pending or issued claim in the Patent Rights that has not irrevocably: (i) expired; (ii) been disclaimed, cancelled or superseded, or if cancelled or superseded, has not been reinstated; and (iii) been revoked, held invalid, or otherwise declared unenforceable or not allowable by a tribunal or patent authority of competent jurisdiction over such claim in such country, in all cases from which no further appeal has or may be taken.

2. GRANT

2.1 **License**. Subject to the limitations and other terms and conditions set forth in this Agreement, including the limitations outlined in Section 2.2 below, The Regents hereby grants to Licensee an exclusive license under the Patent Rights and a nonexclusive license with respect to the Associated Technology, in each case, to make, have made, use, sell, have sold, offer for sale and import Licensed Products in the Field of Use in the Licensed Territory.

Licensee shall have the right, in its discretion, to extend the licenses granted to Licensee hereunder to one or more of Licensee's Affiliates, provided that if any such Affiliate ceases to satisfy the definition of Affiliate (*i.e.*, such entity becomes a Third Party), then any license extended to such Third Party pursuant to this Section 2.1 shall terminate on the date it ceases to satisfy the definition of Affiliate, but Licensee may grant a sublicense to such Third Party in accordance with, and on the terms and conditions of, Section 3. Affiliates to which Licensee extends the licenses granted to Licensee hereunder shall have all of the same rights and obligations, financial and otherwise, that Licensee has under this Agreement. Acts, omissions and liabilities of an Affiliate are considered to be those of Licensee under this Agreement, and Licensee is responsible and liable for all such acts, omissions and liabilities, including without limitation payment to The Regents of royalties or other consideration due to The Regents hereunder.

2.2 **License Conditions**. The license granted in Section 2.1 is subject to the following:

A. The Regents and SCRI expressly reserves the right (a) for itself and other nonprofit and academic research institutions (i) to use Patent Rights and Associated Technology for educational and research purposes (including clinical research and research sponsored by commercial entities), and (ii) to publish results arising therefrom, and (b) for the University of California ("**UC**") to offer and perform clinical diagnostic and prognostic services for patients in the UC healthcare system. The foregoing reserved rights specifically exclude any right for The Regents, so long as Licensee's license to the Patent Rights remains exclusive, to sell, have sold or offer for sale any Licensed Product (other than a

transfer to another academic or research institution under a bailment or materials transfer arrangement pursuant to which the transferee pays or reimburses The Regents for the costs of such Licensed Product), or to grant any Third Party any right or license to sell, have sold or offer for sale any Licensed Product.

B. The Regents' grant to the U.S. Government of a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the invention claimed by the Patent Rights throughout the world. Licensee agrees (and will require all Sublicensees to agree in writing) that, unless a valid waiver is obtained from the applicable funding agency at Licensee's written request, Licensee's exclusive right to use or sell any Licensed Products in the United States is subject to the obligation that such Licensed Product will be manufactured substantially in the United States, to the extent required by 35 U.S.C. § 204 and applicable regulations of Chapter 37 of the Code of Federal Regulations.

3. SUBLICENSES

3.1 **Permitted Sublicensing**. The Regents also grants to Licensee the right to sublicense to Third Parties the rights licensed to Licensee hereunder through up to [*] Sublicensees so long as Licensee's license under the Patent Rights remains exclusive (each, a "**Sublicense**" and each such Third Party that receives a Sublicense, a "**Sublicensee**"). All Sublicenses must be in writing and will be subject to, and contain terms consistent with, the terms in this Agreement, including, without limitation, the provisions contained in Articles 2.2 (License Conditions), 3 (Sublicenses), 4.4 (Validity Challenge), 7 (Books and Records), 9 (Use of Names and Trademarks), 10 (Limited Warranty and Liability), 12 (Patent Marking), 13 (Patent Infringement), 14 (Indemnification), 18 (Compliance with Laws), and 19 (Confidentiality). For clarity, [*]. For the purposes of this Agreement, the operations of all Sublicensees will be deemed to be the operations of Licensee, for which Licensee will be responsible and liable. Licensee must provide The Regents with a copy of each Sublicense issued, including any agreements and amendments executed in relation thereto, within [*] of its execution, provided that [*].

3.2 **Sublicenses Upon Termination**. Upon termination of this Agreement, all Sublicenses will terminate, except that any outstanding Sublicense with a Qualified Sublicensee (defined below) will automatically be assigned by Licensee to, and assumed by, The Regents, subject to this Section 3.2. As a condition to any such assignment, a Qualified Sublicensee shall furnish to The Regents the completed contact information form attached hereto as **Appendix C** within [*] of termination of this Agreement. Any such assigned Sublicense will remain in full force and effect with The Regents as the licensor or sublicensor instead of Licensee, but the duties of The Regents under the assigned Sublicense will not be greater than the duties of The Regents under this Agreement, and the rights of The Regents under the assigned Sublicense will not be less than the rights (*i.e.*, financial and other rights) of The Regents under this Agreement. However, at the option and written request of The Regents, a Qualified Sublicensee will enter into a new direct license agreement with The Regents with respect to the same scope of license under the Patent Rights and Associated Technology, including the same field of use and territories, as in its Sublicense and on substantially the same terms and conditions as this Agreement (such direct license the "**New License**"). If The Regents requests in writing that a Qualified Sublicensee enter into a New License in accordance with this Section 3.2 and delivers a copy of such New License to such Qualified Sublicensee, such Qualified Sublicensee will execute and deliver such New License to The Regents within [*] of receipt of such New License, failing which the Sublicense granted to such Qualified Sublicensee will terminate and The Regents will have no further obligation to such Qualified Sublicensee. "**Qualified Sublicensee**" means a Sublicensee that meets all of the following criteria: [*].

4. CONSIDERATION

4.1 **License Fee**. In partial consideration for the License, Licensee will pay to The Regents a license issue fee of [*] within [*] of the Effective Date. This fee is non-refundable and is not an advance against royalties.

4.2 **License Maintenance Fee**. Licensee must pay to The Regents the applicable annual license maintenance fee set forth below ("**License Maintenance Fee**") beginning on [*] of the Effective Date and continuing annually on each anniversary date of the Effective Date until the First Commercial Sale of the first Licensed Product anywhere in the world (whereupon Licensee's obligation to pay License Maintenance Fees under this Section 4.2 will terminate and Licensee's obligation to pay Minimum Royalties under Section 4.5 will become effective). License Maintenance Fees are non- refundable and are not an advance against royalties.

[*]

4.3 **Earned Royalty**.

A. Subject to paragraphs (a), (b) and (c) of Section 1.8, Licensee must pay to The Regents an earned royalty with respect to Net Sales as follows (each an "**Earned Royalty**"):

(i) **Applied to Net Sales on a per Patent Rights Product basis:** [*] on the first [*] of cumulative Net Sales, and [*] with respect to Net Sales thereafter, and

(ii) **Applied to Net Sales of Associated Technology Products:** [*].

B. The Earned Royalty will be payable on a Licensed Product-by-Licensed Product and country-by-country basis, from the date of the First Commercial Sale of a Licensed Product in a country until: (a) for Patent Rights Products, the expiration of the last to expire Valid Claim of the Patent Rights covering the manufacture, use, sale, offer for sale or import of such Licensed Product in such country; and (b) for Associated Technology Products that are not Patent Rights Products (including, without limitation, an Associated Technology Product that was a Patent Rights Product at the time of First Commercial Sale in such country but ceases to be a Patent Rights Product in such country prior to [*] from the First Commercial Sale of such Licensed Product in such country), [*] from the First Commercial Sale of such Licensed Product in such country (in each case ((a) or (b)), as applicable, the "**Royalty Term**"). On a Licensed Product-by-Licensed Product and country-by-country basis, upon expiration of the Royalty Term with respect to a Licensed Product in a country, the license granted to Licensee hereunder with respect to Associated Technology in relation to such Licensed Product in such country shall automatically become royalty-free, fully paid-up, irrevocable and perpetual.

C. On a Patent Rights Product-by-Patent Rights Product basis, solely with respect to a Patent Rights Product that is also not an Associated Technology Product, if the First Commercial Sale of such Patent Rights Product in at least one of the United States and the European Union has not occurred before the date that is [*] years prior to the expiration date of the longest-lived Valid Claim of the Patent Rights covering the manufacture, use, sale, offer for sale or import of such Patent Rights Product in such jurisdiction, then the Earned Royalty rates for such Patent Rights Product shall be increased such that the new Earned Royalty rates for Net Sales of such Patent Rights Product shall instead be (i) [*] on the first [*] of cumulative Net Sales of such Patent Rights Product, and (ii) [*] of Net Sales of such Patent Rights Product thereafter. For the avoidance of doubt, [*].

