

25,000,000 shares



## Common Stock

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This is an initial public offering of shares of common stock of Lyell Immunopharma, Inc. We are offering 25,000,000 shares of our common stock.

Prior to this offering, there has been no public market for our common stock. The initial public offering price of our common stock is \$17.00 per share.

Our common stock is approved for listing on the Nasdaq Global Select Market under the symbol "LYEL."

We are an "emerging growth company" as defined under the federal securities laws and, as such, have elected to comply with certain reduced reporting requirements in this prospectus and may elect to do so in future filings.

*Investing in our common stock involves a high degree of risk. See the section titled "[Risk Factors](#)" beginning on page 12.*

**Neither the Securities and Exchange Commission nor any other regulatory body has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.**

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	Per Share	Total
Initial public offering price	\$ 17.00	\$425,000,000
Underwriting discounts and commissions(1)	\$ 1.19	\$ 29,750,000
Proceeds to Lyell Immunopharma, Inc., before expenses	\$ 15.81	\$395,250,000

(1) See the section titled "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to an additional 3,750,000 shares of our common stock at the initial public offering price, less the underwriting discounts and commissions.

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The underwriters expect to deliver the shares against payment in New York, New York on June 21, 2021.

**Goldman Sachs & Co. LLC**

**BofA Securities**

**J.P. Morgan**

**Morgan Stanley**

Prospectus dated June 16, 2021

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Neither we nor the underwriters have authorized anyone to provide you any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

## PROSPECTUS SUMMARY

*This summary highlights selected information contained elsewhere in this prospectus, and is qualified in its entirety by the more detailed information and audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should carefully read this entire prospectus, including the information under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus, before making an investment decision. Unless the context requires otherwise, references in this prospectus to "Lyell Immunopharma," "Lyell," the "Company," "we," "us" and "our" refer to Lyell Immunopharma, Inc.*

### Overview

We are a T cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors. We have assembled a world-class team, comprising some of the foremost scientific leaders in the fields of oncology and adoptive cell therapy (ACT), including Drs. Rick Klausner, Nick Restifo, Stan Riddell and Crystal Mackall, who have each interrogated and elucidated the mechanisms of T cell biology and its interactions with cancer for decades. We believe the key to effective cell therapy is the mastery of the identity, fate and function of cells to create living medicines. We take a systematic, interrogative, cell biology-driven approach to overcome what we view as the two major barriers to successful ACT – (1) T cell exhaustion and (2) lack of durable stemness – through the application of our proprietary genetic and epigenetic reprogramming technologies, Gen-R and Epi-R. Our technologies are designed to be applied in a target and modality agnostic manner to chimeric antigen receptor (CAR), tumor-infiltrating lymphocytes (TIL) and T cell receptor (TCR) therapies to fundamentally improve the properties of T cells needed to eradicate solid tumors. We believe our autologous T cell therapies will generate improved, durable clinical outcomes that are potentially curative for patients with solid tumors. We are building a multi-modality product pipeline across several solid tumor indications with high unmet needs and anticipate having four investigational new drug application (IND) submissions by the end of 2022.

### Our Technology Platforms

ACT has demonstrated profound results in some patients suffering from hematologic tumors, but solid tumors are more complex and have evolved multiple mechanisms to evade and ultimately overcome the immune system. This has limited the use of ACTs in non-hematologic settings. We believe T cell exhaustion and lack of durable stemness – the T cell's loss of continual proliferative capacity and abilities of self-renewal and differentiation to effector states to eliminate solid tumors – are two major barriers limiting the efficacy of ACT in solid tumors.

We endeavor to overcome these two major barriers to ACT in solid tumors through our proprietary Gen-R and Epi-R technology platforms.








- **Gen-R** – our proprietary *ex vivo* genetic reprogramming technology to overcome T cell exhaustion, which results from transcriptional and epigenetic changes that occur as T cells differentiate into a dysfunctional state. Our scientific co-founders discovered T cell exhaustion occurs more frequently in solid tumors than in hematologic cancers where CAR T cells have demonstrated efficacy. The discovery of Gen-R came from the realization that chronic antigen

stimulation, or when the T cell is always “on,” combined with an immunosuppressive solid tumor microenvironment (TME), likely promotes the development of T cell exhaustion. In preclinical solid tumor models, Gen-R overcame T cell exhaustion and restored antitumor activity through the optimized overexpression of c-JUN, a protein which, when dysregulated, has been shown to play a crucial role in T cell exhaustion.

- **Epi-R** – our proprietary *ex vivo* epigenetic reprogramming technology to create a novel population of T cells with durable stemness. Stemness, the quality of T cells capable of self-renewal, expansion, persistence and anti-tumor response has been reported in the literature to correlate with clinical responses to immunotherapy. However, we believe *durable* stemness is required for long-term efficacy against solid tumors. Durable stemness relates to the ability of T cells to maintain their stemness until the tumor is eradicated, that is, they have the ability to self-renew despite continued persistent signals from the tumor driving activation, proliferation and differentiation. We believe that as these cells proliferate, they generate progeny cells that can both differentiate to polyfunctional effector cells and/or re-populate the population of less differentiated T cell states as they continue to divide, thereby maintaining stemness. Epi-R is designed to intentionally and reproducibly generate populations of T cells which have this property of durable stemness. Furthermore, relating specifically to TIL, application of Epi-R has generated T cell preparations that exhibit increased polyclonality during expansion, and preserved their ability to target a diversity of tumor neoantigens.

**Our Pipeline**

We are utilizing our Gen-R and Epi-R technology platforms to develop a multi-modality product pipeline with four IND submissions expected by the end of 2022. Each of our programs provide opportunities to expand into additional indications beyond the patient populations we are initially targeting. Our product candidates are summarized in the table below:

	TECHNOLOGY	TARGET	COMMERCIAL RIGHTS	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONE
CAR	Gen-R & Epi-R	ROR-1 (LYL797)		<ul style="list-style-type: none"> <li>• NSCLC</li> <li>• TNBC</li> <li>• Other solid tumors</li> </ul>					Submit IND in Q1 2022
TIL	Epi-R	Polyclonal (LYL845)		<ul style="list-style-type: none"> <li>• Multiple solid tumor histologies</li> </ul>					Submit IND in 2H 2022
TCR	Gen-R	NY-ESO-1*		<ul style="list-style-type: none"> <li>• Synovial sarcoma</li> <li>• Other solid tumors</li> </ul>					Submit INDs in 1H 2022
	Epi-R								

\* Our collaborator, GlaxoSmithKline (GSK), is developing an NY-ESO-1 TCR T cell product candidate, currently in pivotal development. While we are currently evaluating Gen-R and Epi-R in separate preclinical programs for this product candidate, together these programs could represent a single future product opportunity for GSK utilizing one or both of our technology platforms.

***LYL797: ROR1 + Gen-R & Epi-R***

We are applying our Gen-R and Epi-R technology platforms to our lead CAR program, LYL797, which is expected to be an intravenous (IV) administered CAR T cell product candidate targeting ROR1 with a single-chain variable fragment derived from rabbit anti-R12 antibody that recognizes and binds to ROR1 and a proprietary optimized epidermal growth factor receptor (EGFRopt) safety switch. We are initially developing LYL797 for the treatment of ROR1+ non-small cell lung cancer (NSCLC) and triple negative breast cancer (TNBC). ROR1 expression is associated with poor prognosis. Significant subsets of patients with common cancers express ROR1, including TNBC (~60%) and NSCLC (~40%), two of the highest ROR1 expressing indications. If successful, we anticipate expanding into other ROR1+ cancers with a lower incidence of ROR1 expression, including potentially hormone receptor positive (HR+) breast cancer, ovarian and other solid tumors. We expect to submit an IND for LYL797 in the first quarter of 2022.

***LYL845: TIL + Epi-R***

We are applying our Epi-R technology to develop our product candidate, LYL845, which is expected to be an IV administered autologous TIL therapy in multiple solid tumors. TILs have previously shown clinical benefit in patients with melanoma as well as other solid tumors with high mutation burdens including advanced cervical, lung, breast and gastrointestinal cancers. TILs target a variety of tumor antigens, but it is thought that the clinical efficacy of TILs is largely driven by specific recognition of mutated tumor neoantigens. Further, broad TIL efficacy has been limited by poor enrichment of tumor-reactive T cells, poor quality and growth potential of expanded T cells and failure to maintain polyclonality of TILs during production. We have designed LYL845 to incorporate our Epi-R technology to result in enhanced T cell potency, antitumor activity and polyclonality of TILs. If successful, we expect to expand development broadly to potentially include melanoma, cervical, head and neck, pancreatic, breast, colorectal and NSCLC. We expect to submit an IND for LYL845 in the second half of 2022.

***NY-ESO-1***

Our collaborator, GSK, is developing a New York esophageal squamous cell carcinoma 1 (NY-ESO-1) TCR T cell product candidate, NY-ESO-1c259, currently in pivotal development. We are collaborating with them to potentially enhance this clinical-stage product candidate with Gen-R and Epi-R. Preclinical efforts and IND-enabling studies are underway. We anticipate GSK will conduct initial clinical trials with the enhanced product candidate in synovial sarcoma and multiple other solid tumor indications. We anticipate an IND submission in the first half of 2022.

**Our Manufacturing Capabilities**

We believe it is critically important to own, control and continuously monitor all aspects of the cell therapy manufacturing process in order to mitigate risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. We made a strategic decision to invest in building our own manufacturing center to control our supply chain, maximize efficiencies in cell product production time, cost and quality, and have the ability to rapidly incorporate disruptive advancements and new innovations. Controlling manufacturing also enables us to protect proprietary aspects of our Gen-R and Epi-R technology platforms. We view our manufacturing team and capabilities as a significant competitive advantage.

Our LyFE manufacturing center in Bothell, Washington is approximately 73,000 square feet and comprises laboratories, offices and manufacturing suites. LyFE has a flexible and modular design

allowing us to produce plasmid, viral vector and T cell product to control and de-risk the sequence and timing of production of the major components of our supply chain related to our product candidates. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. We believe this capacity is sufficient to support our pipeline programs through pivotal trials and, if approved, early commercialization. We anticipate the facility to be current Good Manufacturing Practices (cGMPs) qualified and capable of cGMP manufacturing by the end of 2021.

## Our Team

The scientific and leadership team we have assembled comprise some of the foremost leaders in the fields of oncology and ACT. These thought leaders have each interrogated and elucidated the mechanisms of T cell biology and its interactions with cancer for decades and have authored over 1,000 publications focused on the interaction between the immune system and cancer. Our management team is comprised of experienced executives who come from academia and industry-leading cell and gene therapy companies including Atara, Juno Therapeutics and Sangamo; oncology therapeutic development companies including Amgen, AstraZeneca, Genentech, Incyte and Seagen; and cancer diagnostic companies including Genomic Health, GRAIL and Illumina. The core members of our scientific and leadership team include:

- **Dr. Rick Klausner.** We were founded in 2018 by Dr. Rick Klausner, former Director of the National Cancer Institute (NCI), co-founder of Juno and GRAIL and whose lab in the 1980s isolated the critical components of the TCR that enabled the creation of CAR T cells. Dr. Klausner is our Executive Chairman. He is well known for his work in cell and molecular biology, immunology and human genetics, and has been the author of more than 300 scientific articles and several books, in addition to receiving numerous awards, honorary degrees and other honors. He oversaw the writing of The National Science Education Standards, the first such standards for U.S. Science Education, and served as Liaison to the White House Office of Science & Technology Policy. He is a member of the National Academy of Sciences, the Institute of Medicine and the American Academy of Arts and Sciences.
- **Liz Homans.** Our CEO, Ms. Homans, brings over 30 years of strategy, product development and commercialization experience. She spent over a decade at Genentech in multiple divisions including global product development, regulatory operations and U.S. sales and marketing. She spent most of her Genentech career leading large complex oncology development programs from Phase 2 through completion of pivotal trials submission, approval and launch. She is also an experienced commercial leader having led the U.S. Xolair franchise through two years of double-digit growth. She completed her tenure at Genentech by managing the U.S. HER2+ breast cancer franchise. Ms. Homans also led global regulatory operations for Roche. Prior to Genentech she spent four years at Jazz Pharmaceuticals where she built the project leadership and portfolio strategy team and she also has nearly a decade of business strategy consulting experience.
- **Dr. Nick Restifo.** Prior to joining Lyell as our Executive Vice President of Research, Dr. Restifo spent 31 years at the NCI with a sole focus on the development of immunotherapeutic treatments for patients with cancer. His contributions to the field include the molecular definition of the qualities of highly effective antitumor T cells identification of the gene expression within tumors that is required for successful immunotherapy and understanding the impact of host factors in cancer immunotherapy. His basic and clinical findings of how immune cells can destroy tumors have become mainstays of cell-based immunotherapies being used worldwide, documented in more than 340 publications and numerous book chapters on cancer immunotherapy.

- **Dr. Stan Riddell.** Dr. Riddell is a Founder of Lyell and Head of our R&D Executive Committee. He is also a Professor, Program in Immunology and the Immunotherapy Integrated Research Center at the Fred Hutchinson Cancer Research, Professor of Medicine at the University of Washington, Distinguished Affiliate Professor at the Technical University of Munich and a cofounder of Juno Therapeutics. Dr. Riddell has designed multiple clinical trials of adoptive T cell therapy using unmodified and genetically modified T cells including the first trial of CD19 CAR modified T cells of defined subset composition, which formed the foundation for Liso-Cel, which is FDA approved for treatment of diffuse large B cell lymphoma. He has more than 225 publications and his research has contributed to understanding the role of human T cell subsets in protective immunity to pathogens and tumors.
- **Dr. Crystal Mackall.** Dr. Mackall, a Founder of Lyell, is the Ernest and Amelia Gallo Family Professor of Pediatrics and Medicine at Stanford University. She serves as Founding Director of the Stanford Center for Cancer Cell Therapy, Associate Director of Stanford Cancer Institute, Leader of the Cancer Immunology and Immunotherapy Program and Director of the Parker Institute for Cancer Immunotherapy at Stanford. During a 27-year tenure culminating as Chief of the Pediatric Oncology Branch, NCI, and now at Stanford, she has led an internationally recognized translational research program focused on immune-oncology.

### **Our Strategy**

Our goal is to utilize our proprietary technologies to develop curative ACT for patients with solid tumors. Key components of our business strategy to achieve this goal include:

- Leverage our two proprietary, cell reprogramming platform technologies to fundamentally improve T cell efficacy and eradicate solid tumors.
- Rapidly advance and continue to pursue our deep multi-modality pipeline of product candidates and leading edge research.
- Continually innovate to develop and advance disruptive, next generation platform technologies for cell-based therapy.
- Establish proprietary, state of the art manufacturing infrastructure and capabilities to control all aspects of cell product preparations.
- Implement digital technologies and cloud solutions to accelerate and enhance our science and operations.
- Aggressively generate, secure and defend intellectual property on our differentiated technology platforms and product candidates.

### **Risks Related to Our Business**

Investing in our common stock involves substantial risk. The risks described under the section titled "Risk Factors" immediately following this prospectus summary may cause us to not realize the full benefits of our objectives or may cause us to be unable to successfully execute all or part of our strategy. Some of the more significant challenges include the following:

- We are a preclinical biopharmaceutical company and have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing net losses for the foreseeable future.

- We operate in a rapidly evolving field and have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- Even if this offering is successful, 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 are early in our research and development efforts and all of our product candidates are still in preclinical development. If we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be harmed.
- Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval and we may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.
- Our cellular therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.
- The results of research, preclinical studies or earlier clinical trials are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- Clinical development involves a lengthy and expensive process with an uncertain outcome.
- We intend to manufacture at least a portion of our product candidates ourselves. Delays in commissioning and receiving regulatory approvals for our manufacturing facility 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, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates.
- We have entered into a collaboration with GSK and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.
- 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.

### **Corporate Information**

We were founded in June 2018 as a Delaware corporation. Our principal executive offices are located at 400 East Jamie Court, Suite 301, South San Francisco, California 94080 and our telephone



number is (650) 695-0677. Our website address is [www.lyell.com](http://www.lyell.com). Information contained in, or accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is only an inactive textual reference.

### **Trademarks and Service Marks**

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

### **Implications of Being an Emerging Growth Company**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). We may take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm under Section 404 of the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We may take advantage of these exemptions for up to five years or until we are no longer an "emerging growth company," whichever is earlier. We will cease to be an emerging growth company prior to the end of such five-year period if certain earlier events occur, including if we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act), our annual gross revenues exceed \$1.07 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of accounting standards that have different effective dates for public and private companies until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, we will not be subject to the same requirements to adopt new or revised accounting standards as other public companies that are not "emerging growth companies."

## The Offering

Common stock offered by us	25,000,000 shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to an additional 3,750,000 shares of our common stock at the initial public offering price, less underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	242,829,956 shares (or 246,579,956 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$391.4 million (or approximately \$450.7 million if the underwriters' option to purchase additional shares of our common stock from us is exercised in full), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, to fund through completion of Phase 1 clinical trials of LYL797 and LYL845, other research and development efforts to further advance our Gen-R, Epi-R and cell rejuvenation technology platforms, expansion of our manufacturing capacity and general corporate purposes, including working capital, operating expenses and other capital expenditures. See the section titled "Use of Proceeds" for additional information.</p>
Risk factors	See the section titled "Risk Factors" and other information included in this prospectus for a discussion of factors you should consider carefully before deciding to invest in our common stock.
Directed share program	At our request, the underwriters have reserved up to 1,250,000 shares of our common stock offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale at the initial public offering price through a directed share program to certain of our directors and officers and certain other parties related to us. Shares purchased by our directors and officers will be subject to the 180-day lock-up restriction described in the section titled "Underwriting." If these persons purchase the reserved shares, it

will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. See the section titled "Underwriting—Directed Share Program" for additional information.

**Nasdaq Global Select Market trading symbol**

"LYEL"

The number of shares of our common stock to be outstanding after this offering is based on 217,829,956 shares of common stock outstanding as of March 31, 2021 (including (i) 194,474,431 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of March 31, 2021 and (ii) 5,525,002 shares of unvested restricted common stock subject to repurchase as of such date) and excludes:

- 40,556,956 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2021, with a weighted-average exercise price of \$3.92 per share;
- 1,930,000 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2021, with a weighted-average exercise price of \$13.20 per share;
- 24,700,000 shares of our common stock reserved for future issuance under our 2021 Equity Incentive Plan (2021 Plan), which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2021 Plan; and
- 2,470,000 shares of our common stock reserved for issuance under our 2021 Employee Stock Purchase Plan (ESPP), which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

Unless otherwise indicated, this prospectus assumes or gives effect to:

- the automatic conversion of all outstanding shares of our convertible preferred stock as of March 31, 2021 into an aggregate of 194,474,431 shares of our common stock upon the closing of this offering;
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase 3,750,000 additional shares of common stock from us in this offering;
- an initial public offering price of \$17.00 per share; and
- the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately after the closing of this offering and the adoption of our amended and restated bylaws upon the closing of this offering.

### Summary Consolidated Financial Data

The following tables set forth our summary consolidated financial data for the periods and as of the dates indicated. The following summary consolidated statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020, except for pro forma amounts, have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The summary consolidated statements of operations and comprehensive loss data for the three months ended March 31, 2020 and 2021, except for pro forma amounts, and the summary consolidated balance sheet data as of March 31, 2021, except for pro forma amounts, have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements included elsewhere in this prospectus and include, in our opinion, all adjustments of a normal and recurring nature that are necessary for the fair statement of the financial information set forth in those statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of results that may be expected for the full year. You should read the following summary consolidated financial data together with the sections titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Selected Consolidated Financial Data" and our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus. The summary consolidated financial data included in this section are not intended to replace the audited consolidated financial statements and unaudited condensed consolidated financial statements and are qualified in their entirety by our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
(in thousands, except per share data)				
<b>Consolidated Statements of Operations and Comprehensive Loss Data</b>				
Revenue	\$ 657	\$ 7,756	\$ 1,256	\$ 2,445
Operating expenses (income):				
Research and development	63,595	182,243	25,500	41,529
General and administrative	39,151	46,881	8,880	16,831
Other operating income, net	—	(9,431)	(120)	(545)
Total operating expenses	102,746	219,693	34,260	57,815
Loss from operations	(102,089)	(211,937)	(33,004)	(55,370)
Interest income, net	8,121	5,939	2,341	354
Other (expense) income, net	(35,409)	1,526	1,423	(27)
Net loss	(129,377)	(204,472)	(29,240)	(55,043)
Other comprehensive gain (loss):				
Net unrealized gain (loss) on marketable securities	454	(198)	632	(93)
Net comprehensive loss	<u>\$(128,923)</u>	<u>\$(204,670)</u>	<u>\$(28,608)</u>	<u>\$(55,136)</u>
Net loss attributed to common stockholders:				
Net loss	\$(129,377)	\$(204,472)	\$(29,240)	\$(55,043)
Deemed dividends upon issuance or repurchase of convertible preferred stock	(1,144)	(3,582)	(3,582)	—
Net loss attributed to common stockholders	<u>\$(130,521)</u>	<u>\$(208,054)</u>	<u>\$(32,822)</u>	<u>\$(55,043)</u>

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
	(in thousands, except per share data)			
Net loss per common share, basic and diluted <sup>(1)</sup>	\$(24.04)	\$ (15.69)	\$ (2.82)	\$ (3.19)
Weighted-average shares used to compute net loss per common share, basic and diluted <sup>(1)</sup>	5,429	13,258	11,656	17,272
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(2)</sup>		\$ (1.04)		\$ (0.26)
Weighted-average shares used to compute pro forma net loss per common share, basic and diluted (unaudited) <sup>(2)</sup>		200,327		211,746

- (1) See Note 14 to our audited consolidated financial statements and Note 11 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per common share and the number of shares used in computing these amounts.
- (2) See the subsection titled "Management's Discussion and Analysis of Financial Conditions and Results of Operations—Unaudited Pro Forma Information" for an explanation of the calculations of our basic and diluted pro forma net loss per common share and the weighted-average number of shares outstanding used in the computation of the per share amount.

	As of March 31, 2021		
	Actual	Pro Forma <sup>(1)</sup> (in thousands)	Pro Forma As Adjusted <sup>(2)</sup>
<b>Consolidated Balance Sheet Data</b>			
Cash, cash equivalents and marketable securities	\$ 640,137	\$ 640,137	\$ 1,031,574
Working capital <sup>(3)</sup>	552,923	552,923	944,758
Total assets	877,189	877,189	1,268,195
Total liabilities	200,269	200,269	199,871
Convertible preferred stock	1,010,968	—	—
Accumulated deficit	(389,186)	(389,186)	(389,186)
Total stockholders' (deficit) equity	(334,048)	676,920	1,068,324

- (1) The pro forma column in the consolidated balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 194,474,431 shares of common stock, which will occur upon the closing of this offering and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation to be in effect immediately after the closing of this offering.
- (2) The pro forma as adjusted column in the consolidated balance sheet data gives effect to (i) the items described in footnote (1) above and (ii) the issuance and sale of 25,000,000 shares of our common stock in this offering at the initial public offering price of \$17.00 per share after deducting underwriting discounts and commissions and estimated offering expenses payable by us.
- (3) Working capital is defined as current assets less current liabilities. See our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

## RISKS FACTORS

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, 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" in this prospectus, before deciding whether to invest in our common stock. 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 Relating to Our Financial Condition, Limited Operating History and Need for Additional Capital**

***We are a preclinical biopharmaceutical company and have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing net losses for the foreseeable future.***

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We are a preclinical biopharmaceutical company, and we do not have any products approved by regulatory authorities and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. Since our inception, we have not generated any revenue from product sales and have incurred significant net losses. Our net losses were \$129.4 million and \$204.5 million for the years ended December 31, 2019 and 2020, respectively, and \$29.2 million and \$55.0 million for the three months ended March 31, 2020 and 2021, respectively. 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. As of March 31, 2021, we had an accumulated deficit of \$389.2 million.

We do not expect to generate revenue from product sales for the foreseeable future, if at all. We 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 anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be driven in large part by our ongoing activities, if and as we:

- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- commence clinical trials of our current and future product candidates;

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

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

We operate in a rapidly evolving field and, having commenced operations in June 2018, have a limited operating history, which makes it difficult to evaluate our business and prospects. Our primary activities to date have included developing T cell therapies, performing research and development, acquiring technology, entering into strategic collaboration and license agreements, enabling manufacturing activities in support of our product candidate development efforts, organizing and staffing the company, business planning, establishing our intellectual property portfolio, 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, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

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

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

- successfully complete our research activities to identify the technologies and product candidates to further investigate in clinical trials;
- successfully complete development activities, including the necessary clinical trials;
- complete and submit regulatory submissions to the U.S. Food and Drug Administration (FDA) the European Medicines Agency (EMA) or other agencies and obtain regulatory approval for indications for which there is a commercial market;

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- 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;
- develop commercial quantities of our products at acceptable cost levels;
- establish and maintain adequate supply of our product candidates, including the starting materials and reagents needed;
- complete our own manufacturing facility such that we can maintain the supply of our product candidates in a manner that is compliant with global legal requirements or to the extent necessary, establish and maintain manufacturing relationships with reliable third parties;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

Our revenues for any product for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. 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.

***Even if this offering is successful, 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 preclinical studies and proceed to clinical development and manufacturing of our product candidates. We also expect to continue to expend resources for the development of our technology platforms. These expenditures will include costs associated with research and development, potentially acquiring or licensing new technologies, conducting preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize. In addition, we may be required to make substantial payments related to our success payment agreements and other contingent consideration payments under our license and collaboration agreements. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the discovery, development and commercialization of our potential product candidates and other unanticipated costs may arise.



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 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 the ongoing COVID-19 pandemic. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

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

We agreed to make success payments payable in cash or publicly-tradeable shares of our common stock at our discretion pursuant to our success payment agreements with Fred Hutchinson Cancer Research Center (Fred Hutch) and The Board of Trustees of the Leland Stanford Junior University (Stanford). These success payments will be based on increases in the per share fair market value of our common stock during the success payment period, and will become due and payable upon the occurrence of certain future events, including an initial public offering of our securities, a change of control or conclusion of the agreed-on success payment period. The total amount of success payments that we may become obligated to make is currently \$400.0 million and may increase in the future due to amendments of our existing success payment agreements or additional success payment agreements that we may enter into in the future. For information related to our success payment obligations, see the subsection titled under “Business—Collaboration, License and Success Payment Agreements.”

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

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

Our success payment obligations are recorded as liabilities on our consolidated balance sheets. Under U.S. generally accepted accounting principles (GAAP), we are required to estimate the fair value of these liabilities as of each quarter end and changes in the estimated fair value are accreted to research and development expense over the service period of the collaboration agreement. Factors that may lead to increases or decreases in the estimated fair value of this liability include, among others, changes in the value of the common stock, changes in volatility and changes in the risk-free rate. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP consolidated financial statements. As of December 31, 2020 and March 31, 2021, the estimated fair values of the liabilities associated with the Fred Hutch success payments were \$8.0 million and \$18.2 million, respectively, and as of December 31, 2020 and March 31, 2021, the estimated fair values of the liabilities associated with the Stanford success payments were \$8.9 million and \$19.6 million, respectively.

## Risks Related to Our Business and Industry

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

We are early in our research and development efforts, and all of our product candidates are still in preclinical development. We have not yet demonstrated our ability to successfully commence or complete any clinical trials (including Phase 3 or other pivotal clinical trials), obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We have invested substantial resources in developing our technology platforms and our product candidates, conducting preclinical studies, building our manufacturing facilities and capabilities and preparing for potential clinical trials, each of which will be required prior to any regulatory approval and commercialization. Our ability to generate revenue from product sales, which we do not expect will occur for several years, if ever, will depend heavily on the successful research and development and eventual commercialization of one or more product candidates. The success of our efforts to identify and develop product candidates will depend on many factors, including the following:

- timely and successful completion of our preclinical studies and research activities to identify and develop product candidates to investigate in clinical trials;
- Submission to proceed with clinical trials under INDs from the FDA, or comparable applications to foreign regulatory authorities that allow the commencement of our planned or future clinical trials for our product candidates;
- completion of preclinical studies and successful enrollment and completion of clinical trials in compliance with Good Clinical Practice (GCP) requirements with positive results;
- 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 or making arrangements with third-party manufacturers or completing our own manufacturing facility for clinical and commercial manufacturing purposes;
- establishing capabilities and infrastructure to obtain the tumor tissues needed to develop and, if successful, commercialize approved products from our TIL program;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other marketed therapies;
- maintaining compliance with regulatory requirements, including the cGMP requirements;

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- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

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

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

We are seeking to identify and develop a broad pipeline of product candidates using our proprietary technology platforms. We have not commenced clinical trials for any product candidates developed with these platforms. The scientific research that forms the basis of our efforts to develop product candidates with our technology platforms is still ongoing. We are not aware of any FDA approved therapeutics utilizing similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our technology platforms are both preliminary and limited. Additionally, we have not tested any of the product candidates in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans or may not accurately predict the safety and efficacy of our product candidates in humans. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates.

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

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personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct substantially all of our operations at our facilities in the San Francisco and Seattle 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 stock options that vest over time. The value to employees of stock options or other equity incentives that vest over time may be significantly affected by factors beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. 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.

### ***Any future litigation or adversarial proceedings against us could be costly and time-consuming to defend.***

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by 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. 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. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby harming our business.

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

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

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

We currently have no marketing, sales and distribution capabilities because all of our product candidates are still in preclinical development. If any of our product candidates complete clinical development and are approved, we intend to 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 to outsource this function to a third party. There are risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third

parties to perform these services. To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would make us subject to a number of risks including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator's willingness or ability to complete its obligations, and our obligations under our arrangements may be adversely affected by business combinations or significant changes in our collaborator's business strategy.

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

***Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.***

Our business could be adversely affected by health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. It is not possible at this time to estimate the overall impact that the COVID-19 pandemic could have on our business. For example, as a result of the COVID-19 pandemic, the States of California and Washington, where our operations are located, have issued orders limiting activities to varying levels, including at the most restrictive level, an order for all residents to remain at home, except for the performance of essential activities, which include biomedical research. We have implemented policies that enable some of our employees to work in the research laboratories and for other employees to work remotely, and such policies may continue for an indefinite period. We have also implemented various safety protocols for all on-site personnel, including the requirement to wear masks and maintain social distance. We continue to evaluate the impact COVID-19 may have on our ability to effectively conduct our business operations as planned, and there can be no assurance that we will be able to avoid part or all of any impact from the spread of COVID-19 or its consequences.

In addition, our preclinical study and future clinical trial plans may be affected by the COVID-19 outbreak. Site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, which may delay enrollment in our future global clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, and we may be unable to obtain blood samples for testing.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. Several measures are currently being implemented by the United States and other governments to address the current COVID-19 pandemic and its economic impacts. At this time, it is impossible to predict the success of these measures and whether or not they will have unforeseen negative consequences for our business. We do not yet know the full extent of potential delays or impacts on our business, our planned preclinical studies or clinical trials, healthcare systems or the global economy as a whole. Nor do we know when and how such regulations may be eased. The foregoing and other continued disruptions to our business as a result of COVID-19 could result in an adverse effect on our business, results of operations, financial condition and cash flows. Furthermore, the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

## Risks Related to Manufacturing

***We intend to manufacture at least a portion of our product candidates ourselves. Delays in commissioning and receiving regulatory approvals for our manufacturing facility 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 expected to support preclinical and development product candidates, and product-specific qualification to support clinical production is needed. If we are not able to qualify a specific product candidate or the appropriate regulatory approvals for the new facility are delayed, we may be unable to manufacture sufficient quantities of our product candidates, if at all, which would limit our development activities and our opportunities for growth.

In addition, our manufacturing facility will be subject to ongoing, periodic inspection by the FDA, EMA, or other applicable regulatory agencies to ensure compliance with cGMPs and current Good Tissue Practices (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 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 agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, EMA, or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to 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 or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

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

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

Developing commercially viable manufacturing processes for cellular therapies is a difficult and uncertain task and requires significant expertise and capital investment. We are still in the early stages of 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, and we have not yet manufactured a cellular therapy for a patient with cancer. In addition, we have only recently completed construction of our Bothell, Washington manufacturing facility and have not commenced any clinical scale operations. Our ability to consistently and reliably manufacture our cellular therapy product candidates is essential to our success, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including cost overruns, potential problems with process scale-up,

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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 products candidates to patients could be delayed. In addition, the complexities of utilizing a patient's own cells as the starting material requires that we have suitable cells capable of yielding a viable cellular therapy product, which may not be possible for severely immune-compromised or heavily pre-treated patients.