D. All Earned Royalties under this Agreement will be computed and paid for each calendar quarter no later than the date the royalty report for such calendar quarter is due under Section 6.2. For purposes of calculating Net Sales, a Licensed Product will be deemed to have been sold upon the earliest of the following (as applicable): [*].

E. If, with respect to a given country, Licensee or a Sublicensee is required to obtain one or more licenses under patent rights owned or controlled by a Third Party that are necessary for the manufacture, use, sale, offer for sale or import of a Licensed Product in such country ("**Third Party Licenses**"), [*] of the royalties actually paid under such Third Party Licenses by Licensee or its Sublicensee for sales of such Licensed Product in such country will be creditable against the Earned Royalty due The Regents on Net Sales of such Licensed Product in such country; *provided, however*, that in no event will the Earned Royalty due The Regents hereunder with respect to Net Sales of such Licensed Product in such country in any calendar quarter be reduced by more than [*] as a result of any and all such credits in the aggregate. Licensee (or a Sublicensee, as applicable) shall use commercially reasonable efforts to include in each Third Party License a royalty anti-stacking provision that is substantially similar to the foregoing provision. On a Third Party License-by-Third Party License basis, prior to the first reduction of any Earned Royalty due The Regents under this Agreement by reason of royalties paid under a Third Party License, Licensee shall disclose to The Regents in writing the royalty obligations under such Third Party License and the patent rights licensed under such Third Party License, and, at The Regents' request, the parties shall discuss the subject matter of the Third Party patent rights and the reasons for Licensee's or its Sublicensee's determination that such Third Party License was necessary for the manufacture, use, sale, offer for sale or import of a Licensed Product in the applicable country(ies).

4.4 Validity Challenge. If Licensee or a Sublicensee, itself or through a third party, institutes any proceeding that contests the validity of any Patent Right during the term of this Agreement, Licensee agrees to pay to The Regents, directly and not into any escrow or other account, all royalties and other amounts due in view of Licensee's and its Sublicensees' activities under this Agreement during the period of challenge and The Regents' attorneys' fees in defending such action. Should the outcome of such contest determine that any challenged patent claim is valid, Licensee (or its Sublicensee, as applicable) will thereafter, and for the remaining term of this Agreement, pay (i) a royalty rate of [*] and (ii) [*].

4.5 Minimum Annual Royalty. Licensee must pay to The Regents the following minimum annual royalties ("**Minimum Annual Royalties**") on or before [*] of each calendar year ("**CY**") following the CY in which the First Commercial Sale of the first Licensed Product anywhere in the world occurs (the "**FCS CY**") and continuing for the remaining term of this Agreement thereafter. The Minimum Annual Royalty paid in a CY will be credited against the Earned Royalty due and owing with respect to Net Sales made during such CY.

[*]

4.6 Sublicensing Income. In addition to pass-through royalties on Net Sales of Licensed Products by Sublicensees under Section 4.3, Licensee will pay to The Regents the applicable percentage set forth below of Sublicensing Income received by Licensee from each Sublicensee ("**Sublicensing Payments**"), with such applicable percentage to be determined based on the stage of development of the most advanced Licensed Product at the time the applicable Sublicense is executed:

A. [*] of Sublicensing Income received under or on account of a Sublicense that is executed [*];

B. [*] of Sublicensing Income received under or on account of a Sublicense that is executed [*]; and

C. [*] of Sublicensing Income received under or on account of a Sublicense that is executed [*].

All Sublicensing Payments shall be paid within [*] of receipt thereof. Sublicensing Income may not be prorated when the Patent Rights are bundled with other intellectual property, without The Regents' prior written consent. For the avoidance of doubt, all payments and consideration that Licensee or a Sublicensee receives as a result of the sale or other disposition of Licensed Products (subject to the deductions and exclusions specified in the definition of Net Sales) will be accounted for by Licensee in the form of an Earned Royalty under Section 4.3, and all payments and consideration that Licensee receives as a result of the grant of a Sublicense (subject to the exclusions specified in the definition of Sublicensing Income) will be accounted for by Licensee in the form of Sublicensing Payments under this Section 4.6.

4.7 Milestone Payments. For each Licensed Product, Licensee must make each of the following payments ("**Milestone Payments**") to The Regents within [*] of the first achievement (whether by Licensee or a Sublicensee or a Third Party acting on behalf of Licensee or a Sublicensee) of the corresponding milestone event indicated below by such Licensed Product.

A. [*].

B. [*].

C. [*].

For clarity, each of the Milestone Payments set forth above will be payable only one time per Licensed Product, for the first achievement of the applicable milestone event by a Licensed Product, regardless of how many times a given Licensed Product achieves such milestone event. Solely for purposes of this milestone payment provision, [*].

4.8 Payment Terms. All consideration due The Regents will be payable and will be made in United States dollars by check payable to "**The Regents of the University of California**" or by wire transfer to an account designated by The Regents, provided The Regents may assign its interest in any consideration it is to receive pursuant to this Agreement to another entity. Licensee is responsible for all bank or other transfer charges. When Licensed Products are sold for monies other than United States dollars, the Earned Royalties and other consideration will first be determined in the foreign currency of the country in which such Licensed Products were sold and then converted into equivalent United States dollars at the rate of exchange for such currency used throughout the applicable Selling Party's accounting system for financial reporting purposes for the calendar quarter for which payment is due.

A. **Taxes**. Sublicensing Income, Earned Royalties, and other consideration accrued in any country outside the United States may not be reduced by any taxes, fees or other charges imposed by the government of such country.

B. **Interest**. In the event that monies are not received by The Regents when due, Licensee will pay to The Regents interest at a rate of [*] simple interest per annum. Such interest will be calculated from the date payment was due until actually received by The Regents. Such accrual of interest will be in addition to and not in lieu of, enforcement of any other rights of The Regents due to such late payment.

4.9 Equity. As additional consideration for this Agreement, Licensee shall, within [*] of The Regents' execution and delivery to Licensee of a Stock Issuance Agreement in substantially the form attached hereto as **Appendix E**, issue and deliver to The Regents a number of shares of common stock of Licensee as set forth in the Stock Issuance Agreement.

4.10 Other UCLA License Agreements. If Licensee is obligated to pay The Regents a payment (other than for patent cost reimbursement), [*] (any such payment a "**License Payment**"), with respect to a given Licensed Product (as such term is defined in this Agreement) under one or more other active license agreements with The Regents that include patents listing UCLA employees as inventors on them (such other license agreements "**Other UCLA License Agreements**"), such License Payment due hereunder will be reduced by [*].

5. COMMERCIAL DILIGENCE

5.1 Development of Licensed Products. Licensee will diligently proceed, directly and/or through a Sublicensee, to research, develop, and seek marketing approval for, Licensed Products and, following receipt of marketing approval therefor, to market and sell Licensed Products in quantities sufficient to meet the market demands therefor. Licensee or a Sublicensee will obtain all necessary governmental approvals in each country where Licensed Products are manufactured, used, sold, offered for sale or imported.

5.2 Development Milestones. On or before the dates indicated below, Licensee will achieve each of the following development milestones with respect to a Licensed Product ("**Development Milestones**"). If Licensee fails to achieve a Development Milestone by the deadline set forth below (taking into account any allowed extensions of these deadlines as set forth herein), then [*]. This right, if exercised by The Regents, supersedes the rights granted in Section 2 (GRANT).

A. [*].

B. [*].

C. [*].

D. [*].

E. [*].

F. [*].

G. [*].

H. [*].

Licensee may extend the deadline to meet any of these Development Milestones in [*] increments, but not more than [*], not more than [*], and not more than [*] in total across all Development Milestones, by making a [*] payment to The Regents for each milestone extension. In the event of any extension, the deadlines to meet any later occurring Development Milestones will be similarly extended.