The process of successfully manufacturing products for clinical testing and commercialization may be particularly challenging, even if such products otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with microbials, 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 which 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 resulting from the ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed. We may also have to write off inventory, incur other charges and expenses for supply of product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. In addition, parts of the supply chain may have long lead times or may come from a small number of suppliers. If we are not able to appropriately manage our supply chain our ability to successfully produce our product candidates could be delayed or harmed. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

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

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

If any manufacturing 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 we are able to replace it 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 could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements or may require regulatory approval before selling any products manufactured at that facility. Such an event could substantially delay our clinical trials or commercialization of our product candidates.

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

***If we are unable to develop or scale our own manufacturing, we may have to 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.***

If we are unable to develop or scale or own manufacturing capabilities for our product candidates, we will be reliant on third parties to manufacture our 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. Engaging a third party manufacturer will require testing and regulatory interactions, and a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any. Our 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 to ensure strict compliance with government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with cGMPs for 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 others, we will not be able to obtain and/or maintain regulatory approval for our product candidates manufactured in these facilities. In addition, we have no 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.

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-



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

### **Risks Related to Our Dependence on Third-Parties**

***We intend to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We do not currently have the ability to independently conduct any clinical trials. We intend to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as

contract research organizations (CROs), to conduct GCP-compliant clinical trials on our product candidates properly and on time. Negotiating budgets and contracts with CROs and study sites may result in delays to our development timelines and increased costs. While we will control only certain aspects of these third parties' activities, nevertheless, we will be responsible for ensuring that each of our trials are conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, 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, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials 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 ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. 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 is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites or any CRO that we may use in the future terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet desired clinical development timelines.

***We do and will continue to or intend to rely on outside scientists and their third-party research institutions for research and development and early clinical testing of our product candidates. These scientists 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.

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

***We have entered into a collaboration with GlaxoSmithKline (GSK) and may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We have entered into a research and development collaboration with GSK for our NY-ESO-1 program and other potential product opportunities. In the future, we may also enter into additional license and collaboration arrangements. Any collaboration arrangement that we enter into is subject to numerous risks, which may include the following:

- the collaborator has significant discretion in determining the efforts and resources that they will apply to a program or product candidate under the collaboration;
- the collaborator may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- the collaborator may delay 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.

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In particular, failure by GSK to meet each of its obligations under our collaboration agreement or failure by GSK to apply sufficient efforts at developing and commercializing collaboration products may adversely affect our business and our results of operations. GSK could independently develop, or develop with its other third party collaborators, products or product candidates that compete directly or indirectly with our products or product candidates and that could adversely impact GSK's willingness to exercise an option under our collaboration or GSK's level of diligence for our collaboration products for which it has exercised an option. Additionally, GSK's exercise of an option for a program that includes a given product candidate may also lead to changes to clinical and regulatory development strategy for such product candidate, at GSK's discretion, which may impact development timelines for such product candidate and may adversely affect the value of our stock. GSK will also require some level of assistance from us with respect to product candidates for which it exercises an option, and this assistance could be burdensome on our organization and resources and disrupt our own development and commercialization activities for product candidates for which we retain rights.

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

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

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

We have entered into, and may desire to enter into in the future, collaborations, licenses or other strategic transactions for the acquisition of products or business opportunities, in each case where we believe such arrangement will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. For example, we entered into a collaboration agreement and stock purchase agreement with PACT Pharma, Inc. (PACT) in June 2020, and in February 2021, we filed a demand for arbitration seeking to, among other things, rescind the agreements with PACT and recover the consideration paid thereunder. 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.

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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 will depend on enrollment and retention of patients in our 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 will require that we enroll and retain a sufficient number of patient candidates. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or adverse events. These types of developments could cause us to delay the trial or halt further development.

Our clinical trials will 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. 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.

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- 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;

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- 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 such patients during the COVID-19 pandemic;
- the availability of new drugs approved for the indication 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 therapies.

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

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

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

### **Risks Related to Regulation and Legal Compliance**

#### ***All of our product candidates are currently in preclinical development, and our future success is dependent on the successful development and regulatory approval of our product candidates.***

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

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product

candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence from and to the satisfaction of the FDA and 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 preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Furthermore, the regulatory approval process for novel product candidates, such as T cell product candidates and next-generation T cell programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

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

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

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

In addition to FDA oversight and oversight by institutional review boards (IRBs) under guidelines promulgated by the National Institutes of Health (NIH), gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee (IBC), a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Although the FDA decides whether trials of cell therapies that involve genetic engineering may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

Actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market 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, preclinical studies or earlier clinical trials are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.***

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

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

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

All of our product candidates are in preclinical development and their risk of failure is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical 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. 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 future clinical trials are



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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 preclinical and clinical trials.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or 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 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 completed any clinical trials required for the approval of our product candidates. We may experience delays in initiating or conducting any future clinical trials, and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned, will achieve expected enrollment rates or will be completed on schedule, if at all. For example, obtaining sufficient and specific tumor tissues will be needed for the anticipated TIL clinical trial. Our inability to obtain the specific tumor tissues or sufficient amount of tumor tissues could delay the clinical trial. 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 preclinical, 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 as to the design or implementation of our clinical trials;
- obtaining regulatory authorization to commence a clinical trial;
- reaching an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining IRB or ethics committee approval at each trial site;
- 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 GCP requirements, or applicable regulatory requirements in other countries;
- 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;

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- manufacturing sufficient quantities of product candidate for use in clinical trials; or
- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the Data Safety Monitoring Board for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above.

Further, a clinical trial may be suspended or terminated by us, the institutional review boards for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or the FDA or other 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 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 a CAR T cell to treat hematologic tumors have shown an increased risk of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome. Adverse events may also be associated with the lymphodepletion regimen utilized with cellular therapies. Additionally, ROR1 is expressed on a number of normal tissues. As a result, ROR1 could cause on-target, off-tumor toxicity. c-JUN is also potentially an oncogene and could cause healthy cells to transform into malignant cells. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidates for any or all targeted indications. The side effects experienced could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims.

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

- regulatory authorities may withdraw or limit approvals of such products and require us to take our approved product off the market;

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- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy (REMS) plan 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 becomes 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 preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. 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 preclinical studies and clinical trials. Preliminary or interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. If the interim,

topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our potential product candidates may be harmed, which could harm our business, operating results, prospects, or financial condition.

***The FDA regulatory approval process is lengthy, time-consuming and inherently unpredictable. If we are not able to obtain required regulatory approval 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 foreign regulatory agencies, that such product candidates are safe, pure and potent for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical 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 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 foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future 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 encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that

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have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the institutional review boards for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or the FDA or other 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 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.

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 candidate.

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, 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

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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, 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 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.

If a regulatory agency 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 agency 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 agency 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, or withdraw regulatory approval;
- suspend any of our preclinical studies and clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;

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- impose restrictions on our operations, including closing our and our contract manufacturers' facilities; or
- seize or detain products, refuse to permit the import or export of products, or require us to conduct a product recall.

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

Moreover, the policies of the FDA and of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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 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; 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) and teaching hospitals and, beginning in 2022, information regarding payments and transfers of value provided to and other healthcare professionals during the previous year. 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.

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, 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 future earnings.

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

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality and expand access to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives, as well as executive, judicial and Congressional challenges to existing healthcare laws that have significantly affected, and could continue to significantly affect, the healthcare industry. For example, the U.S. Supreme Court is currently reviewing the constitutionality of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, together with subsequent amendments and regulations (collectively, the ACA); it is unclear when a decision will be made. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

***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. 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



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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 European Union 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.

Similarly, a significant trend in the healthcare industry is cost containment. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. 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 are 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.

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

We intend to engage CROs and other third parties to conduct our planned preclinical studies or clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO or clinical site or other vendor staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

In addition, any third parties conducting our clinical trials 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 clinical 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 is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for 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 preclinical 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 are conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires 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 GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where

the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

### **Risks Relating to Our Intellectual Property**

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

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

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

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

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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 U.S. and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product candidate.

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first nonprovisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. 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 U.S. 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 reasonable 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

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

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and to the extent to which our technology and processes may infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

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

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

Presently we have rights to the intellectual property, through licenses from third parties and under patent applications that we own or will own, to develop our product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

Our product candidates may also require specific formulations, manufacturing methods, or technologies to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify. We may fail to obtain any of these

licenses at a reasonable cost or on reasonable terms; such failure would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

We have acquired or licensed, or may require in the future, intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act of 1980, 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”). 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 preissuance 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 in the U.S. 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 This Offering and Ownership of Our Common Stock**

***We do not know whether a market will develop for our common stock or what the market price of our common stock will be. As a result, it may be difficult for you to sell your shares of our common stock.***

There is currently no public trading market for our common stock. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price, or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations, clinical trial results, regulatory approval process and progression of our product pipeline may not meet the expectations of securities research analysts and investors. As a result of these and other factors, the price of our common stock may fall.

***You will incur immediate and substantial dilution as a result of this offering.***

If you purchase common stock in this offering, you will incur immediate and substantial dilution of \$12.60 per share, representing the difference between the initial public offering price of \$17.00 per share, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, and our pro forma net tangible book value per share after giving effect to this offering and reclassification of all of our outstanding common stock and redeemable convertible preferred stock into a single class of common stock prior to the closing of the offering. As of March 31, 2021, there were 40,556,956 shares of common stock issuable upon exercise of outstanding stock options with a weighted-average exercise price of \$3.92 per share. Subsequent to March 31, 2021, we granted an additional 1,930,000 shares of common stock with a weighted-average exercise price of \$13.20 per share. To the extent that these outstanding options are exercised, or we issue additional equity or convertible securities in the future, or the underwriters exercise their option to purchase additional shares, you will incur further dilution. See the section titled "Dilution" for a further description of the dilution you will experience immediately after this offering.

***Insiders will continue to have substantial influence over us after this offering, which could limit your ability to affect the outcome of key transactions, including a change of control.***

After this offering, our directors, executive officers, holders of more than 5% of our outstanding stock and their respective affiliates will beneficially own shares representing approximately 28.2% of our outstanding common stock, excluding any shares of common stock that may be purchased pursuant to our directed share program described in "Underwriting." As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section titled "Use of Proceeds" in this prospectus. Our management may spend a portion or all of the net proceeds from this offering in ways that our stockholders may not desire or that may not yield a favorable return. The failure by our management to apply these funds effectively could harm our business, financial condition, results of operations and

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prospects. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***Participation in this offering by our existing stockholders and their affiliated entities may reduce the public float for our common stock.***

To the extent certain of our existing stockholders and their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our shares, meaning the number of shares of our common stock that are not held by officers, directors and controlling stockholders. A reduction in the public float could reduce the number of shares that are available to be traded at any given time, thereby adversely impacting the liquidity of our common stock and depressing the price at which you may be able to sell shares of common stock purchased in this offering.

***We do not anticipate paying any dividends on our common stock for the foreseeable future. Investors in this offering may never obtain a return on their investment.***

We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Instead, we plan to retain any earnings to maintain and expand our existing operations. In addition, any future credit facility or debt securities may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. If we do not pay cash dividends, you could receive a return on your investment in our common stock only if you are able to sell your shares in the future and the market price of our common stock has increased when you sell your shares. As a result, investors seeking cash dividends should not purchase our common stock.

***Delaware law and provisions in our amended and restated certificate of incorporation and bylaws that will be in effect prior to the closing of this offering 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 that will be in effect prior to the closing of this offering 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 will:

- 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;

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

***We have in the past identified a material weakness in our internal control over financial reporting. If we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, 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 will be 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. This assessment will need to include the disclosure of any material weaknesses in such internal control. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

In connection with the finalization of our consolidated financial statements as of and for the year ended December 31, 2019, we and our independent auditors concluded that a material weakness existed in our internal control over financial reporting relating to the review of the technical accounting for settlement of tranche liabilities. Specifically, in connection with our Series A preferred stock financing in 2019, we recorded a correcting adjustment to increase other non-operating expense for the change in fair value of the Series A preferred tranche liability after we initially recorded the amount as a deemed dividend. There were and have been no other tranche liabilities after the settlement of this liability in February 2019.

Although we believe that we have remediated this material weakness by hiring additional accounting and financial reporting personnel and have not identified any material weaknesses in connection with the finalization of our consolidated financial statements as of and for the year ended December 31, 2020, we cannot assure you that we will not identify other material weaknesses in the future. Furthermore, we may not have identified all material weaknesses, and our current controls and any new controls that we develop may become inadequate because of changes in personnel or conditions in our business or otherwise. Accordingly, we cannot assure you that any future material weaknesses will not result in a material misstatement of our consolidated financial statements and/or our failure to meet our public reporting obligations. In addition, if we and/or our independent registered public accounting firm are unable to conclude that our internal control over financial reporting is effective in the future, investor confidence in the accuracy and completeness of our consolidated financial statements would be adversely affected, which could significantly harm our business and the value of our common stock.

#### **General Risk Factors**

***If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely consolidated financial statements could be impaired.***

Pursuant to Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2021. When we lose our status as an "emerging growth company" and become an "accelerated filer" or a "large accelerated filer," our independent registered public accounting firm will be required to attest to 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. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff.

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We cannot assure you that there will not be future material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the U.S. Securities and Exchange Commission (SEC), or other regulatory authorities. 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.

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

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the 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. 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 may be volatile, which could result in substantial losses for investors purchasing shares in this offering.***

The initial public offering price for our common stock will be determined through negotiations with the underwriters. This initial public offering price may differ from the market price of our common stock after the offering. As a result, you may not be able to sell your common stock at or above the initial public offering price. Some of the factors that may cause the market price of our common stock to fluctuate include:

- the timing and results of preclinical studies and clinical trials for our product candidates;
- failure or discontinuation of any of our product development and research programs;
- the success of existing or new competitive product candidates or technologies;
- results of clinical trials, or regulatory approvals of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes including those concerning patent applications, issued patents, or other proprietary rights;

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- the impact of COVID-19 on our business and on global economic conditions;
- 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 and the expiration of market standoff or lock-up agreements;
- 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; and
- the other factors described in this “Risk Factors” section.

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

***If securities 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 will rely in part on the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or securities analysts. If no or few analysts commence coverage of us, the trading price of our stock could decrease. Even if we do obtain analyst coverage, 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 following this offering could cause the price of our common stock to decline.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time following the expiration of the market standoff and lock-up agreements or the early release of these agreements or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, and could reduce the market price of our common stock. After this offering, we will have 242,829,956 shares of common stock that will be outstanding. Of these shares, the 25,000,000 shares we are selling in this offering may be resold in the public market immediately, unless purchased by our affiliates. Substantially all of the remaining shares of our common stock that



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will be outstanding after this offering are currently prohibited or otherwise restricted under securities laws, market standoff agreements entered into by our stockholders with us, or lock-up agreements entered into by our stockholders with the underwriters; however, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, these shares will be able to be sold in the public market beginning 180 days after the date of this prospectus. The representatives may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act. See the section titled "Shares Eligible for Future Sale" for additional information.

Moreover, after this offering, holders of an aggregate of approximately 194.5 million shares of our common stock will 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. We also plan to register all shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the section titled "Underwriting" in this prospectus. 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. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships, alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or our products, or grant licenses on terms unfavorable to us. Certain of the foregoing transactions may require us to obtain stockholder approval, which we may not be able to obtain.

### ***We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.***

We are an "emerging growth company" as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 not being required to comply with the auditor requirements to

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communicate critical audit matters in the auditor's report on the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and we have not included all of the executive compensation related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

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

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

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

***We will incur increased costs as a result of operating as a public company. Our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Section 404, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements and rules of The Nasdaq Stock Market LLC (Nasdaq Listing Rules), and other applicable U.S. rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we

expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. 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.

Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC after we become a public company. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements.

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

As of December 31, 2020, we had federal and state net operating loss (NOLs) carryforwards of approximately \$116.1 million and \$61.2 million, respectively. Under the Tax Cuts and Jobs Act of 2017 (the Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), our NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (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 and may experience ownership changes as a result of this offering and/or 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. For example, California recently imposed limits on the usability of California state NOLs and tax credits to offset California taxable income in tax years beginning after December 31, 2019 and before January 1, 2023. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

***Our business and operations would suffer in the event of computer system failures or security breaches.***

Our internal computer systems, and those of our partners, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. 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.

While we have not experienced any material system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

***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.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, 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, clinical trials, research and development costs, regulatory approvals, 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 prospectus 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 of our estimates regarding expenses, revenue opportunities, capital requirements and needs for additional financing;
- the scope, progress, results and costs of developing LYL797, LYL845 or any other product candidates we may develop, and conducting preclinical studies and clinical trials, including for LYL797 and LYL845;
- the timing and costs involved in obtaining and maintaining regulatory approval of LYL797, LYL845 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for our product candidates for various diseases;
- our expectations regarding GSK’s plans for the NY-ESO-1 program;
- our plans relating to commercializing LYL797, LYL845 or any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales force;
- the size of the market opportunity for LYL797, LYL845 or any other product candidates we may develop in each of the diseases we target;
- our reliance on third parties to conduct nonclinical research activities for LYL797, LYL845 or any other product candidates we may develop;
- the characteristics, safety, efficacy and therapeutic effects of LYL797, LYL845 or any other product candidates we may develop;
- our estimates of the number of patients in the United States who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials, including the timing thereof;
- the ability of our clinical trials to demonstrate the safety and efficacy of LYL797, LYL845 or any other product candidates we may develop, and other positive results;
- the success of competing therapies that are, or may become, available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;

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- our plans relating to the further development and manufacturing of LYL797, LYL845 or any other product candidates we may develop, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply LYL797, LYL845 or any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of LYL797, LYL845 or any other product candidates we may develop, as well as the pricing and reimbursement of LYL797, LYL845 or any other product candidates we may develop, if approved;
- our continued reliance on third parties to conduct additional clinical trials of LYL797, LYL845 or any other product candidates we may develop, and for the manufacture of our product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights, including LYL797, LYL845 or any other product candidates we may develop;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations (CROs) and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act; and
- our anticipated use of our existing cash, cash equivalents and marketable securities and the proceeds from this offering.

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 prospectus and are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this prospectus. 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 the forward-looking statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this prospectus, whether as a result of any new information, future events or otherwise.

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 prospectus, 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.

## MARKET, INDUSTRY AND OTHER DATA

We obtained the industry, market and competitive position data used throughout this prospectus from our own internal estimates and research, as well as from independent market research, industry and general publications and surveys, governmental agencies and publicly available information in addition to research, surveys and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of our industry and market, which we believe to be reasonable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires. In addition, while we believe the industry, market and competitive position data included in this prospectus is reliable and based on reasonable assumptions, such data involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

## USE OF PROCEEDS

We estimate that we will receive net proceeds from this offering of approximately \$391.4 million (or approximately \$450.7 million if the underwriters' option to purchase 3,750,000 additional shares of our common stock is exercised in full) based on the initial public offering price of \$17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets.

We currently intend to use the net proceeds we receive from this offering, together with our existing cash, cash equivalents and marketable securities, as follows:

- approximately \$130.0 million to fund through completion of the Phase 1 clinical trial of LYL797;
- approximately \$130.0 million to fund through completion of the Phase 1 clinical trial of LYL845;
- approximately \$100.0 million to fund other research and development efforts to further advance our Gen-R, Epi-R and cell rejuvenation technology platforms;
- approximately \$100.0 million to further expand our manufacturing capabilities for our product candidates; and
- the remainder for general corporate purposes, including working capital, operating expenses and other capital expenditures.

We may also use a portion of the net proceeds and our existing cash, cash equivalents and marketable securities to in-license, acquire, or invest in complementary businesses, technology platforms, products or assets. However, we have no current commitments or obligations to do so.

We believe, based on our current operating plan, that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operations into 2025. In particular, we expect that the net proceeds from this offering will allow us to further advance our Gen-R, Epi-R and cell rejuvenation technology platforms as well as progress the development of LYL797 and LYL845. However, our expected use of proceeds from this offering described above represents our current intentions based on our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the proceeds to be received upon the closing of this offering or the actual amounts that we will spend on the uses set forth above. The net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will not be sufficient for us to fund LYL797 and LYL845 through regulatory approval, and we anticipate needing to raise additional capital to complete the development and commercialization of LYL797 and LYL845 and any future product candidates we may develop.

The amounts and timing of our actual expenditures will depend on numerous factors, including the time and cost necessary to conduct our planned clinical trials, the results of our planned clinical trials and other factors described in the section titled "Risk Factors" in this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. Therefore, our actual expenditures may differ materially from the estimates described above. We may find it necessary or advisable to use the net proceeds for other purposes. We will have broad discretion over how to use the net proceeds to us from this offering. We intend to invest the net proceeds to us from this offering that are not used as described above in short-term, investment-grade, interest-bearing instruments.



## DIVIDEND POLICY

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

**CAPITALIZATION**

The following table sets forth our cash, cash equivalents and marketable securities and capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis, giving effect to the (i) automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 194,474,431 shares of our common stock which will occur upon the closing of this offering, and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering, and (ii) filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering; and
- on a pro forma as adjusted basis, giving effect to the (i) pro forma adjustments set forth above and (ii) our receipt of net proceeds from the sale of 25,000,000 shares of common stock in this offering at the initial public offering price of \$17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this table together with the sections titled “Selected Consolidated Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Description of Capital Stock,” and our unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus.

	As of March 31, 2021		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Cash, cash equivalents and marketable securities	<u>\$ 640,137</u>	<u>\$ 640,137</u>	<u>\$ 1,031,574</u>
Series A convertible preferred stock, \$0.0001 par value per share; 97,933,475 shares authorized, 97,386,669 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 210,158	\$ —	\$ —
Series AA convertible preferred stock, \$0.0001 par value per share; 30,253,189 shares authorized, 30,253,189 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	146,325	—	—
Series B convertible preferred stock, \$0.0001 par value per share; 23,929,531 shares authorized, 23,929,531 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	162,018	—	—
Series C convertible preferred stock, \$0.0001 par value per share; 42,905,042 shares authorized, 42,905,042 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	492,467	—	—

	As of March 31, 2021		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share and per share amounts)		
Stockholders' (deficit) equity:			
Preferred stock, \$0.0001 par value per share; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized, pro forma and pro forma as adjusted; no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value per share; 264,905,000 shares authorized, 17,830,523 shares issued and outstanding, actual; 500,000,000 shares authorized, pro forma and pro forma as adjusted; 217,829,956 shares issued and outstanding, pro forma; 242,829,956 shares issued and outstanding, pro forma as adjusted	2	22	24
Additional paid-in capital	54,973	1,065,921	1,457,323
Accumulated other comprehensive income	163	163	163
Accumulated deficit	(389,186)	(389,186)	(389,186)
Total stockholders' (deficit) equity	<u>(334,048)</u>	<u>676,920</u>	<u>1,068,324</u>
Total capitalization	<u>\$ 676,920</u>	<u>\$ 676,920</u>	<u>\$1,068,324</u>

The number of shares of our common stock to be issued and outstanding, pro forma and pro forma as adjusted in the table above is based on 217,829,956 shares of common stock outstanding as of March 31, 2021 (including (i) 194,474,431 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of March 31, 2021 and (ii) 5,525,002 shares of unvested restricted common stock subject to repurchase as of such date, but which are not considered outstanding for accounting purposes), and excludes:

- 40,556,956 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2021, with a weighted-average exercise price of \$3.92 per share;
- 1,930,000 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2021, with a weighted-average exercise price of \$13.20 per share;
- 24,700,000 shares of our common stock reserved for future issuance under our 2021 Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2021 Plan; and
- 2,470,000 shares of our common stock reserved for issuance under our ESPP, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

## DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the initial public offering price per share of common stock and the pro forma as adjusted net tangible book value per share immediately after this offering.

As of March 31, 2021, we had a historical net tangible book value (deficit) of (\$334.3) million, or (\$14.31) per share of common stock based on the 23,355,525 shares of common stock outstanding as of such date, including 5,525,002 shares subject to repurchase as of such date. Our historical net tangible book value per share represents total tangible assets less total liabilities and convertible preferred stock, which is not included within permanent equity, divided by the number of shares of common stock outstanding as of March 31, 2021, including 5,525,002 shares subject to repurchase as of such date.

Our pro forma net tangible book value as of March 31, 2021 was \$676.7 million, or \$3.11 per share. Pro forma net tangible book value per share represents the amount of our total tangible assets less our total liabilities, divided by 217,829,956 shares of common stock outstanding as of such date, including 5,525,002 shares subject to repurchase as of such date, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 194,474,431 shares of our common stock and the related reclassification of the carrying value of our convertible preferred stock to permanent equity upon the closing of this offering, and (ii) the filing and effectiveness of our amended and restated certificate of incorporation that will be in effect immediately after the closing of this offering.

After giving effect to the sale by us of 25,000,000 shares of common stock in this offering at the initial public offering price of \$17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been \$1,068.1 million, or \$4.40 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$1.29 per share to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value of \$12.60 per share to investors purchasing common stock in this offering. We determine dilution by subtracting the pro forma as adjusted net tangible book value per share after this offering from the amount of cash paid by an investor for a share of common stock in this offering. The following table illustrates this dilution on a per share basis:

Initial public offering price per share		\$17.00
Historical net tangible book deficit per share as of March 31, 2021	\$(14.31)	—
Pro forma increase in historical net tangible book value per share attributable to the pro forma transaction described in the preceding paragraphs	17.42	—
Pro forma net tangible book value per share as of March 31, 2021	3.11	—
Increase in pro forma as adjusted net tangible book value per share attributable to investors purchasing shares in this offering	\$ 1.29	—
Pro forma as adjusted net tangible book value per share after this offering		\$ 4.40
Dilution in pro forma as adjusted net tangible book value per share to investors purchasing shares in this offering		<u>\$12.60</u>

If the underwriters exercise their option to purchase additional shares of common stock in full, the pro forma net tangible book value per share, as adjusted to give effect to this offering, would be \$4.57 per share, and the dilution in pro forma net tangible book value per share to investors in this offering would be \$12.43 per share.

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The foregoing discussion and tables above (other than the historical net tangible book value calculation) are based on 217,829,956 shares of common stock outstanding as of March 31, 2021 (including (i) 194,474,431 shares issuable upon the conversion of all outstanding shares of our convertible preferred stock as of March 31, 2021 and (ii) 5,525,002 shares of unvested restricted common stock subject to repurchase as of such date), and excludes:

- 40,556,956 shares of our common stock issuable upon the exercise of outstanding stock options as of March 31, 2021, with a weighted-average exercise price of \$3.92 per share;
- 1,930,000 shares of our common stock issuable upon the exercise of outstanding stock options granted subsequent to March 31, 2021, with a weighted-average exercise price of \$13.20 per share;
- 24,700,000 shares of our common stock reserved for future issuance under our 2021 Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under our 2021 Plan; and
- 2,470,000 shares of our common stock reserved for issuance under our ESPP, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for future issuance under our ESPP.

To the extent that any outstanding options are exercised or new options are issued under our stock-based compensation plans, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering.

## SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data for the periods and as of the dates indicated. The following selected consolidated statements of operations and comprehensive loss data for the years ended December 31, 2019 and 2020, except for pro forma amounts, and our selected consolidated balance sheet data as of December 31, 2019 and 2020, have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The selected consolidated statements of operations and comprehensive loss data for the three months ended March 31, 2020 and 2021, except for pro forma amounts, and the selected consolidated balance sheet data as of March 31, 2021, have been derived from our unaudited condensed consolidated financial statements included elsewhere in this prospectus. Our unaudited condensed consolidated financial statements were prepared on a basis consistent with our audited consolidated financial statements and include, in our opinion, all adjustments of a normal and recurring nature that are necessary for the fair statement of the financial information set forth in those statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and our interim results are not necessarily indicative of the results that may be expected for the full year. You should read the following selected financial data together with the sections titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Summary Consolidated Financial Data” and our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus. The selected consolidated financial data included in this section are not intended to replace the audited consolidated financial statements and unaudited condensed consolidated financial statements and are qualified in their entirety by our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus.

	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
(in thousands, except per share data)				
<b>Consolidated Statements of Operations and Comprehensive Loss Data</b>				
Revenue	\$ 657	\$ 7,756	\$ 1,256	\$ 2,445
Operating expenses (income):				
Research and development	63,595	182,243	25,500	41,529
General and administrative	39,151	46,881	8,880	16,831
Other operating income, net	—	(9,431)	(120)	(545)
Total operating expenses	<u>102,746</u>	<u>219,693</u>	<u>34,260</u>	<u>57,815</u>
Loss from operations	(102,089)	(211,937)	(33,004)	(55,370)
Interest income, net	8,121	5,939	2,341	354
Other (expense) income, net	<u>(35,409)</u>	<u>1,526</u>	<u>1,423</u>	<u>(27)</u>
Net loss	(129,377)	(204,472)	(29,240)	(55,043)
Other comprehensive gain (loss):				
Net unrealized gain (loss) on marketable securities	454	(198)	632	(93)
Net comprehensive loss	<u>\$(128,923)</u>	<u>\$(204,670)</u>	<u>\$(28,608)</u>	<u>\$(55,136)</u>
Net loss attributed to common stockholders:				
Net loss	\$(129,377)	\$(204,472)	\$(29,240)	\$(55,043)
Deemed dividends upon issuance or repurchase of convertible preferred stock	<u>(1,144)</u>	<u>(3,582)</u>	<u>(3,582)</u>	<u>—</u>
Net loss attributed to common stockholders	<u>\$(130,521)</u>	<u>\$(208,054)</u>	<u>\$(32,822)</u>	<u>\$(55,043)</u>

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	Year Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
	(in thousands, except per share data)			
Net loss per common share, basic and diluted <sup>(1)</sup>	\$(24.04)	\$ (15.69)	\$ (2.82)	\$ (3.19)
Weighted-average shares used to compute net loss per common share, basic and diluted <sup>(1)</sup>	5,429	13,258	11,656	17,272
Pro forma net loss per common share, basic and diluted (unaudited) <sup>(2)</sup>		\$ (1.04)		\$ (0.26)
Weighted-average shares used to compute pro forma net loss per common share, basic and diluted (unaudited) <sup>(2)</sup>		200,327		211,746

- (1) See Note 14 to our audited consolidated financial statements and Note 11 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per common share and the number of shares used in computing these amounts.
- (2) See the subsection titled "Management's Discussion and Analysis of Financial Conditions and Results of Operations—Unaudited Pro Forma Information" for an explanation of the calculations of our basic and diluted pro forma net loss per common share and the weighted-average number of shares outstanding used in the computation of the per share amount.

	As of December 31,		As of March 31,
	2019	2020	2021
	(in thousands)		
<b>Consolidated Balance Sheet Data</b>			
Cash, cash equivalents and marketable securities	\$ 471,032	\$ 692,614	\$ 640,137
Working capital <sup>(1)</sup>	418,214	568,262	552,923
Total assets	555,631	908,280	877,189
Total liabilities	147,576	189,840	200,269
Convertible preferred stock	519,163	1,010,968	1,010,968
Accumulated deficit	(129,671)	(334,143)	(389,186)
Total stockholders' deficit	(111,108)	(292,528)	(334,048)

- (1) Working capital is defined as current assets less current liabilities. See our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.








## 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 the section titled “Selected Consolidated Financial Data,” and our audited consolidated financial statements and unaudited condensed consolidated financial statements and the related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus 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.” See also the section titled “Special Note Regarding Forward-Looking Statements.”

### Overview

We are a T cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors. We have assembled a world-class team, comprising some of the foremost scientific leaders in the fields of oncology and ACT, including Drs. Rick Klausner, Nick Restifo, Stan Riddell and Crystal Mackall, who have each interrogated and elucidated the mechanisms of T cell biology and its interactions with cancer for decades. We believe the key to effective cell therapy is the mastery of the identity, fate and function of cells to create living medicines. We take a systematic, interrogative, cell biology-driven approach to overcome what we view as the two major barriers to successful ACT – (1) T cell exhaustion and (2) lack of durable stemness – through the application of our proprietary epigenetic and genetic reprogramming technology platforms, Gen-R and Epi-R. Our technology platforms are designed to be applied in a target and modality agnostic manner to CAR, TIL and TCR therapies to fundamentally improve the properties of T cells needed to eradicate solid tumors. We believe our autologous T cell therapies will generate improved, durable clinical outcomes that are potentially curative for patients with solid tumors.