5.3 Affordable Access Plan. Within [*] of the First Commercial Sale of a Licensed Product in the U.S. or Europe (whichever occurs first), Licensee will provide The Regents with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), Licensee agrees to discuss such reasoning with The Regents in good faith within [*] ("**Initial Discussion**") and, if following such Initial Discussion The Regents concludes an Affordable Access Plan is reasonable

and desired, to provide an Affordable Access Plan to The Regents within [*] of such Initial Discussion. The "**Affordable Access Plan**" shall include the following -- to the extent such Plan includes confidential information, Licensee will also provide a non-confidential version or statement of such Plan that The Regents can make available to third parties:

A. A specified set of low- and middle-income countries ("**LMICs**") in which the Licensee does not intend to commercialize the Licensed Products (the "**Non-Commercialized Territory**"); and

B. Licensee's and/or its Sublicensees' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations.

Within [*] of The Regents' request (but no more often than once annually), Licensee agrees to confer with The Regents to review Licensee's progress, and to consider in good faith any reasonable modifications suggested by The Regents, with respect to its Affordable Access Plan ("**Progress Discussions**"). For clarity, while The Regents may invite a designated entity to join either the Initial and/or Progress Discussions under this Section 5.3, such discussions will at all times be made subject to the confidentiality obligations set forth in Section 19 (Confidentiality).

6. PROGRESS AND ROYALTY REPORTS

6.1 **Progress Reports**. Beginning on [*], and continuing [*] thereafter until the First Commercial Sale of a Licensed Product anywhere in the world, and annually [*] of each year after such First Commercial Sale, Licensee will complete and submit to The Regents the progress report form attached to this Agreement as **Appendix D**.

6.2 **Royalty Reports**. Beginning with the First Commercial Sale and continuing for the term of this Agreement, Licensee will make quarterly royalty reports to The Regents on or before [*]. Each royalty report will cover Licensee's most recently completed calendar quarter and will include at least the information identified in the Royalty Report attached hereto as **Appendix B (ROYALTY STATEMENT)**, including a breakdown of the Earned Royalties on a Licensed Product-by-Licensed Product basis, as well as identification of which of the Patent Rights cover each such Licensed Product.

7. BOOKS AND RECORDS

7.1 **Accounting**. Licensee must keep, and will cause its Sublicensees to keep, accurate financial and development books and records of all Licensed Products in development, manufactured, used, sold, transferred, provided, or otherwise disposed of, and all Sublicensing Income and other amounts received under a Sublicense, as necessary to determine the amount of Earned Royalties and Sublicensing Income payments due to The Regents hereunder and Licensee's compliance with its financial and Development Milestone obligations hereunder. Books and records must be preserved for at least [*] from the date of the royalty payment to which they pertain.

7.2 **Auditing**. Books and records kept in accordance with Section 7.1 (as well as any books and records that Licensee elects to retain for longer than [*] period set forth in Section 7.1 above) shall be available, upon [*] prior written notice to Licensee, during normal business hours, for examination and copying by an independent certified public accounting firm selected by The Regents and reasonably acceptable to Licensee for the purpose of verifying the calculation of royalties and other payments due under Section 4 and Licensee's reporting obligations with respect thereto, as well as its reporting with respect to its Development Milestone obligations under this Agreement. In conducting examinations pursuant to this Section 7.2, the independent certified public accounting firm shall have access to all records which such accountant reasonably believes to be relevant to the calculation of royalties and other payments under Section 4 and Licensee's reporting obligations with respect thereto, as well as to Licensee's reporting with respect to its Development Milestone obligations under this Agreement. Licensee may require such accounting firm to execute a reasonable and customary confidentiality agreement with Licensee. Such accounting firm may disclose to The Regents its audit report and any information, including, without limitation, work papers, notes, interim reports and other work product of the accountant (but excluding any direct source documents of Licensee or any Sublicensee), that the accounting firm reasonably believes to be relevant to the calculation of royalties and any other payments under Section 4 and Licensee's reporting obligations with respect thereto, which The Regents will maintain as Confidential Information pursuant to this Agreement (but for clarity, The Regents will have the right to use all such information to enforce the rights it has under this Agreement). If The Regents asserts Licensee has underpaid under the Agreement, then The Regents agrees to provide Licensee with copy of The Regents' accounting firm's audit report to Licensee that supports such determination. If The Regents' accounting firm's audit report indicates that Licensee has underpaid under this Agreement, Licensee shall remit the amount of such underpayment to The Regents within [*] of receipt of the audit report. The Regents will bear the

fees and expenses of examination, but if an underpayment of more than [*] of the total amounts due for any year is discovered in any such examination, then Licensee will bear the fees and expenses of that examination.

8. LIFE OF THIS AGREEMENT

8.1 **Term**. The term of this Agreement will commence on the Effective Date and, unless earlier terminated in accordance with this Section 8, continue until the expiration of the last-to-expire Royalty Term for any and all Licensed Products. The termination or expiration of this Agreement will not relieve Licensee of its obligation to pay any fees, royalties or other payments owed to The Regents at the time of such termination or expiration and will not impair any accrued right of The Regents, including the right to receive Earned Royalties in accordance with Section 4 (Consideration). Upon early termination (but not expiration) of this Agreement, Licensee will provide The Regents with written certification that it has ceased all use of the Patent Rights and the related Licensed Product lines, except to the extent expressly permitted by, and subject to the terms of, Section 8.4. Upon expiration (but not early termination) of this Agreement, the license granted to Licensee to Associated Technology pursuant to Section 2.1 shall become royalty-free, fully-paid, irrevocable and perpetual.

8.2 **Termination by The Regents**.

A. If Licensee fails to perform or violates any term of this Agreement or fails to timely pay any amount when due, or after the date of First Commercial Sale fails to sell Licensed Products for [*], then The Regents may give written notice of default ("**Notice of Default**") to Licensee. If Licensee fails to repair the default within [*] of the effective date of Notice of Default, The Regents may terminate this Agreement and its licenses by a second written notice ("**Notice of Termination**"). If a Notice of Termination is sent to Licensee, this Agreement will automatically terminate on the effective date of such Notice of Termination.

B. The Regents shall have the right to terminate this Agreement upon written notice to Licensee if (i) Licensee files a voluntary petition in bankruptcy, (ii) an involuntarily petition in bankruptcy is filed against Licensee and such petition is not dismissed within [*] of filing, (iii) Licensee makes an assignment for the benefit of creditors, or (iv) the business or assets of Licensee are placed in the hands of a receiver, assignee or trustee.

8.3 **Termination by Licensee**. Licensee may terminate this Agreement at any time by providing a notice of termination to The Regents with a statement confirming it has abandoned the commercialization of Licensed Products, which termination will be effective [*] from the date such termination notice is sent by Licensee. Licensee may terminate its obligations under this Agreement with respect to Associated Technology only if it certifies in writing that it has destroyed and ceased all use of the Associated Technology (except, on an Associated Technology Product-by-Associated Technology Product basis, for use of the Associated Technology for an Associated Technology Product in a country for which the Royalty Term had expired prior to such termination), as well as any Associated Technology Products for which the applicable Royalty Term in a country had not expired prior to such termination.

8.4 **Disposition of Licensed Products on Hand Upon Termination**. Upon termination of this Agreement, unless this Agreement was terminated by The Regents based on Licensee's failure to timely pay financial obligations owed pursuant to this Agreement, Licensee may continue to sell any previously made Licensed Products during the [*] period immediately following the effective date of the termination of this Agreement; provided that, in such case, Licensee must continue to fulfill all obligations associated therewith as if this Agreement had not terminated, including the obligation to pay Earned Royalties on Net Sales of such Licensed Products and submit royalty reports by the due dates required under this Agreement.

8.5 **Accrued Rights and Obligations; Surviving Provisions**. The termination or expiration of this Agreement will not relieve either party of any obligation accruing prior to termination or expiration, including Licensee's obligation to pay any fees, Earned Royalties or other payments owed to The Regents at the time of such termination or expiration, and will not impair any accrued right of either party, including The Regents' right to receive Earned Royalties in accordance with Section 4 (Consideration). In addition, the following provisions of this Agreement will survive termination or expiration of this Agreement: Sections 1 (Definitions); 3.2 (Sublicenses Upon Termination); 4.9 (Equity); 7 (Books and Records); 8.4 (Disposition of Licensed Products on Hand Upon Termination), 8.5 (Accrued Rights and Obligations; Surviving Provisions), 9 (Use of Names and Trademarks); 10 (Limited Warranty and Liability); 14 (Indemnification); 15 (Notices); 16 (Assignability); 17 (Governing Laws); 19 (Confidentiality); and 20 (Miscellaneous).

9. USE OF NAMES AND TRADEMARKS

9.1 Use of Name. Nothing contained in this Agreement will be construed as conferring any right on either party, to use in advertising, publicity or other promotional activities any name, trade name, trademark or other designation of the other party or of SCRI (including a contraction, abbreviation or simulation of any of the foregoing). The Regents and SCRI may list Licensee's name as a licensee of technology from The Regents without further identifying the technology. Unless required by law or unless the required authorizations are obtained (contact [*] for more information), the use by Licensee of SCRI's name, the name "**Seattle Children's Hospital**", the name "**The Regents of the University of California**" or the name of any campus of the University of California in advertising, publicity or other promotional activities is expressly prohibited.