We are utilizing our Gen-R and Epi-R technology platforms to develop a multi-modality product pipeline across several solid tumor indications with high unmet needs and anticipate having four IND submissions by the end of 2022. Each of our programs provide opportunities to expand into additional indications beyond the patient populations we are initially targeting. Our product candidates are summarized in the table below:

	TECHNOLOGY	TARGET	COMMERCIAL RIGHTS	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONE
CAR	Gen-R & Epi-R	ROR-1 (LYL797)		<ul style="list-style-type: none"> <li>• NSCLC</li> <li>• TNBC</li> <li>• Other solid tumors</li> </ul>					Submit IND in Q1 2022
TIL	Epi-R	Polyclonal (LYL845)		<ul style="list-style-type: none"> <li>• Multiple solid tumor histologies</li> </ul>					Submit IND in 2H 2022
TCR	Gen-R	NY-ESO-1*		<ul style="list-style-type: none"> <li>• Synovial sarcoma</li> <li>• Other solid tumors</li> </ul>					Submit INDs in 1H 2022
	Epi-R								

\* Our collaborator, GlaxoSmithKline (GSK), is developing an NY-ESO-1 TCR T cell product candidate, currently in pivotal development. While we are currently evaluating Gen-R and Epi-R in separate preclinical programs for this product candidate, together these programs could represent a single future product opportunity for GSK utilizing one or both of our technology platforms.



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We were incorporated in June 2018. Our primary activities to date have included developing T cell therapies, performing research and development, acquiring technology, entering into strategic collaboration and license agreements, enabling manufacturing activities in support of our product candidate development efforts, organizing and staffing the company, business planning, establishing our intellectual property portfolio, raising capital and providing general and administrative support for these activities. All of our programs are currently in preclinical development, and we have not yet tested any product candidates in humans and do not have any products approved for sale. Since our inception, we have incurred net losses each year. Our net losses were \$129.4 million and \$204.5 million for the years ended December 31, 2019 and 2020, respectively, and \$29.2 million and \$55.0 million for the three months ended March 31, 2020 and 2021, respectively. As of March 31, 2021, we had an accumulated deficit of \$389.2 million. Our net losses resulted primarily from our research and development programs and, to a lesser extent, general and administrative costs associated with our operations.

To date, we have funded our operations primarily from the issuance and sale of our convertible preferred stock and to a lesser extent from a collaboration, and we have not generated any revenue from product sales. From June 29, 2018 (inception) through March 31, 2021, we raised an aggregate of \$980.7 million in gross proceeds from the sales of our convertible preferred stock. As of March 31, 2021, we had cash, cash equivalents and marketable securities of \$640.1 million. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from this offering, will be sufficient to meet our working capital and capital expenditure needs into 2025.

We anticipate that our expenses and operating losses will increase substantially over the foreseeable future. The expected increase in expenses will be driven in large part by our ongoing activities, if and as we:

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

We believe it is critically important to own, control and continuously monitor all aspects of the cell therapy manufacturing process in order to mitigate risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. We made a strategic decision to invest substantial capital in building our own manufacturing facility to control our supply chain, maximize efficiencies in cell product production time, cost and quality and have the ability to rapidly incorporate disruptive advancements and new innovations. Controlling manufacturing also enables us to protect proprietary aspects of our Gen-R and Epi-R technology platforms. We view our manufacturing team and capabilities as a significant competitive advantage.

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In 2019, we 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. This LyFE manufacturing center has a flexible and modular design allowing us to produce plasmid, viral vector and T cell product to control and de-risk the sequence and timing of production of the major components of our supply chain related to our product candidates. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. We anticipate the facility to be cGMP qualified by the end of 2021. We believe this capacity is sufficient to support our pipeline programs through pivotal trials and, if approved, early commercialization. We anticipate continued investment in our manufacturing facility and capabilities to support our operating strategy.

The global COVID-19 pandemic continues to evolve rapidly, and we will continue to monitor it closely. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain and will depend on certain developments, including the duration and spread of the outbreak and its impact on our clinical trial plans, CROs, contract manufacturing organizations and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. While the implications of the COVID-19 pandemic on our operations remain uncertain, to date, we have not experienced delays in our discovery and development activities as a result of the COVID-19 pandemic. We have closely monitored the COVID-19 pandemic and have strived to follow recommended containment and mitigation measures, including the guidance from the Centers for Disease Control and Prevention (CDC) as well as the states of California and Washington and applicable counties. For most of the pandemic, essential laboratory and support employees worked in our facilities to continue and progress experiments. We implemented preventative measures at our facilities in order to minimize the risk of employee exposure to the virus, including the following requirements: that each employee who entered a facility agreed to comply with social distancing, frequent hand washing and the requirement to wear masks. We also increased cleaning of high touch areas, provided hand sanitizing stations and implemented an employee questionnaire to ensure employee health status and to provide for limited on-site tracing if needed. Finally, commencing in early March 2020, we suspended all non-essential business travel and directed all employees who are not essential laboratory personnel to work from home. We expect to continue such measures for the near foreseeable future. We will continue to actively monitor the situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state, or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

We anticipate that we will need to raise additional capital in the future to fund our operations, including the commercialization of any approved product candidates. Until such time, if ever, as we can generate significant product revenue, we expect to finance our operations with our existing cash, cash equivalents and marketable securities, the net proceeds from this offering, any future equity or debt financings and upfront and milestone and royalties payments, if any, received under future licenses or collaborations. We may not be able to raise additional capital on terms acceptable to us or at all. If we are unable to raise additional capital when desired, our business, results of operations, and financial condition would be adversely affected.

### **Collaboration, License and Success Payment Agreements**

Below is a summary of the key terms for certain of our collaboration and license agreements. For a more detailed description of these and our collaboration, license and success payment agreements, see the section titled “Business—Collaboration, License and Success Payment Agreements” and Notes 2 and 3 to our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus.

### **Fred Hutch**

In December 2018, we entered into an exclusive license agreement with Fred Hutch to access certain intellectual property for the development of CARs and TCRs. In connection with this agreement, we paid \$150,000 in cash and issued to Fred Hutch 1,075,000 shares of our common stock for total consideration of \$0.8 million.

In December 2018, we entered into a research and collaboration agreement with Fred Hutch for the development of cellular immunotherapy products. Pursuant to this agreement, we are required to fund \$12.0 million in research performed by Fred Hutch, and we recorded research and development expense of \$3.7 million and \$4.1 million for the years ended December 31, 2019 and 2020, respectively, and \$1.0 million for both the three months ended March 31, 2020 and 2021.

We also entered into a letter agreement with Fred Hutch in December 2018, pursuant to which we may be required to make success payments (Fred Hutch Success Payments) up to an aggregate of \$200.0 million based on increases in the fair market value of our Series A convertible preferred stock, or any security into which such stock has been converted or exchanged. All shares of Series A convertible preferred stock will automatically convert into shares of common stock upon the closing of this offering on a one-for-one basis. The potential Fred Hutch Success Payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the fair value of the Series A convertible preferred stock (or common stock into which it is converted upon the closing of this offering) relative to its original issuance price at pre-determined valuation measurement dates. The Fred Hutch Success Payments can be achieved over a maximum of nine years from the effective date of the agreement. The following table summarizes the potential success payments, which are payable in cash, cash equivalents or, at our discretion, publicly-tradeable shares of our common stock:

<b>Multiple of initial equity value at issuance</b>	<b>10x</b>	<b>20x</b>	<b>30x</b>	<b>40x</b>	<b>50x</b>
Per share Series A convertible preferred 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 valuation measurement dates are triggered by the following events: the one-year anniversary of an initial public offering of our common stock and each two-year anniversary of the initial public offering 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.

The estimated fair value of the Fred Hutch Success Payments as of December 31, 2019 and 2020 and March 31, 2021 was \$3.8 million, \$8.0 million and \$18.2 million, respectively. With respect to Fred Hutch Success Payments, we recognized expense of \$0.4 million and \$4.8 million for the years ended December 31, 2019 and 2020, respectively, and \$2.1 million and \$8.1 million for the three months ended March 31, 2020 and 2021, respectively.

### **Stanford**

In January 2019, we entered into an exclusive license agreement with Stanford to access certain intellectual property for the development of CARs and TCRs. In connection with this agreement, we paid \$400,000 in cash and issued Stanford 910,000 shares of our common stock, for total consideration of \$3.0 million, which was recorded as research and development expense for the year ended December 31, 2019. We are also required to pay Stanford an annual maintenance fee on the second anniversary of the agreement date, and each anniversary thereafter until the date of the first commercial sale of a licensed product. Under the agreement, we may also be required to make certain

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pre-specified development milestone payments up to an aggregate of \$3.7 million for the first licensed product for each target, and pre-specified commercial milestone payments up to an aggregate of \$2.5 million for all licensed products.

In October 2020, we entered into a research and collaboration agreement with Stanford for the development of cellular immunotherapy products. Pursuant to this agreement, we are required to fund \$12.0 million in research performed by Stanford, and we recorded research and development expense of \$0.8 million for both the year ended December 31, 2020 and the three months ended March 31, 2021. There was no expense recorded associated with the research and collaboration agreement with Stanford for the year ended December 31, 2019 and the three months ended March 31, 2020.

We also entered into a letter agreement with Stanford in October 2020, pursuant to which we may be required to make success payments (Stanford Success Payments) up to an aggregate of \$200.0 million based on increases in the fair market value of our Series A convertible preferred stock, or any security into which such stock has been converted or exchanged. All shares of Series A convertible preferred stock will automatically convert into shares of common stock upon the closing of this offering on a one-for-one basis. The potential Stanford Success Payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the fair value of the Series A convertible preferred stock (or common stock into which it is converted upon the closing of this offering) relative to its original issuance price at pre-determined valuation measurement dates. The Stanford Success Payments can be achieved over a maximum of nine years from the effective date of the agreement. The following table summarizes the potential success payments, which are payable in cash, cash equivalents or, at our discretion, publicly-tradeable shares of our common stock:

<b>Multiple of initial equity value at issuance</b>	<b>10x</b>	<b>20x</b>	<b>30x</b>	<b>40x</b>	<b>50x</b>
Per share Series A convertible preferred 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 valuation measurement dates are triggered by the following events: the one-year anniversary of an initial public offering of our common stock and each two-year anniversary of the initial public offering 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.

The estimated fair value of the Stanford Success Payments as of December 31, 2020 and March 31, 2021 was \$8.9 million and \$19.6 million, respectively. With respect to Stanford Success Payments, we recognized expense of \$0.6 million for the year ended December 31, 2020 and \$1.9 million for the three months ended March 31, 2021. There was no expense recorded associated with the Stanford Success Payments for the year ended December 31, 2019 and the three months ended March 31, 2020.

### **GSK Collaboration Agreement**

In May 2019, we entered into a collaboration agreement with GSK, amended in June 2020 (the GSK Agreement), for potential T cell therapies that apply our platform technologies and cell therapy innovations to TCRs or CARs under distinct collaboration programs. Pursuant to the GSK Agreement, we received an upfront payment of \$45.0 million, which was recorded as deferred revenue and revenue is recognized as the research and development services are rendered. For potential TCR or CAR therapies that are the subject of a collaboration program under the GSK Agreement, we are responsible for certain research and development activities, at our cost, up to GSK's option point. These are expensed as research and development as incurred. Generally, each party is responsible for its own cost and expense to conduct each collaboration program. In April 2021, GSK exercised its

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option to the NY-ESO-1 TCR with Gen-R program and GSK will assume responsibility for future research and development of this program at its cost and expense. We are eligible to receive up to two one-time payments, totaling approximately \$200.0 million in aggregate, for technology validation of Lyell's cell therapy innovations. For each cell therapy target for which there has been a joint collaboration program, we also could receive up to approximately \$400.0 million in aggregate in development and sales milestones for a target that is already within GSK's pipeline and meets certain criteria, up to approximately \$900.0 million in aggregate in development and sales milestones for all other targets, and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK's pipeline and meet certain criteria, or from high single digit to low teens for all other targets. Royalties and milestones are paid once per target, even if there is more than one Lyell innovation applied to a T cell therapy directed to that target.

### ***NCI License Agreement***

In December 2020, we entered into a license agreement with NCI to access certain intellectual property for the development of treatment of human cancers. In connection with this agreement, we paid \$100,000 upfront, and a prorated annual maintenance payment for 2020 of approximately \$3,100, for total consideration of approximately \$103,100, which was recorded in research and development expense for the year ended December 31, 2020. We are also required to pay NCI annual maintenance payments which may be credited against earned royalties. Under the agreement, we may also be required to make certain prespecified development milestone payments up to an aggregate of \$3.1 million, and pre-specified commercial milestone payments up to a maximum aggregate of \$12.0 million for all licensed products.

### **Components of Operating Results**

#### ***Revenue***

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

To date, we have generated revenue primarily from the recognition of a portion of the upfront payment under the GSK Agreement that we entered into in May 2019. As we continue to conduct research under the GSK Agreement, we will recognize revenue based upon our estimate of the progress made. 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 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 which have not reached technological feasibility and do not have an alternative future use are expensed as incurred.

Research and development expenses also include non-cash expense related to the change in the estimated fair value of the liabilities associated with our success payments granted to Fred Hutch and Stanford. See the subsection titled “—Critical Accounting Policies and Significant Judgments and Estimates—Success Payments” below. Research and development expenses related to our success payment liabilities are unpredictable and may vary significantly from quarter to quarter and year to year due to changes in our assumptions used in the calculation.

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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 preclinical studies, commencing clinical trials, completing clinical trials, seeking regulatory approval 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 all of our product candidates are still in preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the preclinical 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 preclinical 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 preclinical studies and future 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,

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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 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 due to the increased 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 SEC requirements, director and officer insurance costs and investor and public relations costs.

### *Other Operating Income, Net*

Other operating income, net consists primarily of gains recorded on the sale of assets and upon lease remeasurement.

### **Interest Income, Net**

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

### **Other (Expense) Income, Net**

Other (expense) income, net consists primarily of the changes in the fair value of our convertible preferred tranche liabilities and an equity warrant investment held.

### **Deemed Dividends Upon Issuance or Repurchase of Convertible Preferred Stock**

For the year ended December 31, 2019, deemed dividends upon issuance or repurchase of convertible preferred stock consists of the amount by which the fair value of the convertible preferred stock, not subject to our convertible preferred stock tranche liabilities from our Series A convertible preferred stock financing, exceeded the cash proceeds from the sale and issuance of such convertible preferred stock. For the three months ended March 31, 2020 and the year ended December 31, 2020, deemed dividends upon issuance or repurchase of convertible preferred stock consists of the amount by which the cash paid for the repurchase of convertible preferred stock exceeded the carrying value of such convertible preferred stock.

## Results of Operations

### Comparison of the Three Months Ended March 31, 2020 and 2021

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

	Three Months Ended March 31,		Change
	2020	2021	
Revenue	\$ 1,256	\$ 2,445	\$ 1,189
Operating expenses (income):			
Research and development	25,500	41,529	16,029
General and administrative	8,880	16,831	7,951
Other operating income, net	(120)	(545)	(425)
Total operating expenses	34,260	57,815	23,555
Loss from operations	(33,004)	(55,370)	(22,366)
Interest income, net	2,341	354	(1,987)
Other income (expense), net	1,423	(27)	(1,450)
Net loss	<u>\$(29,240)</u>	<u>\$(55,043)</u>	<u>\$(25,803)</u>
Net loss attributed to common stockholders:			
Net loss	\$ (29,240)	\$ (55,043)	\$ (25,803)
Deemed dividends upon issuance or repurchase of convertible preferred stock	(3,582)	-	3,582
Net loss attributed to common stockholders	<u>\$(32,822)</u>	<u>\$(55,043)</u>	<u>\$(22,221)</u>

#### Revenue

Revenue was \$1.3 million and \$2.4 million for the three months ended March 31, 2020 and 2021, respectively. Revenue recognized for the three months ended March 31, 2020 and 2021 was primarily related to the recognized portion of the upfront license fee pursuant to the GSK Agreement, which was effective in July 2019. The increase of \$1.2 million is due to increased research and development activities under the GSK Agreement for the three months ended March 31, 2021 compared to the three months ended March 31, 2020.