10. LIMITED WARRANTY AND LIABILITY

10.1 The Regents warrants to Licensee that it has the lawful right to grant this license. Except as expressly set forth in this Agreement, this license and the associated Patent Rights and Licensed Products and Associated Technology are provided by The Regents and **SCRI WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY OF ANY KIND, EXPRESS OR IMPLIED. NEITHER THE REGENTS NOR SCRI MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY THAT USE OR COMMERCIALIZATION OF THE PATENT RIGHTS OR LICENSED PRODUCTS OR ASSOCIATED TECHNOLOGY WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER RIGHTS.**

This Agreement does not express or imply (a) a warranty or representation as to the validity, enforceability, or scope of any Patent Rights or Associated Technology; (b) a warranty or representation that anything made, used, sold, offered for sale, imported or otherwise exploited under any license granted in this Agreement is or will be free from infringement of patents, copyrights, or other rights of third parties; (c) an obligation on behalf of The Regents, SCRI, or the U.S. Government to bring or prosecute actions or suits against third parties for patent infringement; (d) by implication, estoppel or otherwise, any grant of any license or other rights under any patents or other rights of The Regents, SCRI, or the U.S. Government, other than Patent Rights, regardless of whether such patents or other rights are dominant or subordinate to Patent Rights; or (e) any obligation for The Regents, SCRI, or the U.S. Government to furnish (i) any advancements, developments, or other improvements to the Patent Rights which are not entitled to the priority dates of Patent Rights, or (ii) any know-how, technology or information not provided in Patent Rights or Associated Technology.

10.2 OTHER THAN WITH RESPECT TO LICENSEE'S OBLIGATIONS UNDER SECTION 14.1 (INDEMNIFICATION), IN NO EVENT WILL LICENSEE BE LIABLE TO THE REGENTS OR SCRI, NOR WILL THE REGENTS OR SCRI BE LIABLE TO LICENSEE OR ITS SUBLICENSEES (OR THEIR RESPECTIVE AFFILIATES), FOR ANY LOST PROFITS, COSTS OF PROCURING SUBSTITUTE GOODS OR SERVICES, LOST BUSINESS, OR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR OTHER SPECIAL DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY AND BREACH OF WARRANTY) EVEN IF LICENSEE OR ITS SUBLICENSEES (OR THEIR RESPECTIVE AFFILIATES), OR THE REGENTS OR SCRI, AS APPLICABLE, HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. NEITHER THE REGENTS NOR SCRI WILL BE LIABLE FOR ANY DIRECT DAMAGES SUFFERED BY LICENSEE, SUBLICENSEES, JOINT VENTURES, OR AFFILIATES ARISING OUT OF OR RELATED TO PATENT RIGHTS TO THE EXTENT ASSIGNED OR LICENSED BY THE REGENTS' OR SCRI'S INVENTORS TO THIRD PARTIES.

11. PATENT FILING, PROSECUTION AND MAINTENANCE

11.1 Ownership and Prosecution. The Patent Rights will be held in the name of The Regents (and SCRI, as applicable). Subject to Licensee's compliance with its Patent Cost reimbursement obligations under Section 11.2, The Regents shall diligently prosecute and maintain the Patent Rights using outside counsel selected by The Regents and shall instruct its outside counsel to provide copies of all correspondence filed with and received in relation to the Patent Rights from the applicable patent office (e.g., patent applications, office actions, office action responses, etc.) during the term of this Agreement to Licensee promptly following filing or receipt thereof, to provide Licensee with drafts of material submissions relating to Patent Rights for review reasonably in advance of the anticipated filing thereof, and Licensee may request The Regents' counsel to provide to Licensee on a quarterly basis a rolling 12-month calendar of upcoming filing deadlines with respect to the Patent Rights. While The Regents will control all Patent Actions and all decisions with respect to Patent Actions, it will consider in good faith incorporating any reasonable comments or suggestions provided by Licensee with respect to Patent Actions and draft material submissions relating to Patent Rights, e.g., to amend any patent application under the Patent Rights to include claims reasonably requested by Licensee to protect the products contemplated to be sold by Licensee under this Agreement. Licensee has the right to provide instructions regarding Patent Actions via a written request to The Regents [*] prior to the deadline set by the patent office in the territory such Patent Action is to take place (a "**Patent Prosecution Request**").

11.2 **Past & Ongoing Patent Costs**. Licensee will bear all out-of-pocket costs incurred by The Regents for Patent Actions ("**Patent Costs**"). Licensee must reimburse to The Regents Patent Costs incurred prior to the Effective Date ("**Past Patent Costs**") within [*] of Licensee's receipt of an invoice from The Regents. As of the Effective Date, Past Patent Costs not previously reimbursed by Licensee total [*]. Licensee shall pay [*] within [*] of the Effective Date, [*] within [*] of the Effective Date, and the balance, [*] within [*] of the Effective Date. Licensee will also bear all documented Patent Costs incurred during the term of this Agreement ("**Ongoing Patent Costs**"). If The Regents' patent counsel's estimated cost for undertaking a given Patent Action exceeds [*] (for clarity, such estimate is on a per Patent Action basis), The Regents will inform Licensee of such estimate prior to the date when such costs are anticipated to be incurred, and Licensee will be required to pay in advance the estimated amount of such Ongoing Patent Costs ("**Advanced Payment**") before The Regents authorizes its patent counsel to proceed with such Patent Action. Reimbursement by Licensee for all other Ongoing Patent Costs shall be due within [*] of Licensee's receipt of an invoice from The Regents.

Failure to make this Advanced Payment before the date when such costs are due to The Regents will be deemed to be an election by Licensee not to secure the patent rights associated with the specific phase of patent prosecution in the applicable territory, and such patent application(s) and patent(s) will not be part of the Patent Rights and therefore not be subject to this Agreement, and Licensee will have no further rights or license to them. In the event that an Advanced Payment for anticipated Ongoing Patent Costs paid by Licensee is greater than the actual Ongoing Patent Costs incurred for the applicable Patent Action, the excess amount is creditable against future Ongoing Patent Costs. In the event that the actual Ongoing Patent Costs incurred for the applicable Patent Action exceed the Advanced Payment paid by Licensee, Licensee shall pay such excess Ongoing Patent Costs within [*] following Licensee's receipt of an invoice from The Regents for such excess Ongoing Patent Costs. At The Regents' sole discretion, rather than requiring an Advanced Payment for estimated Ongoing Patent Costs as described above, or with respect to any Ongoing Patent Costs for which an Advanced Payment is not required, The Regents may (1) bill Licensee for Ongoing Patent Costs after such amounts are incurred, in which case payment will be due to The Regents within [*] of Licensee's receipt of an invoice from The Regents, or (2) have Ongoing Patent Costs directly billed to Licensee by The Regents' patent counsel.

11.3 **Termination of Obligations & Rights**. Licensee may terminate its license with respect to any or all of Patent Rights by providing written notice to The Regents ("**Patent Termination Notice**"). Termination of Licensee's obligations with respect to such patent application or patent will be effective [*] after receipt of such Patent Termination Notice by The Regents. In addition, if Licensee fails to timely (i) provide a Patent Prosecution Request pursuant to Section 11.1, or (ii) pay for any Patent Costs as required by Section 11.2, then The Regents shall have the right to terminate this Agreement with respect to the applicable patent application(s) and patent(s) (subject to Licensee's option to cure such breach pursuant to Section 8.2A). For the avoidance of doubt immediately effective upon such termination, Licensee will have no further right or license to such patent applications and patents and Licensee will remain liable for any Patent Costs incurred prior to such termination with respect to such patent applications and patents.

11.4 **Patent Extensions**. If it is legally possible to extend the term of any patent included within the Patent Rights for a Patent Rights Product under the Drug Price Competition and Patent Term Restoration Act of 1984 and/or European, Japanese and other foreign counterparts, then Licensee will apply for such extension, unless Licensee, in its sole discretion, applies for an extension of the term of another patent (other than a patent within the Patent Rights) covering such Patent Rights Product, where (a) such other patent has a longer term than any applicable patent within the Patent Rights that covers such Patent Rights Product in the applicable jurisdiction or (b) Licensee determines in good faith after consultation with outside patent counsel that, based on the facts and circumstances, such other patent is less vulnerable to a successful patent challenge by a potential competitor desiring to obtain approval of a biosimilar for such Patent Rights Product than any applicable patent within the Patent Rights that covers such Patent Rights Product in the applicable jurisdiction. Licensee will prepare all documents and The Regents agrees to execute the documents and to take additional action as Licensee reasonably requests in connection therewith. Licensee will be liable for all costs relating to such application. If either party (in the case of The Regents, the licensing officer responsible for administration of this Agreement) receives notice pertaining to the infringement or potential infringement of any issued patent included with Patent Rights under the Drug Price Competition and Patent Term Restoration Act of 1984 (and/or foreign counterparts of this law) then that party will within [*] notify the other party after receipt of such notice of infringement.

12. PATENT MARKING

12.1 Licensee will mark all Licensed Products or their containers in accordance with the appropriate patent number reference(s) in compliance with the requirements of applicable patent marking laws.

13. PATENT INFRINGEMENT

13.1 Infringement Notice. In the event either party learns of infringement of potential commercial significance of any Patent Right, such party will promptly provide the other party with written notice, including evidence of such infringement, if available ("**Infringement Notice**"). For so long as Licensee's license under the Patent Rights remains exclusive, neither Licensee nor The Regents (on behalf of itself or SCRI) will notify such infringer regarding such potential infringement until receiving the written permission of the other party, subject to Sections 13.2 and 13.3. For the avoidance of doubt, if Licensee breaches the foregoing restriction and a declaratory judgment action is filed by such infringer against The Regents (and/or SCRI, as applicable), then Licensee will reimburse The Regents for The Regents' (and/or SCRI's, as applicable) out of pocket costs in defending the Patent Rights as a result of such declaratory judgment. Notwithstanding the foregoing, in no event will publication of the Patent Rights, patent marking of Licensed Products, or any statement to the general public by Licensee of the fact that it has a license to the Patent Rights constitute a notice by Licensee to a third party of the existence of any Patent Rights in violation of this Section 13.1. Both The Regents and Licensee will use their diligent efforts to cooperate with each other to terminate such infringement without litigation.

13.2 Licensee-Initiated Suit and The Regents' (and/or SCRI's, as applicable) Joinder. If infringing activity of potential commercial significance by the infringer has not been abated within [*] following the date the Infringement Notice takes effect, then so long as Licensee's license under Section 2.1 remains exclusive and such infringement falls within Licensee's Field of Use and Licensed Territory, Licensee may institute suit for patent infringement against the infringer. The Regents or SCRI may voluntarily join such suit but may not otherwise commence suit against the infringer for the acts of infringement that are the subject of Licensee's suit or any judgment rendered in that suit. Licensee may not join The Regents or SCRI as a party in a suit initiated by Licensee without The Regents' or SCRI's prior written consent. If The Regents or SCRI joins a suit initiated by Licensee, then Licensee will pay any costs incurred by The Regents or SCRI arising out of such suit, including but not limited to, any legal fees of counsel that The Regents (and/or SCRI, as applicable) selects and retains to represent it in the suit. Upon The Regents' prior express written consent, Licensee will have the right to permit a Sublicensee to exercise Licensee's rights under this Section 13.2.

13.3 The Regents-Initiated Suit. If, within [*] following the date the Infringement Notice takes effect, infringing activity of potential commercial significance by the infringer has not been abated and if Licensee has not brought suit against the infringer, then The Regents or SCRI may institute suit for patent infringement against the infringer; provided that, at the request of Licensee, The Regents will, prior to instituting suit, give Licensee a reasonable opportunity to present any reasons why Licensee believes that such a suit by The Regents (and/or SCRI, as applicable) may have an adverse effect on the Licensed Products or The Regents' (and/or SCRI's, as applicable) interests in relation to the Patent Rights or Licensed Products and will consider any such reasonable reasons in good faith. If The Regents (and/or SCRI, as applicable) institutes such suit, then Licensee may not join such suit without The Regents' and SCRI's consent and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of The Regents' or SCRI's suit or any judgment rendered in that suit; *provided, however*, that, in the event Licensee desired to bring suit itself against the infringer but was not able to so because of The Regents' or SCRI's refusal to consent to be joined in a suit brought by Licensee, The Regents will not bring a suit against the Infringer and will not consent to be joined in a suit brought by SCRI against the infringer.

13.4 Cooperation. Any litigation proceedings will be controlled by the party bringing the suit, except that The Regents and SCRI may be represented by independent counsels of their choice in any suit brought by Licensee. The Regents, SCRI and Licensee agree to be bound by all final and non-appealable determinations of patent infringement, validity and enforceability (but no other issue) resolved by any adjudicated judgment in a suit brought in compliance with this Section 13 (Patent Infringement). Any agreement made by Licensee for purposes of settling litigation or other dispute that provides for the grant of a sublicense under the Patent Rights shall comply with the requirements of Section 3 (Sublicenses) of this Agreement.

13.5 Costs & Recovery. Each party will cooperate with the other in litigation proceedings instituted hereunder but at the expense of the party who initiated the suit (unless such suit is being jointly prosecuted by the parties). Any recovery or settlement received in connection with any suit will first be shared by The Regents, SCRI and Licensee on a pro rata basis (based on litigation costs incurred) to cover any litigation costs each incurred and next will be paid to The Regents or Licensee to cover any litigation costs it incurred in excess of the litigation costs of the other. In any suit initiated by Licensee, any recovery in excess of litigation costs will be shared between Licensee and The Regents as follows: (i) for any recovery other than amounts paid for willful infringement, Licensee will retain [*] of such recovery, and The Regents will receive [*] of such recovery; and (ii) for any recovery for willful infringement, Licensee will retain [*] of such recovery and The Regents will receive [*] of such recovery. In any suit initiated by The Regents, [*] of any recovery in excess of litigation costs will belong to The Regents. Notwithstanding the foregoing, if Licensee joins such suit at The Regents' request or is involuntarily joined, The Regents will receive [*] of any recovery and Licensee will receive the remaining [*]. To the extent SCRI is entitled under the applicable inter-institutional agreement between The Regents and SCRI to share in any recovery for

infringement of an issued patent within the Patent Rights, The Regents' sharing obligation shall be satisfied exclusively out of the amounts to which The Regents is entitled under this Section 13.5, and Licensee shall have no obligation to share any amounts to which it is entitled under this Section 13.5 with SCRI or to contribute toward satisfaction of The Regents' sharing obligations.

14. INDEMNIFICATION

14.1 **Indemnification**. Licensee will, and will require its Sublicensees to, indemnify, hold harmless and defend The Regents, SCRI, and The Regents' and SCRI's respective officers, trustees, directors, workforce members, employees and agents, and the inventors of the Patent Rights, and the sponsors of the research that led to the invention claimed by the Patent Rights, and their respective employers (collectively, "**Indemnified Parties**"), against any and all Third Party claims, suits, losses, damage, costs, fees and expenses (collectively, "**Losses**") resulting from, or arising out of, the exercise of this license or any Sublicense, except for that portion of any such Losses that are directly and solely caused by The Regents' or SCRI's gross negligence or willful misconduct or a breach of this Agreement by The Regents. This indemnification will include, but not be limited to, any product liability. The Regents shall (i) promptly notify Licensee in writing of any claim or suit brought against The Regents (or SCRI) for which The Regents (or SCRI) intends to invoke the provisions of this Section 14.1 (Indemnification), and Licensee shall have the right to control the defense and settlement thereof (subject to Licensee's information disclosure obligations and the consent requirements set forth below), and (ii) provide Licensee, at Licensee's expense, with reasonable assistance and information with respect to the defense of such claims. Licensee will keep The Regents informed of its defense of any claims pursuant to this Section 14.1. In defending any such Indemnified Parties, Licensee may in no event make any admission of liability or admission of wrongdoing on the part of the Indemnified Party. Licensee will not settle any claim against any Indemnified Party without such Indemnified Party's written consent if such settlement (a) would include any admission of liability or admission of wrongdoing on the part of the Indemnified Party, (a) would impose any restriction on the Indemnified Party's conduct of any of its activities, (c) would require the Indemnified Party to pay any amount for such Losses, or (d) would not include an unconditional release of the Indemnified Party from all liability for claims that are the subject matter of the settled claim. If The Regents or SCRI is advised by legal counsel that there will be a conflict of interest if the Licensee's counsel defends any claim under this Section 14.1, then The Regents (or SCRI) may retain counsel of its choice to represent it and Licensee will pay all expenses for such representation.