#### Research and Development Expenses

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

	Three Months Ended March 31,		Change
	2020	2021	
Personnel	\$10,755	\$14,833	\$ 4,078
Success payments	2,070	9,967	7,897
Facilities and technology	5,628	7,537	1,909
Research and laboratory	4,944	4,476	(468)
Collaborations and licenses	1,843	4,013	2,170
Other	260	703	443
Total research and development expenses	<u>\$25,500</u>	<u>\$41,529</u>	<u>\$16,029</u>



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Research and development expenses were \$25.5 million and \$41.5 million for the three months ended March 31, 2020 and 2021, respectively. The increase of \$16.0 million was primarily due to:

- an increase of \$7.9 million associated with our Fred Hutch and Stanford success payments liabilities primarily due to the increase in the estimated per share fair value of our Series A preferred stock (or common stock into which it is converted upon the closing of this offering);
- an increase in personnel-related expenses of \$4.1 million, including \$2.8 million of stock-based compensation expense, which was primarily related to an increase in headcount to expand our research and development capabilities;
- an increase in collaborations and licenses costs of \$2.2 million, including costs incurred in connection with strategic collaborations and costs to license technology; and
- an increase in facilities and technology costs of \$1.9 million including rent, depreciation, information technology related expenses and other allocated overhead costs.

### *General and Administrative Expenses*

General and administrative expenses were \$8.9 million and \$16.8 million for the three months ended March 31, 2020 and 2021, respectively. The increase of \$7.9 million was primarily due to an increase of \$6.7 million in stock-based compensation expense primarily related to award modifications and new awards granted. Additionally, consulting and legal costs increased \$0.7 million.

### *Interest Income, Net*

Interest income, net, was \$2.3 million and \$0.4 million for the three months ended March 31, 2020 and 2021, respectively. The decrease of \$1.9 million was primarily due to lower interest rates on cash, cash equivalents and marketable securities balances.

### *Other Income (Expense), Net*

For the three months ended March 31, 2020 and 2021, other income (expense), net consisted primarily of the addition in 2020, and the subsequent changes in fair value, of an equity warrant investment held.

### Comparison of the Years Ended December 31, 2019 and 2020

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

	Year Ended December 31,		Change
	2019	2020	
Revenue	\$ 657	\$ 7,756	\$ 7,099
Operating expenses (income):			
Research and development	63,595	182,243	118,648
General and administrative	39,151	46,881	7,730
Other operating income, net	—	(9,431)	(9,431)
Total operating expenses	<u>102,746</u>	<u>219,693</u>	<u>116,947</u>
Loss from operations	(102,089)	(211,937)	(109,848)
Interest income, net	8,121	5,939	(2,182)
Other (expense) income, net	(35,409)	1,526	36,935
Net loss	<u>\$(129,377)</u>	<u>\$(204,472)</u>	<u>\$ (75,095)</u>
Net loss attributed to common stockholders:			
Net loss	\$(129,377)	\$(204,472)	\$ (75,095)
Deemed dividends upon issuance or repurchase of convertible preferred stock	(1,144)	(3,582)	(2,438)
Net loss attributed to common stockholders	<u>\$(130,521)</u>	<u>\$(208,054)</u>	<u>\$ (77,533)</u>

#### Revenue

Revenue was \$0.7 million and \$7.8 million for the years ended December 31, 2019 and 2020, respectively. Revenue recognized for the years ended December 31, 2019 and 2020 was related to the recognized portion of the upfront license fee pursuant to the GSK Agreement, which was effective in July 2019. The increase of \$7.1 million is due to the longer recognition period as we performed a full year of research and development activities under the GSK Agreement for the year ended December 31, 2020 compared to only a portion of the year for the year ended December 31, 2019.

#### 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
	2019	2020	
Collaborations and licenses	\$10,392	\$ 79,015	\$ 68,623
Personnel	31,634	54,112	22,478
Facilities and technology	11,378	24,560	13,182
Research and laboratory	8,355	17,914	9,559
Success payments	436	5,337	4,901
Other	1,400	1,305	(95)
Total research and development expenses	<u>\$63,595</u>	<u>\$182,243</u>	<u>\$118,648</u>

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Research and development expenses were \$63.6 million and \$182.2 million for the years ended December 31, 2019 and 2020, respectively. The increase of \$118.6 million was primarily due to:

- an increase of \$68.6 million associated with collaborative agreements and license agreements primarily related to the commitment agreement upfront payment to PACT of \$63.6 million, consisting of the \$50.0 million upfront payment and \$13.6 million deemed to be the difference between the purchase price of the preferred stock shares we purchased from PACT and the associated value of the preferred shares, and \$7.5 million in acquired in-process research and development expense related to the asset acquisition of Immulus, Inc. (Immulus), recorded for the year ended December 31, 2020;
- an increase in personnel-related expenses of \$22.5 million, including \$10.1 million of stock-based compensation expense, which was primarily related to an increase in headcount to expand our research and development capabilities;
- an increase in facilities and technology costs of \$13.2 million including rent, depreciation, information technology related expenses and other allocated overhead costs;
- an increase in research and laboratory of \$9.6 million, including laboratory supplies, preclinical studies, and other external research expenses; and
- an increase of \$4.9 million associated with our Fred Hutch and Stanford success payments liabilities.

### *General and Administrative Expenses*

General and administrative expenses were \$39.2 million and \$46.9 million for the years ended December 31, 2019 and 2020, respectively. The increase of \$7.7 million was primarily due to an increase of \$7.4 million in stock-based compensation expense primarily related to award modifications. Additionally, facilities and information technology related expenses increased \$2.9 million. These increases were partially offset by a decrease in consulting and legal costs of \$1.6 million.

### *Other Operating Income, Net*

For the year ended December 31, 2020, other operating income, net consisted primarily of a gain recorded on the sale of assets of \$4.9 million and a gain recorded upon lease remeasurement of \$2.9 million.

### *Interest Income, Net*

Interest income, net, was \$8.1 million and \$5.9 million for the years ended December 31, 2019 and 2020, respectively. The decrease of \$2.2 million was due to lower interest rates on cash, cash equivalents, and marketable securities balances, partially offset by higher average cash, cash equivalents and marketable securities balances in 2020 compared to 2019.

### *Other (Expense) Income, Net*

For the year ended December 31, 2019, other (expense) income, net consisted primarily of expense recorded due to the change in fair value of our convertible preferred tranche liabilities of \$35.4 million. For the year ended December 31, 2020, other (expense) income, net consisted primarily of the addition and the change in fair value of an equity warrant investment held of \$1.3 million.

## **Unaudited Pro Forma Information**

Immediately prior to the completion of this offering, all outstanding shares of our convertible preferred stock will convert into shares of our common stock. The unaudited pro forma basic and

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diluted net loss per common share for the year ended December 31, 2020 and the three months ended March 31, 2021 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the conversion of all outstanding shares of convertible preferred stock into shares of common stock, as if such conversion had occurred at the beginning of the period, or their issuance dates if later. Pro forma net loss per share does not include the shares expected to be sold in this offering.

The following table sets forth the computation of the unaudited pro forma basic and diluted net loss per common share for the periods presented:

	Year Ended December 31, 2020	Three Months Ended March 31, 2021
<b>Numerator</b>		
Net loss attributed to common stockholders	\$ (208,054)	\$ (55,043)
<b>Denominator</b>		
Weighted-average common shares outstanding	13,258	17,272
Weighted-average convertible preferred stock	187,069	194,474
Pro forma weighted-average shares outstanding, basic and diluted	200,327	211,746
Pro forma net loss per common share, basic and diluted	\$ (1.04)	\$ (0.26)

## 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. As of March 31, 2021, we had \$640.1 million in cash, cash equivalents and marketable securities. Since our inception, we have incurred significant operating losses. We have not yet commercialized any product candidates and we do not expect to generate revenue from sales of any product candidates for a number of years, if ever. We had an accumulated deficit of \$389.2 million as of March 31, 2021. From June 29, 2018 (inception) through March 31, 2021, we raised an aggregate of \$980.7 million in gross proceeds from the sales of our convertible preferred stock.

### 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 preclinical studies and clinical trials, developing new product candidates, establishing internal manufacturing capabilities and funding our operations generally. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from this offering, will be sufficient to meet our working capital and capital expenditure needs into 2025. However, we anticipate that we will need to raise additional capital in the future to fund our operations, including the commercialization of any approved product candidates. 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, preclinical development and clinical trials for our current and future product candidates;

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- 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, 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 of operating as a public company;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- addressing or responding to any potential disputes or litigation; and
- the extent to which we acquire or invest in businesses, products and technology platforms.

Until such time as we complete preclinical 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, 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 would 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 the ongoing COVID-19 pandemic and otherwise. If we are unable to raise additional capital when desired, our business, results of operations and financial condition would be adversely affected.

## Cash Flows

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

	Years Ended December 31,		Three Months Ended March 31,	
	2019	2020	2020	2021
Net cash provided by (used in):				
Operating activities	\$ 39,474	\$(160,874)	\$ (23,592)	\$ (33,597)
Investing activities	(422,433)	(273,516)	(116,079)	136,677
Financing activities	351,156	476,790	476,419	884
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (31,803)</u>	<u>\$ 42,400</u>	<u>\$ 336,748</u>	<u>\$ 103,964</u>

### Operating Activities

During the three months ended March 31, 2020, net cash used in operating activities was \$23.6 million, consisting primarily of our net loss of \$29.2 million, partially offset by non-cash adjustments to reconcile net loss to net cash used in operating activities of \$6.2 million. These adjustments consisted primarily of stock-based compensation expense of \$3.3 million, \$2.1 million for revaluation of our success payment liabilities to Fred Hutch and \$1.6 million in non-cash lease expense, partially offset by a non-cash income of \$1.4 million associated with the equity warrant investment. Additionally, net operating assets decreased \$0.5 million, which included \$1.3 million of non-cash revenue recognized for the three months ended March 31, 2020.

During the three months ended March 31, 2021, net cash used in operating activities was \$33.6 million, consisting primarily of our net loss of \$55.0 million, partially offset by non-cash adjustments to reconcile net loss to net cash used in operating activities of \$26.2 million. These adjustments consisted primarily of stock-based compensation expense of \$12.7 million, \$10.0 million for revaluation of our success payment liabilities to Fred Hutch and Stanford, depreciation and amortization of \$2.0 million and \$1.0 million in non-cash lease expense. Additionally, net operating assets decreased \$4.8 million, which included \$2.4 million of non-cash revenue recognized for the three months ended March 31, 2021.

During the year ended December 31, 2019, net cash provided by operating activities was \$39.5 million, consisting primarily of the upfront payment received in connection with the GSK Agreement of \$103.6 million. This was partially offset by our net loss of \$129.4 million reduced by non-cash adjustments to reconcile net loss to net cash provided by operating activities of \$58.0 million. The non-cash adjustments to reconcile net loss to net cash provided by operating activities consisted primarily of a loss of \$35.4 million associated with the remeasurement of our convertible preferred stock tranche liabilities from our Series A convertible preferred stock financing, stock-based compensation expense of \$15.7 million, \$3.6 million for the issuance of stock in connection with license agreements and \$3.1 million in non-cash lease expense.

During the year ended December 31, 2020, net cash used in operating activities was \$160.9 million, consisting primarily of our net loss of \$204.5 million, partially offset by non-cash adjustments to reconcile net loss to net cash used in operating activities of \$43.9 million. These adjustments consisted primarily of stock-based compensation expense of \$33.3 million, \$5.3 million for revaluation of our success payment liabilities to Fred Hutch and Stanford, depreciation and amortization of \$4.3 million, \$3.5 million in non-cash acquired in-process research and development expense related to the asset acquisition of Immulus, and non-cash lease expense, net of gain on lease

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remeasurement, of \$3.2 million, partially offset by a non-cash gain of \$4.9 million recorded on the sale of assets to Outpace Bio, Inc. (Outpace). Additionally, we recognized \$7.8 million of non-cash revenue for the year ended December 31, 2020.

### *Investing Activities*

During the three months ended March 31, 2020, cash used in investing activities was \$116.1 million, consisting of net purchases of marketable securities of \$109.2 million and purchases of property and equipment of \$6.9 million.

During the three months ended March 31, 2021, cash provided by investing activities was \$136.7 million, consisting of net sales and maturities of marketable securities of \$155.9 million, partially offset by purchases of property and equipment of \$19.2 million.

During the year ended December 31, 2019, cash used in investing activities was \$422.4 million, consisting of net purchases, sales and maturities of marketable securities of \$372.4 million, purchases of other investments of \$34.0 million and purchases of property and equipment of \$16.0 million.

During the year ended December 31, 2020, cash used in investing activities was \$273.5 million, consisting of net purchases, sales and maturities of marketable securities of \$178.6 million, purchases of other investments of \$43.4 million and purchases of property and equipment of \$51.5 million.

### *Financing Activities*

During the three months ended March 31, 2020, cash provided by financing activities was \$476.4 million, consisting of \$492.5 million in net proceeds from the sale of our convertible preferred stock, partially offset by the repurchase of preferred and common stock of \$16.1 million.

During the three months ended March 31, 2021, cash provided by financing activities was \$0.9 million, consisting of proceeds from the exercise of stock options.

During the year ended December 31, 2019, cash provided by financing activities was \$351.2 million, consisting primarily of net proceeds from the sale of our convertible preferred stock.

During the year ended December 31, 2020, cash provided by financing activities was \$476.8 million, consisting primarily of \$492.5 million in net proceeds from the sale of our convertible preferred stock, partially offset by the repurchase of preferred and common stock of \$16.1 million.

## **Contractual Obligations and Commitments**

The following table summarizes our significant contractual obligations and commitments as of December 31, 2020 (in thousands):

	Payments Due by Period				Total
	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years	
Operating lease obligations(1)	\$ 10,096	\$ 21,788	\$ 23,283	\$ 58,962	\$ 114,129
Collaboration minimum funding(2)	7,362	6,857	1,714	—	15,933
<b>Total contractual obligations</b>	<b>\$ 17,458</b>	<b>\$ 28,645</b>	<b>\$ 24,997</b>	<b>\$ 58,962</b>	<b>\$ 130,062</b>

(1) Represents future minimum lease payments under our operating leases as of December 31, 2020, excluding expected tenant incentives to be received. The minimum lease payments above do not include any related common area maintenance charges, real estate taxes and other executory costs.

(2) Represents non-cancellable minimum funding requirements related to certain collaboration agreements.

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Other than disclosed in the table above, payment obligations under our license, collaboration and acquisition agreements as of December 31, 2020 are contingent upon future events such as our achievement of pre-defined development, regulatory and commercial milestones, or royalties on net product sales. See the section titled “Business—Collaboration, License and Success Payment Agreements” for more information about these payment obligations. As described under the subsection titled “—Critical Accounting Policies and Significant Judgments and Estimates—Success Payments” below, we are also obligated to make up to \$200.0 million in success payments to Fred Hutch and up to \$200.0 million in success payments to Stanford based on increases in the per share fair value of our Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged. The success payments are payable in cash or cash equivalents or, at our discretion, publicly-tradeable shares of our common stock. As of December 31, 2020, the timing and likelihood of achieving the milestones and success payments and generating future product sales are uncertain and therefore, any related payments are not included in the table above.

### **Off-Balance Sheet Arrangements**

Since our inception, we did not have, and we do not currently have, any off-balance sheet arrangements as defined under the rules and regulations of the SEC.

### **JOBS Act Accounting Election**

We are an “emerging growth company,” as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statement, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited consolidated financial statements and have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use the extended transition period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our audited consolidated financial statements and unaudited condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the audited consolidated financial statements and the unaudited condensed 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



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described in more detail in the notes to our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus, we believe that the following accounting policies are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

### **Revenue**

We recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods and services. To determine revenue recognition for arrangements within the scope of Accounting Standards Codification (ASC) 606, *Revenue from Contracts with Customers*, (ASC 606), we perform 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, we 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, we do 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 we may earn are subject to significant uncertainties of research and development related achievements, which generally are deemed to be not probable until such milestones are actually achieved. Additionally, we develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation, for which we recognize revenue as or when the performance obligations are satisfied. At the end of each subsequent reporting period, we re-evaluate the variable consideration and any related constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis.

Revenue allocated to performance obligations is recognized using an estimate of the percentage of completion of the project based on the costs incurred on the project as a percentage of the total expected costs. The determination of the percentage of completion requires management to estimate the costs to complete the project. A detailed estimate of the costs to complete is reassessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate will be adjusted and the revenue will be recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate would be recognized as an adjustment to revenue in the period in which the change in estimate occurs. Determining the estimate of the cost-to-complete requires significant judgment and may have a significant impact on the amount and timing of revenue recognition.

### **Research and Development Expenses**

We record research and development costs in the periods in which they are incurred. We accrue for research and development costs based on the estimated services performed, but not yet invoiced, pursuant to contracts with research institutions or other service providers that conduct and manage preclinical studies and other research services on our behalf and record these costs in accrued liabilities and other current liabilities. We make judgments and estimates in determining the accrued liabilities balance at each reporting period. Payments made prior to the receipt of goods or services to be used in research and development are recorded as prepaid expenses until the goods or services are received.

Research and development costs also include the estimated fair value of the potential liabilities associated with the rights to success payments granted to Fred Hutch and Stanford.

To date, we have not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed may vary from our estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to our accruals could materially affect our results of operations.

### **Success Payments**

We granted rights to success payments to Fred Hutch and Stanford pursuant to the terms of our collaboration agreements with each of those entities. Pursuant to the terms of these agreements, on each contractually prescribed measurement date, we may be required to make success payments based on increases in the estimated per share fair value of our Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, payable in cash or cash equivalents or, at our discretion, publicly-tradeable shares of our common stock. The success payments are accounted for under ASC 718, *Compensation – Stock Compensation*, with the expense being recorded in research and development expenses. Once the service period is complete, the instrument will be accounted for under ASC 815, *Derivatives and Hedging*, and continue to be remeasured each reporting period with all changes in value recognized immediately in other income or expense.

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

The assumptions used to estimate the fair value of the success payment liability are subject to a significant amount of judgment including the estimated fair value of the Series A convertible preferred stock, expected volatility of our common stock, estimated term and estimated number of valuation measurement dates. A small change in the assumptions, or a change in our stock price, may have a relatively large change in the estimated fair value of the success payment liability.

### **Stock-Based Compensation**

We recognize compensation costs related to restricted stock awards and stock options granted to employees and nonemployees based on the estimated fair value of the awards on the date of grant, and we recognize forfeitures as they occur. For restricted stock awards the fair value of our common stock is used to determine the resulting stock-based compensation expense. For stock options we estimate the grant date fair value, and the resulting stock-based compensation expense, using the Black-Scholes option pricing model. The fair value of the stock-based awards is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period.

The Black-Scholes option pricing model requires the use of highly subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Fair Value of Common Stock*—See the subsection titled “—Common Stock Valuations” below.

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- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. We use 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 options.
- *Expected Volatility*—Since we are not yet a public company and do not have any trading history for our common stock, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a time period equal to the expected term of the stock option grants. The comparable companies are chosen based on their size, stage in the product development cycle and area of specialty. We will continue to apply this process until sufficient historical information regarding the volatility of our own stock price becomes available.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected Dividend*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

See Note 12 to our audited consolidated financial statements and Note 10 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted in the years ended December 31, 2019 and 2020, and the three months ended March 31, 2020 and 2021. Such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

The intrinsic value of all outstanding options as of March 31, 2021 was approximately \$530 million, based on the initial public offering price of \$17.00 per share, of which approximately \$198 million is related to vested options and approximately \$332 million is related to unvested options.

### **Common Stock Valuations**

Prior to this offering, we were a privately-held company with no active public market for our common stock. Therefore, our board of directors, with the assistance and upon the recommendation of management, has for financial reporting purposes periodically determined the estimated per share fair value of our common stock on the date of grant in part using contemporaneous independent third-party valuations consistent with the American Institute of Certified Public Accountants Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation* (Practice Aid). Within the contemporaneous valuations performed by our board of directors, a range of factors, assumptions and methodologies were used. The significant objective and subjective factors included, but are not limited to:

- our most recently available valuations of our common stock performed by an independent third-party valuation firm;
- the prices of shares of our convertible preferred stock sold to investors in arm's length transactions, and the rights, preferences, and privileges of our convertible preferred stock relative to our common stock;
- committed future rounds of funding;
- our stage of development and material risks related to our business;

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- our results of operations and financial position, including our levels of available capital resources;
- progress of our research and development activities;
- the lack of marketability of our common stock as a private company;
- the hiring of key personnel and the experience of management;
- the likelihood of achieving a liquidity event of an initial public offering for our stockholders, given prevailing market conditions;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors;
- the status of strategic transactions, including the acquisition of intellectual property and technology;
- trends and developments in our industry; and
- external market conditions affecting the life sciences and biotechnology industry sectors.

Our board of directors exercises significant judgment in estimating the fair value of our common stock. Such estimates involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different. Changes in judgments could have a material impact on our results of operations.

For our valuations performed in 2019 and prior to September 2020, in accordance with the Practice Aid, we determined the option pricing model (OPM) method was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. In an OPM framework, the backsolve method for inferring the equity value implied by a recent financing transaction involves making assumptions for the expected time to liquidity, volatility, discount for lack of marketability and risk-free rate and then solving for the value of equity such that value for the most recent financing equals the amount paid.

For our valuations performed in or subsequent to September 2020, in accordance with the Practice Aid, we determined the hybrid method of the OPM method and an initial public offering scenario was the most appropriate method for determining the fair value of our common stock based on our stage of development and other relevant factors. The initial public offering scenario reflected the value of our common shares assuming we complete a near-term initial public offering. Under the hybrid OPM and initial public offering scenario method, the per share value calculated under the OPM and the initial public offering scenario are weighted based on expected exit outcomes and the quality of the information specific to each allocation methodology to arrive at a final estimated fair value per share value of the common stock before a discount for lack of marketability is applied.

Following the closing of this offering, our board of directors will determine the fair market value of our common stock based on its closing price as reported on the date of grant on the primary stock exchange on which our common stock is traded.

### **Internal Control over Financial Reporting**

In connection with the audit of our 2019 consolidated financial statements, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting relating to the review of the technical accounting for settlement of tranche liabilities. While we believe that we have remediated this material weakness by hiring additional

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accounting and financial reporting personnel and have not identified any material weaknesses in connection with the finalization of our 2020 consolidated financial statements, we cannot assure you that we will not identify other material weaknesses in the future. See the section titled “Risk Factors— We have in the past identified a material weakness in our internal control over financial reporting. If we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, 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.” Pursuant to Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2022. When we lose our status as an “emerging growth company” and become an “accelerated filer” or a “large accelerated filer,” our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting.

### **Recently Adopted and Recent Accounting Pronouncements**

See Note 2 to our audited consolidated financial statements included elsewhere in this prospectus 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.

### **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, cash equivalents and restricted cash of \$244.8 million as of March 31, 2021, which consisted of bank deposits, 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 \$395.8 million as of March 31, 2021. The primary objective of our investment activities is to preserve capital to fund our operations while earning a low-risk return. 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 1% change in market interest rates during any of the periods presented would not have had a material effect on our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus. We had no debt outstanding as of March 31, 2021.

#### ***Foreign Currency Exchange Risk***

All of our employees and our 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 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 elsewhere in this prospectus.

***Effects of Inflation***

Inflation generally affects us by increasing our cost of labor and in the future our clinical trial costs. We believe that inflation has not had a material effect on our audited consolidated financial statements and unaudited condensed consolidated financial statements included elsewhere in this prospectus.

**JOBS Act**

As an emerging growth company under the JOBS Act, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period to enable us to comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We also intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering, (ii) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (iii) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.



## FOUNDER'S VISION

One of the most dramatic advances in medicine over the past decade has been the emergence of immunotherapy for cancer. The development of checkpoint blockade therapy by Jim Allison, the development of TIL therapy by Steve Rosenberg and the development of CAR-T therapy by Carl June and others have taught us that autologous T cells are capable of treating and sometimes eradicating cancer. Lyell is a next generation autologous T cell therapy company whose goal is to bring to patients—simply stated—curative therapy for any solid tumor.

While our goal is ambitious, it is actually grounded in the abundant evidence that autologous T cells can eradicate even advanced and refractory cancer, but only occasionally and only in a few cancers. Our goal is therefore not to prove this possibility, but to make it reliably and predictably effective, widely applicable and practicable for any cancer in any patient!

Our approach has been to examine currently available human data to understand the underlying reasons and correlates of why and when autologous T cell therapy against solid tumors is sometimes successful and more often fails.

Through this, we have identified what we believe are the two most important barriers to successful therapy:

- Exhaustion of T cells
- Ability to create the effective and self-renewing—properties which we term durable stemness—therapeutic product in each dose we give to patients

The primacy of these barriers and the solutions for them that we have developed come from the labs of our three scientific founders, Nick Restifo, Stan Riddell and Crystal Mackall. We are striving to overcome these two barriers with our ability to reprogram T cells to adopt those qualities correlated with, and thus necessary for, successful solid tumor eradication. The pursuit to elucidate and overcome these barriers is our foundation and ethos.

We have created T Cell Reprogramming Platforms that we believe can be directed at almost any cancer. While many are exploring new ways to manufacture T cell therapies, we are asking not “how” to manufacture cell preparations, but “what” T cells and their properties we need to manufacture. Our goal is to fundamentally redefine the very composition of adoptive cell therapy preparations, and therefore their reliable efficacy. We believe that these platforms are applicable to any modality for targeting tumors, be they CARs, TILs or cloned TCRs and our clinical programs will incorporate each of these targeting modalities.

Our story is the story of our science. The execution of that science has been the product of one of the most remarkable teams that I have ever worked with. We are committed to continued scientific innovation, and so while our first two T cell reprogramming platforms are ready to be tested in the clinic, we continue to develop next generation reprogramming platforms, including one based on our ability to rejuvenate, or turn back the age of, T cells.

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We have built an end-to-end company capable of discovering new science, designed to translate that science into products, manufacture those products and clinically test our science and products.

We believe that the use of living cells as therapies will be a big part of the future of medicine, representing the third evolution in therapeutics, the first being the use of small molecules which defined the pharmaceutical industry, the second, the use of biologic macromolecules which defined the biotech industry and finally, cell therapy—living, dynamic therapy to confront an always-evolving disease. It will be our ability to define and control the identity, fate and function of these cells that will enable us to create cell-based curative therapies and it is within this new paradigm of medicine that we have built Lyell.

For me personally, Lyell represents the culmination of a long journey—from the work in my own lab in the 1980's that helped define how T cells are turned on, and the discovery of the molecular engine that underlies CAR T cells and the activity of all T cells when they see their target antigens; to overseeing the nation's cancer program as NCI Director in the 1990s; to my co-founding of Juno Therapeutics.

The dream of creating curative therapies for cancer for the many patients and families confronting this disease has inspired and motivated me to stay on that journey. It is the privilege of building companies that can take science into the clinic, with aspirations to change the lives of those patients, that I hope will be the beginning of the end of that journey.

Richard D. Klausner, M.D.  
Founder and Executive Chairman



## BUSINESS

### Overview

We are a T cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors. We have assembled a world-class team, comprising some of the foremost scientific leaders in the fields of oncology and ACT, including Drs. Rick Klausner, Nick Restifo, Stan Riddell and Crystal Mackall, who have each interrogated and elucidated the mechanisms of T cell biology and its interactions with cancer for decades. We believe the key to effective cell therapy is the mastery of the identity, fate and function of cells to create living medicines. We take a systematic, interrogative, cell biology-driven approach to overcome what we view as the two major barriers to successful ACT – (1) T cell exhaustion and (2) lack of durable stemness – through the application of our proprietary epigenetic and genetic reprogramming technologies, Gen-R and Epi-R. Our technologies are designed to be applied in a target and modality agnostic manner to CAR, TIL and TCR therapies to fundamentally improve the properties of T cells needed to eradicate solid tumors. We believe our autologous T cell therapies will generate improved, durable clinical outcomes that are potentially curative for patients with solid tumors. We are building a multi-modality product pipeline across several solid tumor indications with high unmet needs and anticipate making four IND submissions by the end of 2022.

### Our Technology Platforms

ACT has demonstrated profound results in some patients suffering from hematologic tumors, but solid tumors are more complex and have evolved multiple mechanisms to evade and ultimately overcome the immune system. This has limited the use of ACTs in non-hematologic settings. We believe T cell exhaustion and lack of durable stemness – the T cell's loss of continual proliferative capacity, and abilities of self-renewal and differentiation to effector states to eliminate solid tumors – are two major barriers limiting the efficacy of ACT in solid tumors.

We endeavor to overcome these two major barriers to ACT in solid tumors through our proprietary Gen-R and Epi-R technology platforms.








- **Gen-R** – our proprietary *ex vivo* genetic reprogramming technology to overcome T cell exhaustion, which results from transcriptional and epigenetic changes that occur as T cells differentiate into a dysfunctional state. Our scientific co-founders discovered T cell exhaustion occurs more frequently in solid tumors than in hematologic cancers where CAR T cells have demonstrated efficacy. The discovery of Gen-R came from the realization that chronic antigen stimulation, or when the T cell is always “on,” combined with an immunosuppressive solid TME, likely promotes the development of T cell exhaustion. In preclinical solid tumor models, Gen-R overcame T cell exhaustion and restored antitumor activity through the optimized overexpression of c-JUN, a protein which, when dysregulated, has been shown to play a crucial role in T cell exhaustion.
- **Epi-R** – our proprietary *ex vivo* epigenetic reprogramming technology to create a novel population of T cells with durable stemness. Stemness, the quality of T cells capable of self-renewal, expansion, persistence and anti-tumor response has been reported in the literature to correlate with clinical responses to immunotherapy. However, we believe *durable* stemness is required for long-term efficacy against solid tumors. Durable stemness relates to the ability of T cells to maintain their stemness until the tumor is eradicated, that is, they have the ability to self-renew despite continued persistent signals from the tumor driving activation, proliferation and differentiation. We believe that as these cells proliferate, they generate progeny cells that can both differentiate to polyfunctional effector cells, and/or re-populate the population of less differentiated T cell states as they continue to divide, thereby maintaining stemness. Epi-R is

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designed to intentionally and reproducibly generate populations of T cells which have this property of durable stemness. Furthermore, relating specifically to TIL, application of Epi-R has generated T cell preparations that exhibit increased polyclonality, i.e. the retention of a broad repertoire of TCR clonotypes.

### Our Pipeline

We are utilizing our Gen-R and Epi-R technology platforms to develop a multi-modality product pipeline with four IND submissions expected by the end of 2022. Each of our programs provide opportunities to expand into additional indications beyond the patient populations we are initially targeting. Our product candidates are summarized in the table below:

	TECHNOLOGY	TARGET	COMMERCIAL RIGHTS	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONE
CAR	Gen-R & Epi-R	ROR-1 (LYL797)		<ul style="list-style-type: none"> <li>• NSCLC</li> <li>• TNBC</li> <li>• Other solid tumors</li> </ul>					Submit IND in Q1 2022
TIL	Epi-R	Polyclonal (LYL845)		<ul style="list-style-type: none"> <li>• Multiple solid tumor histologies</li> </ul>					Submit IND in 2H 2022
TCR	Gen-R	NY-ESO-1*		<ul style="list-style-type: none"> <li>• Synovial sarcoma</li> <li>• Other solid tumors</li> </ul>					Submit INDs in 1H 2022
	Epi-R								

\* Our collaborator, GlaxoSmithKline (GSK), is developing an NY-ESO-1 TCR T cell product candidate, currently in pivotal development. While we are currently evaluating Gen-R and Epi-R in separate preclinical programs for this product candidate, together these programs could represent a single future product opportunity for GSK utilizing one or both of our technology platforms.

#### LYL797: ROR1 + Gen-R + Epi-R

We are applying our Gen-R and Epi-R technology platforms to our lead CAR program, LYL797, which is expected to be an IV administered CAR T cell product candidate targeting ROR1 with a single-chain variable fragment derived from rabbit anti-R12 antibody that recognizes and binds to ROR1 and a proprietary optimized EGFRopt safety switch. We are initially developing LYL797 for the treatment of ROR1+ NSCLC and TNBC. ROR1 expression is associated with poor prognosis. Significant subsets of patients with common cancers express ROR1, including TNBC (~60%) and NSCLC (~40%), two of the highest ROR1 expressing indications. If successful, we anticipate expanding into other ROR1+ cancers with a lower incidence of ROR1 expression, including potentially HR+ breast cancer, ovarian and other solid tumors. We expect to submit an IND for LYL797 in the first quarter of 2022.