14.2 **Insurance**. Commencing no later than the Effective Date of this Agreement and during the term of this Agreement, Licensee, at its sole cost and expense, will insure its activities in connection with any work performed hereunder and will obtain, keep in force, and maintain Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

Prior to the first use of any Licensed Product in or on a human:

[*]: [*];
[*]: [*];
[*]: [*]; and
[*].

Commencing no later than [*] before the first use of any Licensed Product in or on a human:

[*]: [*];
[*]: [*];
[*]: [*];
[*]: [*]; and
[*].

Commencing no later than (i) [*] before the anticipated or (ii) the actual date (whichever is sooner) of market introduction of any Licensed Product:

[*]: [*];
[*]: [*];
[*]: [*];
[*]: [*]; and
[*].

During the time in which Licensee, or any entity acting on Licensee's behalf, has patients enrolled in a clinical trial of a Licensed Product, Licensee will also insure against liability from any clinical trials for an amount not less than [*].

If the above insurance is written on a claims-made form, it must continue for [*] following termination or expiration of this Agreement. The coverage and limits above will not in any way limit Licensee's liability under Section 14.1 (Indemnification).

14.3 Certificates; Notification. Upon the execution of this Agreement, Licensee will furnish The Regents with certificates of insurance evidencing compliance with all applicable requirements set forth above. Thereafter, The Regents may from time to time request updated certificates of insurance evidencing compliance with all then-applicable requirements set forth above. Such certificates will indicate The Regents and SCRI as an additional insured(s) under the coverage described above in Section 14.2 (Insurance) and include a provision that the coverage will be primary and will not participate with, nor will be excess over, any valid and collectable insurance or program of self-insurance maintained by The Regents. Licensee will provide The Regents written notice if such insurance levels are reduced or cancelled.

15. NOTICES

15.1 Any notice or payment hereunder will be deemed to have been properly given when sent in writing in English to the respective address below and will be deemed effective on the date of delivery (including by overnight courier) if delivered in person; three (3) business days after the date of mailing if mailed by first-class certified mail, postage paid; or if sent via email, when the recipient acknowledges having received that email, provided that automated replies and "read receipts" will not be considered acknowledgement of receipt.

For Licensee: [*]

For The Regents: [*]

All Advanced Payments due under this Agreement must be sent via wire transfer as follows. In order to ensure that funds are properly credited to your account, please reference invoice number or UC Control Number on all wire transfers.

Wire:

[*]

[*]

ACH:

[*]

[*]

15.2 Licensee Contact Information. Licensee must furnish to The Regents the completed licensee contact information form attached hereto as **Appendix C** concurrent to execution of this Agreement and incorporated herein by this reference, showing the contacts responsible for (i) Progress Reports, (ii) Patent Prosecution, and (iii) Financial Obligations.

16. ASSIGNABILITY

This Agreement is binding upon, and will inure to the benefit of, The Regents, its successors and assigns. Neither this Agreement, nor any of the rights or obligations under this Agreement, may be assigned, transferred or delegated (with any such action described herein as an "**Assignment**"), in whole or in part, by operation of law or otherwise, without the prior written consent of The Regents (and any purported Assignment shall be null and void) except if:

A. such Assignment is in conjunction with a bona fide arms' length transaction to the successor in interest of the Licensee by way of merger, acquisition, sale of stock or sale of all or substantially all of the Licensee's business or assets to which this Agreement relates; or

B. (1) the proposed assignment complies with U.S. law; (2) neither the proposed assignee, any entity or individual who owns or controls [*] or more of the proposed assignee, or any executive officer of the proposed assignee is on any restricted party list maintained by the U.S. government (such as the Office of Foreign Assets Control's Specially Designated Nationals and Blocked Persons list, the Bureau of Industry and Security's Denied Parties List, the Entry List and the Office of Defense Trade Controls' Debarred Persons Lists); (3) neither the proposed assignee nor any executive of the proposed assignee has been convicted of any crime in the four years immediately preceding the assignment and the proposed assignee confirms, in writing, that it is not aware of any pending investigation of any crime committed by the proposed assignee or any of its executive officers; and (4) the proposed assignee confirms, in writing, that (i) all of The Regents' rights under the Agreement (e.g., audit) shall continue after the Assignment, and (ii) all obligations, terms, conditions and restrictions that apply to Licensee under the Agreement shall apply to the proposed assignee with the same force and effect. An Assignment made pursuant to this Section 16Bc shall, within [*] of such Assignment, be accompanied by (i) a written representation from the Licensee and proposed assignee to The Regents that these conditions have been met, and (ii) payment to The Regents of all royalties and other amounts due from Licensee as of the date of the Assignment. Licensee shall at all times remain liable to The Regents (jointly and severally with the proposed assignee) for the full and complete performance of Licensee's obligations that arose under the Agreement prior to an Assignment made pursuant to this Section 16B.

17. GOVERNING LAWS AND VENUE

Choice of Law & Venue: THIS AGREEMENT WILL BE INTERPRETED AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, excluding any choice of law rules that would direct the application of the laws of another jurisdiction and without regard to which party drafted particular provisions of this Agreement, but the scope and validity of any patent or patent application will be governed by the applicable laws of the country of such patent or patent application. Any legal action brought by the parties hereto relating to this Agreement will be conducted in Los Angeles, California.

18. COMPLIANCE WITH LAWS

18.1 If this Agreement or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, Licensee will assume all legal obligations to do so. Licensee will notify The Regents if it becomes aware that this Agreement is subject to a United States or foreign government reporting or approval requirement. Licensee will make all necessary filings and pay all costs including fees, penalties and all other out-of-pocket costs associated with such reporting or approval process.

18.2 Licensee agrees to comply with all applicable international, national, state, regional and local laws and regulations in performing its obligations hereunder and in its use, manufacture, sale or import of the Licensed Products. Licensee will observe all applicable United States and foreign laws with respect to the transfer or provision of Licensed Products and related technical data to foreign countries, including, without limitation, the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulations. Licensee agrees to manufacture and use Licensed Products in compliance with applicable government importation laws and regulations of a particular country for Licensed Products made outside the particular country in which such Licensed Products are used, sold or otherwise exploited.

19. CONFIDENTIALITY

19.1 During the term of this Agreement and for [*] after the termination or expiration of this Agreement, each party will treat and maintain the other party's confidential information ("**Confidential Information**") in confidence using at least the same degree of care as such party (the "**Receiving Party**") uses to protect its own confidential information of a like nature and will use the Confidential Information of the other party (the "**Disclosing Party**") solely to the extent necessary to exercise the Receiving Party's rights or perform the Receiving Party's obligations under this Agreement. Confidential Information can be written, oral, or both. The negotiated terms of this Agreement constitute the Confidential Information of both Parties. Confidential Information of The Regents includes patent prosecution related information and Associated Technology. Confidential Information of Licensee includes any progress reports and royalty reports delivered by Licensee to The Regents pursuant to this Agreement, any Sublicense agreement provided by Licensee to The Regents (including the terms and conditions thereof), and all information of Licensee to which The Regents or its accounting firm obtains access as a result of

any audit conducted pursuant to Section 7.2 (but for clarity, The Regents will have the right to use all such information to enforce the rights it has under this Agreement).

19.2 The Receiving Party (and, in the case of The Regents as the Receiving Party, SCRI) may disclose Confidential Information to its employees, trustees, directors, workforce members, agents, consultants, contractors, and co-owners (as applicable) and, in the case of Licensee, its Sublicensees, provided that such parties are bound by a like duty of confidentiality as that found in this Section 19 (Confidentiality). In addition, Licensee may disclose Confidential Information of The Regents to potential Sublicensees and to actual and potential investors in, or other financing sources of, Licensee and may disclose the terms of this Agreement to third parties in connection with due diligence investigations of the Licensee, provided, in each case, that such parties are bound by reasonable obligations of confidentiality and non-use. In addition, notwithstanding the preceding provisions of this Section 19.2, Licensee shall have the right to disclose to potential investors in, and other financing sources of, Licensee, on a non-confidential basis, the existence of this Agreement and the fact that Licensee has obtained an exclusive license under the Patent Rights. Notwithstanding anything to the contrary contained in this Agreement, The Regents and SCRI may release this Agreement, including any terms contained herein and information regarding payments or other income received in connection with this Agreement to the inventors, senior administrative officials employed by The Regents or SCRI, and individual Regents upon their request, provided such individuals are informed of the confidential nature of such information. In addition, notwithstanding anything to the contrary in this Agreement, if a Third Party inquires whether a license to Patent Rights is available, then The Regents and SCRI may disclose the existence of this Agreement and the scope of the license granted hereunder.

19.3 Nothing contained herein will restrict or impair, in any way, the right of the Receiving Party to use or disclose any Confidential Information of the Disclosing Party that the Receiving Party can demonstrate by competent evidence: (a) was previously known to it prior to its disclosure by the Disclosing Party, as evidenced by the Receiving Party's written records; (b) is now, or becomes in the future, public knowledge other than through acts or omissions of the Receiving Party in breach of this Agreement; or (c) was obtained lawfully and on a non-confidential basis from sources independent of the Disclosing Party, as evidenced by the Receiving Party's written records. In addition, nothing contained herein will restrict or impair, in any way, the right of The Regents to disclose Confidential Information of Licensee that The Regents is required to disclose pursuant to the California Public Records Act.

19.4 The Receiving Party also may disclose Confidential Information of the Disclosing Party that is required to be disclosed (i) to a governmental entity or agency in connection with seeking any governmental or regulatory approval, governmental audit, or other governmental contractual requirement, (ii) by order of a court of competent jurisdiction, or (ii) by law, e.g., California Public Records Act, provided that the Receiving Party uses reasonable efforts to give the Disclosing Party sufficient notice of such required disclosure to allow the Disclosing Party reasonable opportunity to object to, and to take legal action to prevent, such disclosure. Nothing in this Agreement will be construed to prevent The Regents or SCRI from reporting de- identified raw terms of this Agreement as part of a larger database.

19.5 Upon termination (but not expiration) of this Agreement, the Receiving Party will destroy or return any of the Disclosing Party's Confidential Information, including all Associated Technology (subject to Section 19.3), in its possession within [*] following the termination of this Agreement and provide each other with prompt written notice that such Confidential Information has been returned or destroyed. The Receiving Party may, however, retain one copy of such Confidential Information for the purpose of monitoring compliance with its continuing obligations hereunder or to the extent required by law, provided that such retained copy shall remain subject to the Receiving Party's obligations under the preceding provisions of this Section 19.

20. MISCELLANEOUS

20.1 **Entire & Binding Agreement**. This Agreement, which includes the attached Appendices A (Patent Rights), B (Royalty Statement), C (Licensee Contact Information), D (Form of Semiannual/Annual Progress Report), E (Stock Issuance Agreement), and F (Associated Technology), embodies the entire understanding of the parties and supersedes all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof. The parties acknowledge that concurrently with execution of this Agreement they are executing that certain Exclusive License Agreement related to UCLA Case No. [*], which separate agreement shall not be affected by any term of this Agreement and will remain in full force and effect in accordance with its terms. This Agreement is not binding on the parties until it has been signed below on behalf of each party and is then effective as of the Effective Date. No amendment or modification of this Agreement is valid or binding on the parties unless made in writing and signed on behalf of each party. In case any of the provisions contained in this Agreement is held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of this Agreement and such unenforceable provision shall be modified so that it is valid, legal, and enforceable and, to the fullest extent possible, reflects the intention of the parties.

20.2 **Headings**. The headings of the several sections are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

20.3 **Waiver**. No waiver by either party of any breach or default of any of the agreements contained herein will be deemed a waiver as to any subsequent and/or similar breach or default. No waiver of any right, remedy, or breach or default of this Agreement, shall be effective unless in writing and signed by the party to be charged.

20.4 **Independent Contractors**. In performing their respective duties under this Agreement, each of the parties will be operating as an independent contractor. Nothing contained herein will in any way constitute any association, partnership, or joint venture between the parties hereto, or be construed to evidence the intention of the parties to establish any such relationship. Neither party will have the power to bind the other party or incur obligations on the other party's behalf without the other party's prior written consent.

20.5 **Force Majeure**. Other than with respect to any financial obligation, a party to this Agreement may delay the performance of that portion of any obligation hereunder if the performance of that portion of such obligation is rendered impossible due to any war, riot, or insurrection; strikes, lockouts, or other serious labor disputes; epidemic or pandemic; or floods, fires, explosions, or other natural disasters. The party subject to a Force Majeure event shall promptly notify the other party of the occurrence and particulars of such event and shall use reasonable efforts to avoid or remove such causes of non- performance as soon as is reasonably practicable. When such events have abated, the non-performing party's obligations herein shall resume. Regardless of the reason for the Force Majeure event, the other party will have the right to terminate this Agreement if the non-performing party does not resume performance within [*] of the date such non- performing party asserted its performance was delayed by such event.

20.6 **Counterparts**. This Agreement may be executed in one or more counterparts, each of which together will constitute one and the same Agreement. For purposes of executing this Agreement, a facsimile (including a PDF image delivered via email) copy of this Agreement, including the signature pages, will be deemed an original. The parties agree that neither party will have any rights to challenge the use or authenticity of a counterpart of this Agreement based solely on that its signature, or the signature of the other party, on such counterpart is not an original signature.

[SIGNTURE PAGE FOLLOWS:]

IN WITNESS WHEREOF, both The Regents and Licensee have executed this Agreement by their respective and duly authorized officers on the day and year written.

KALTHERA, INC.

By: /s/ [*]__
Signature

Name: [*]__

Title: [*]__

Date: 2/22/2021 | 2:40 PM PST__

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By: /s/ [*]__
Signature

Name: [*]__

Title: [*]__

Date: 2/22/2021 | 2:50 PM PST__

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

By: /s/ [*]__
Signature

Name: [*]__

Title: [*]__

Date: 2/22/2021 | 3:43 PM PST__

APPENDIX A

PATENT RIGHTS

[*]

APPENDIX B

ROYALTY STATEMENT

[*]

APPENDIX C

LICENSEE CONTACT INFORMATION

[*]

APPENDIX D

FORM OF SEMI-ANNUAL[1]/ANNUAL[2] PROGRESS REPORT

[*]

[1] [*]
[2] [*]

APPENDIX E

STOCK ISSUANCE AGREEMENT

[*]

APPENDIX F

ASSOCIATED TECHNOLOGY

[*]

Lyell Immunopharma, Inc.

Insider Trading Policy

Adopted by the Board of Directors: April 19, 2021

Last Amended by the Board of Directors: December 11, 2024

Introduction

During the course of your relationship with Lyell Immunopharma, Inc. ("***Lyell***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about Lyell or other publicly traded companies that Lyell has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in Lyell's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Lyell securities and in the securities of other applicable publicly-traded companies, in each case by our employees, directors and consultants who are advised that they are subject to this policy ("***designated consultants***") and the other persons subject to this policy as described below.

Statement of Policy

It is the policy of Lyell that a Covered Person (as defined below) who is aware of material nonpublic information relating to Lyell **may not**, directly or indirectly:

1. engage in any transactions in Lyell's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;
2. recommend the purchase or sale of any Lyell's securities;
3. disclose material nonpublic information to persons within Lyell whose jobs do not require them to have that information, or outside of Lyell to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with Lyell's policies regarding the protection or authorized external disclosure of information regarding Lyell; or
4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to Lyell at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve Lyell's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of Lyell

that no Covered Person may either (a) recommend to another person that they buy, hold or sell Lyell's securities **at any time** or (b) disclose material nonpublic information to persons within Lyell whose jobs do not require them to have that information, or outside of Lyell to other persons (unless the disclosure is made in accordance with Lyell's policies regarding the protection or authorized external disclosure of information regarding Lyell).

In addition, it is the policy of Lyell that no Covered Person who, in the course of his or her relationship with Lyell, learns of confidential information that is material to any other publicly traded company with which Lyell does business, including a partner, supplier or collaborator of Lyell or an economically-linked company such as a competitor of Lyell, may trade in that company's securities until the information becomes public or is no longer material to that other company.

There are no exceptions to this policy, except as specifically noted.

Transactions Subject to this Policy

This policy applies to all transactions in securities issued by Lyell, as well as derivative securities that are not issued by Lyell, such as exchange-traded put or call options or swaps relating to Lyell's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of Lyell's common stock in the public market but also any other purchases, sales, transfers or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

Persons Subject to this Policy

This policy applies to you and all other employees, directors and designated consultants of Lyell and its subsidiaries. This policy also applies to members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund). The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy. All persons subject to this policy as described in this section are referred to in this policy as "***Covered Persons***."

Material Nonpublic Information

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results, projections or forecasts;
- status of product or product candidate development or regulatory approvals;
- clinical or pre-clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;
- major contract awards;
- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for Lyell's securities;
- gain or loss of a significant licensor, licensee or supplier;
- changes to or new corporate partner relationships or collaborations;
- notice of issuance or denial of patents, the acquisition of other material intellectual property rights or other significant intellectual property developments;
- regulatory developments, including product approvals or non-approvals, or halts of clinical trials;
- management or control changes;
- employee layoffs;
- a disruption to or a delay in manufacturing of Lyell's products or product candidates;
- a disruption in Lyell's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- actual or threatened litigation, settlements, SEC or other investigations or a major development in or the resolution of any such litigation, settlements or investigations;
- communications with government agencies;
- significant write-offs;
- litigation or settlements; and
- impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on

Wednesday, then you may execute a transaction in our securities on Monday. Depending on the particular circumstances, Lyell may determine that a longer waiting period should apply to the release of specific material nonpublic information.

Blackout Periods

Because our workplace culture tends to be open, odds are that the vast majority of our employees, directors and designated consultants will possess material nonpublic information at certain points during the year. To minimize even the appearance of insider trading among our employees, directors and designated consultants, we have established "quarterly trading blackout periods" during which Lyell employees, directors, designated consultants and their Related Persons—regardless of whether they are aware of material nonpublic information or not—may not conduct any trades in Lyell securities. That means that, except as described in this policy, all Lyell employees, directors, designated consultants and their Related Persons will be able to trade in Lyell securities only during limited open trading window periods that generally will begin after two full trading days have elapsed since the public dissemination of Lyell's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Lyell securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "***quarterly trading blackout period***" will generally begin at the end of the day that is the 15th of the last month of each fiscal quarter for which financial results will be released and end after two full trading days have elapsed since the public dissemination of Lyell's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the Chief Executive Officer, Chief Financial Officer or Chief Business Officer, there exists undisclosed information that would make trades by Lyell's employees, directors and designated consultants inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person. A Lyell employee, director or designated consultant who believes that special circumstances require him or her to trade during a quarterly blackout period should consult the Chief Business Officer. Permission to trade during a blackout period will be granted only where the circumstances are extenuating, the Chief Business Officer concludes that the person is not in fact aware of any material nonpublic information relating to Lyell or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

Event-Specific Trading Blackouts

From time to time, an event may occur that is material to Lyell and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the Chief Executive Officer, Chief Financial Officer or Chief Business Officer may not trade in Lyell's securities. In that situation, Lyell will notify the designated individuals that neither they nor their Related Persons may trade in the Lyell's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout.

The quarterly and event-specific trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

Exceptions to this Policy

This policy does not apply in the case of the following transactions, except as specifically noted:

1. ***Option Exercises***. This policy does not apply to the exercise of options granted under Lyell's equity compensation plans for cash or, where permitted under the option, by a net exercise transaction with the Company or by delivery to Lyell of already-owned Lyell stock. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.
2. ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to Lyell to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under Lyell's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.
3. ***ESPP***. This policy does not apply to the purchase of stock by employees under Lyell's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.
4. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), and as permitted by Lyell, employees, directors and designated consultants may establish a trading plan under which a broker is instructed to buy and sell Lyell securities based on pre-determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of Lyell securities pursuant to that Trading Plan are not subject to this policy. To be properly established, an employee's, director's or designated consultant's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and Lyell's 10b5-1 Trading Plan Guidelines at a time when they were unaware of any material nonpublic information relating Lyell and when Lyell was not otherwise in a trading blackout period. Moreover, all Trading Plans must be reviewed and approved by Lyell before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws.
5. ***Gifts.*** This policy does not apply to *bona fide* charitable gifts of Lyell securities that have been pre-cleared by Lyell's Chief Business Officer, Chief Financial Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift. Pre-clearance must be obtained at least two business days in advance of the proposed gift, and pre-cleared gifts not completed within five business days will require new pre-clearance. Lyell may choose to shorten this period.
6. ***Domestic Relations Order***. This policy does not apply to the acquisition or disposition of Lyell's securities by a Covered Person pursuant to a domestic relations order, as defined in the Internal Revenue Code of 1986, as amended, or Title I of the Employee Retirement Income Security Act of 1974, as amended, or the rules thereunder (such transaction, an "***Exempted Transfer***"), provided that except with respect to such Exempted Transfer, the Covered Person shall continue to be subject to this policy in all respects (including any securities of Lyell acquired in such transaction, if any).

Special and Prohibited Transactions

1. ***Inherently Speculative Transactions.*** No Lyell employee, director or designated consultant may engage in short sales, transactions in put options, call options or other derivative securities on an

exchange or in any other organized market, or in any other inherently speculative transactions with respect to Lyell's stock.

2. ***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Lyell employee, director or designated consultant to continue to own Lyell's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Lyell employee, director or designated consultant may no longer have the same objectives as Lyell's other stockholders. Therefore, Lyell employees, directors and designated consultants are prohibited from engaging in any such transactions.
3. ***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Lyell's securities, Lyell employees, directors and designated consultants are prohibited to use Lyell's securities as collateral for a loan and holding Lyell's securities in a margin account.
4. ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Lyell employee, director or designated consultant is in possession of material nonpublic information. Lyell therefore strongly discourages placing standing or limit orders on Lyell's securities. If a Covered Person determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

Pre-Clearance and Advance Notice of Transactions; Designated Persons

Lyell's board of directors has initially designated the Chief Business Officer of the Company as the Clearing Officer. In addition to the requirements above, officers, directors and other applicable members of management and employees who have been notified that they are subject to pre-clearance requirements (collectively, "***Restricted Persons***") face a further restriction: They may not engage in any transaction in, or enter into, modify or terminate any contract, instruction or written plan or arrangement in, Lyell's securities without first obtaining pre-clearance of the transaction from the Clearing Officer or her designee, at least two business days in advance of the proposed transaction, even during an open trading window. The Clearing Officer or her designee will then determine whether the transaction may proceed and, if so, will direct the Compliance Officer (as identified in Lyell's Section 16 Compliance Program) to help comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within three business days will require new pre-clearance. Lyell may choose to shorten this period.

Restricted Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Compliance Coordinator or Chief Business Officer. Once any transaction takes place, the officer, director, applicable member of management or employee must immediately notify

the Compliance Coordinator and any other individuals identified under the heading "Notification of Execution of Transaction" in Lyell's Section 16 Compliance Program so that Lyell may assist in any Section 16 reporting obligations.

Short-Swing Trading, Control Stock and Section 16 Reports

Officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), which are described in Lyell's Section 16 Compliance Program, and any notices of sale required by Rule 144.

Policy's Duration

This policy continues to apply to your transactions in Lyell's securities or the securities of other applicable public companies, as more specifically set forth in this policy, even after your relationship with Lyell has ended. If you are aware of material nonpublic information when your relationship with Lyell ends, you may not trade Lyell's securities or the securities of other applicable companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave Lyell during a trading blackout period, then you may not trade Lyell's securities or the securities of other applicable companies until the trading blackout period has ended.

Individual Responsibility

Covered Persons have ethical and legal obligations to maintain the confidentiality of information about Lyell and to not engage in transactions in Lyell's securities or securities of other applicable public companies while aware of material nonpublic information, as more specifically set forth in this policy. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of Lyell or any employee or director of Lyell pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by Lyell for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

Penalties

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by Lyell, including termination of employment. Anyone who has questions about this policy should contact their own attorney or Lyell's Chief Business Officer, at compliance@lyell.com.

Amendments

Lyell is committed to continuously reviewing and updating its policies and procedures. Lyell therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of Lyell's policies regarding insider trading which can be found on the Policies page of LyellWeb (https://sites.google.com/lyell.com/lyell/resources/policies).

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-277495 and 333-283533) and related Prospectuses of Lyell Immunopharma, Inc.,

(2) 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,

(3) Registration Statement (Form S-8 No. 333-270145) pertaining to the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan, and

(4) Registration Statements (Form S-8 Nos. 333-263952 and 333-277494) pertaining to the Lyell Immunopharma, Inc. 2021 Equity Incentive Plan and the Lyell Immunopharma, Inc. 2021 Employee Stock Purchase Plan

of our report dated March 11, 2025, with respect to the consolidated financial statements of Lyell Immunopharma, Inc. included in this Annual Report (Form 10-K) of Lyell Immunopharma, Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

San Mateo, California

March 11, 2025

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: March 11, 2025 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: March 11, 2025 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, 2024, 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: March 11, 2025

By: /s/ CHARLES NEWTON
Charles Newton
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 11, 2025