#### LYL845: TIL + Epi-R

We are applying our Epi-R technology to develop our product candidate, LYL845, which is expected to be an IV administered autologous TIL therapy in multiple solid tumors. TIL have previously shown clinical benefit in patients with melanoma as well as other solid tumors with high mutation burdens including advanced cervical, lung, breast and gastrointestinal cancers. TILs target a variety of tumor antigens, but it is thought that the clinical efficacy of TILs is largely driven by specific recognition of mutated tumor neoantigens. Further, broad TIL efficacy has been limited by poor enrichment of tumor-reactive T cells, poor quality and growth potential of expanded T cells, and failure to maintain polyclonality of TILs during production. We have designed LYL845 to incorporate our Epi-R technology to result in enhanced T cell potency, antitumor activity and polyclonality of TILs. If successful, we

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expect to expand development broadly to potentially include melanoma, cervical, head and neck, pancreatic, breast, colorectal and NSCLC. We expect to submit an IND for LYL845 in the second half of 2022.

### *NY-ESO-1*

Our collaborator, GSK, is developing a NY-ESO-1 TCR T cell product candidate, NY-ESO-1 C239, currently in pivotal development. We are collaborating with them to potentially enhance this product candidate with Gen-R and Epi-R. Preclinical efforts and IND-enabling studies are underway. We anticipate GSK will conduct initial clinical trials with an enhanced product candidate in synovial sarcoma and multiple other solid tumor indications. We anticipate an IND submission in the first half of 2022.

### ***Our Manufacturing Capabilities***

We believe it is critically important to own, control and continuously monitor all aspects of the cell therapy manufacturing process in order to mitigate risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. 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, cost and quality, and have the ability to rapidly incorporate disruptive advancements and new innovations. Controlling manufacturing also enables us to protect proprietary aspects of our Gen-R and Epi-R technology platforms. We view our manufacturing team and capabilities as a significant competitive advantage.

Our LyFE manufacturing center is approximately 73,000 square feet and comprises laboratories, offices and manufacturing suites. LyFE has a flexible and modular design allowing us to produce plasmid, viral vector and T cell product to control and de-risk the sequence and timing of production of the major components of our supply chain related to our product candidates. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. We believe this capacity is sufficient to support our pipeline programs through pivotal trials and, if approved, early commercialization. We anticipate the facility to be cGMP qualified by the end of 2021.

### **Our Team**

The scientific and leadership team we have assembled comprise some of the foremost leaders in the fields of oncology and ACT. These thought leaders have each interrogated and elucidated the mechanisms of T cell biology and its interactions with cancer for decades and have authored over 1,000 publications focused on the interaction between the immune system and cancer. Our management team is comprised of experienced executives who come from academia and industry-leading cell and gene therapy companies including Atara, Juno Therapeutics and Sangamo; oncology therapeutic development companies including Amgen, AstraZeneca, Genentech, Incyte and Seagen; and cancer diagnostic companies including Genomic Health, GRAIL and Illumina. The core members of our scientific and leadership team include:

- **Dr. Rick Klausner.** We were founded in 2018 by Dr. Rick Klausner, former Director of the NCI, co-founder of Juno and GRAIL and whose lab in the 1980s isolated the critical components of the TCR that enabled the creation of CAR T cells. Dr. Klausner is our Executive Chairman. He is well known for his work in cell and molecular biology, immunology and human genetics, and has been the author of more than 300 scientific articles and several books, in addition to receiving numerous awards, honorary degrees and other honors. He oversaw the writing of The National Science Education Standards, the first such standards for U.S. Science

Education, and served as Liaison to the White House Office of Science & Technology Policy. He is a member of the National Academy of Sciences, the Institute of Medicine and the American Academy of Arts and Sciences.

- **Liz Homans.** Our CEO, Ms. Homans, brings over 30 years of strategy, product development and commercialization experience. She spent over a decade at Genentech in multiple divisions including global product development, regulatory operations and U.S. sales and marketing. She spent most of her Genentech career leading large complex oncology development programs from Phase 2 through completion of pivotal trials submission, approval and launch. She is also an experienced commercial leader having led the U.S. Xolair franchise through two years of double-digit growth. She completed her tenure at Genentech by managing the U.S. HER2+ breast cancer franchise. Ms. Homans also led global regulatory operations for Roche. Prior to Genentech she spent four years at Jazz Pharmaceuticals where she built the project leadership and portfolio strategy team, and she also has nearly a decade of business strategy consulting experience.
- **Dr. Nick Restifo.** Prior to joining Lyell as our Executive Vice President of Research, Dr. Restifo spent 31 years at the NCI with a sole focus on the development of immunotherapeutic treatments for patients with cancer. His contributions to the field include the molecular definition of the qualities of highly effective antitumor T cells; identification of the gene expression within tumors that is required for successful immunotherapy; and understanding the impact of host factors in cancer immunotherapy. His basic and clinical findings of how immune cells can destroy tumors have become mainstays of cell-based immunotherapies being used worldwide, documented in more than 340 publications and numerous book chapters on cancer immunotherapy.
- **Dr. Stan Riddell.** Dr. Riddell is a Founder of Lyell and Head of our R&D Executive Committee. He is also a Professor, Program in Immunology and the Immunotherapy Integrated Research Center at the Fred Hutchinson Cancer Research, Professor of Medicine at the University of Washington, Distinguished Affiliate Professor at the Technical University of Munich, and a cofounder of Juno Therapeutics. Dr. Riddell has designed multiple clinical trials of adoptive T cell therapy using unmodified and genetically modified T cells including the first trial of CD19 CAR modified T cells of defined subset composition, which formed the foundation for Liso-Cel, which is FDA approved for treatment of diffuse large B cell lymphoma. He has more than 225 publications and his research has contributed to understanding the role of human T cell subsets in protective immunity to pathogens and tumors.
- **Dr. Crystal Mackall.** Dr. Mackall, a Founder of Lyell, is the Ernest and Amelia Gallo Family Professor of Pediatrics and Medicine at Stanford University. She serves as Founding Director of the Stanford Center for Cancer Cell Therapy, Associate Director of Stanford Cancer Institute, Leader of the Cancer Immunology and Immunotherapy Program and Director of the Parker Institute for Cancer Immunotherapy at Stanford. During a 27-year tenure culminating as Chief of the Pediatric Oncology Branch, NCI, and now at Stanford, she has led an internationally recognized translational research program focused on immunoncology.

## Our Strategy

Our goal is to utilize our proprietary technology platforms to develop curative ACT for patients with solid tumors. Key components of our business strategy to achieve this goal include:

- **Leverage our two proprietary, cell reprogramming technology platforms to fundamentally improve T cell efficacy and eradicate solid tumors.** We seek to produce T cell therapies that eradicate solid tumors by addressing the major barriers to ACT efficacy, including overcoming exhaustion of T cells, establishing durable stemness and targeting cancer cells safely

and with high specificity. We are advancing two primary technology platforms for reprogramming T cells to be effective in eradicating tumors: Gen-R and Epi-R.

- **Rapidly advance our deep multi-modality pipeline of product candidates.** Our proprietary technology platforms are designed to be applied in a target and modality agnostic manner to CAR, TIL and TCR cell therapies. We believe our autologous T cell therapies will generate improved, durable clinical outcomes that are potentially curative for patients with solid tumors. We expect four IND submissions by the end of 2022 from our multi-modality product pipeline.
- **Continually innovate to develop and advance disruptive, next generation platform technologies for cell-based therapy.** We are committed to continuing to discover, develop and advance disruptive technologies that have the potential to revolutionize ACT and its promise to cure patients with solid tumors. For example, we believe our T cell rejuvenation platform technology may represent the next frontier of epigenetic reprogramming for cell-based therapy.
- **Establish proprietary state of the art manufacturing infrastructure and capabilities to control all aspects of cell product preparations.** We have and will continue to invest in manufacturing to mitigate the risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. Controlling manufacturing also enables us to protect proprietary aspects of Gen-R and Epi-R, and rapidly incorporate new innovations. We expect our multi-product manufacturing facility, which can produce plasmid, lentivirus and cells, to be cGMP qualified by the end of 2021.
- **Implement digital technologies and cloud solutions to accelerate and enhance our science and operations.** High-performance cloud computing, scalable cloud storage, robotic and artificial intelligence, coupled with our collaboration with Amazon Web Services (AWS), enable real time monitoring of our manufacturing process and deep insights from our research, manufacturing and future clinical development efforts. This approach is being leveraged to inform our next generation cell therapies.
- **Aggressively generate, secure and defend intellectual property on our differentiated technology platforms and product candidates.** We have developed and secured intellectual property, including know-how, through our internal research efforts, licensing agreements and collaborations. We rigorously analyze, file and protect our intellectual property.

## Background

### *The Third Wave of Medicine: Cells as Therapeutics*

We are at the beginning of the third wave of modern therapeutic innovation where researchers are exploring approaches to harness the power of living immune cells to treat disease. The first wave of therapeutic innovation started with the mastery of small molecule chemistry which created the pharmaceutical industry. The second wave of modern medicine began in the 1980s with the birth of biotechnology and was based on the ability to master the design and production of protein-based macromolecules.

With some notable exceptions, the first and second wave approaches have not been able to cure patients with late stage, metastatic cancer. We believe the third wave of innovation, one utilizing living immune cells, has the potential to deliver the promise of curative therapies for cancer patients with late-stage solid tumors. The recent development and approvals of T cells engineered with CARs targeting CD19 in B-cell hematologic cancers demonstrated that complete responses could be achieved in a significant percentage of late-stage patients with large treatment-refractory tumor burdens. That said, the promise of cell therapy has not proven to be reliable in solid tumors broadly, which represent over 90% of cancers.

We are pioneering the reprogramming of living cells to become therapeutic agents for solid tumors. We believe the key to the development of cell therapy is the mastery of the identity, fate and function of cells to create living medicines. Our goal is to create curative therapies for solid tumor patients, and we believe the utilization of living immune cells has the potential to deliver, consistently and reliably, on the promise of ACT.

### **Targeting Cancer Cells: ACT Modalities and Their Limited Efficacy Against Solid Tumors to Date**

Most of the activity in ACT for cancer has focused on ways to provide the requisite specificity of the T cells to cancer: identifying appropriate tumor-specific targets, evaluating their frequency on cancers versus healthy tissues, and evaluating the best ways to traffic immune cells to them and attack the cancer. There are three main modalities to achieve target specificity in ACT today: CARs, TCRs, and TILs, and unfortunately, with very few exceptions, they have not meaningfully improved clinical outcomes in patients suffering from solid tumor cancers.

- **CARs:** Chimeric antigen receptors are artificial cell surface receptors that are genetically engineered onto T cells and comprise an extracellular binding domain specific to a surface molecule on tumor cells. CARs are linked to an intracellular activation domain that turns the T cells “on” to kill target tumor cells when the antibody portion binds to the tumor cell target.

CAR-based ACT has shown efficacy in some cancers, including durable complete remissions. The greatest clinical benefit has been demonstrated in B cell malignancies where the adoptive transfer of autologous T cells engineered with a CAR targeting CD19 has been shown to induce complete remission in 40 – 90% of patients resulting in the approval of four CD19 CAR T cell therapies. However, CAR T cells have thus far demonstrated limited efficacy in solid tumors. Furthermore, the identification of targets with sufficient differential expression between tumor and normal tissues has limited the broader development of CAR T cell therapies in solid tumors.

- **TCRs:** T cell receptors are directed against fragments of intracellular proteins that are presented by the human leukocyte antigen (HLA) complex on the surface of target cells. T cells can be engineered with a cloned TCR that mono-specifically directs the T cell to recognize a neoantigen that arises from the tumor’s mutated proteins or to recognize an aberrant or overexpressed self-protein. TCRs specific for neoantigens have the advantage of being tumor specific, meaning that normal tissues do not express these neoantigens thereby reducing the risk of normal tissue toxicity.

TCR-based ACT has been utilized clinically to treat a limited number of cancers. Although there has been some clinical success in treating cancer patients with TCR-engineered T cell products, most patients infused with these cells do not experience durable, complete responses to therapy.

- **TILs:** Tumor infiltrating lymphocytes are T cells which have entered and reside within the tumor. They are polyclonal in nature, i.e. they are able to recognize multiple tumor neoantigens. A TIL-based ACT approach isolates and expands TILs from tumor masses and reinfuses the expanded cells into the patient. The polyclonality of TILs is a major advantage to address the heterogeneity and antigen loss challenges of solid tumors. As with TCRs, the risk of normal tissue toxicity is mitigated because the targets for these T cells are directed against neoantigens which arise from the accumulation of mutations in genes unique to the cancer.

While a handful of clinical trials, primarily academic, have demonstrated TILs may generate durable responses in certain tumor types such as melanoma, they have shown limited efficacy in patients with other prevalent solid tumor cancers. Regardless, most patients treated with TIL therapy do not respond to treatment, and most patients who do respond will eventually relapse.

## **Barriers to ACT Efficacy in Solid Tumors**

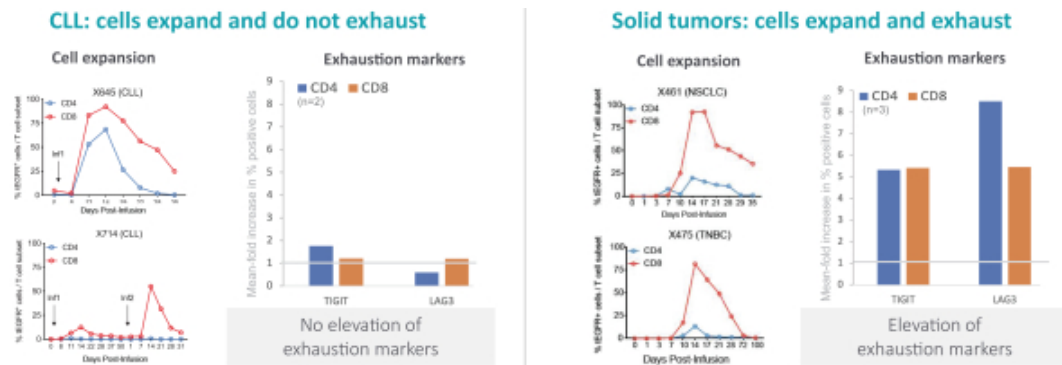
### *T Cell Exhaustion*

T cell exhaustion is a state of cell differentiation characterized by impairment of effector function, elevated expression of inhibitory receptors such as PD-1 (also an activation marker), LAG3, TIM-3 and TIGIT. T cells that recognize cancer cells or that respond to chronic infections such as those caused by human immunodeficiency virus and hepatitis viruses in humans and certain strains of lymphocytic choriomeningitis virus in mice frequently enter this state of exhaustion. Because T cell exhaustion is observed in tumor-specific T cells in most solid tumors, we believe this is a primary mechanism preventing T cells from eliminating cancer cells and presents a barrier for the effectiveness of ACT in solid tumors. Solid tumors have a more organized, immunosuppressive TME than hematologic cancers, which when combined with chronic antigen stimulation, drives tumor-reactive T cells to lose function and renders them incapable of tumor destruction. Animal model and clinical data demonstrate that adoptively transferring tumor-specific T cells, including CAR T cells, to treat solid tumors can result in the development of characteristic features of exhaustion in transferred T cells, including upregulation of inhibitory receptors, loss of effector function and the inability to proliferate, persist and eliminate the tumor.

It is now well established that CAR T cells can be effective in hematologic tumors, including ALL, NHL and MM. In a revealing clinical experiment performed by Fred Hutch in collaboration with our founder, Dr. Riddell, it was demonstrated that CAR T cells specific for ROR1 expressed on both solid tumors (NSCLC, TNBC) and a hematologic tumor, chronic lymphocytic leukemia (CLL), exhaust after administration to patients with these solid tumors but remain functional after administration to patients with CLL. Data from this clinical experiment with ROR1 CAR T cells in NSCLC, TNBC and CLL were reported. This experiment found that in two refractory CLL patients, the ROR1 positive tumor cells were eliminated, including one complete response. The elimination of ROR1 positive tumor cells was associated with the expansion of CAR T cells in the blood and accumulation of CAR T cells in the bone marrow. There was limited upregulation of inhibitory receptors associated with exhaustion on the CAR T cells expanding in the patient compared to the infusion product in the CLL patients. On the other hand, in the solid tumor patients, ROR1 CAR T cells only expanded in some patients. Isolation of these expanded T cells from the blood, showed that they had upregulated multiple inhibitory receptors, including PD-1, LAG3, TIM-3 and TIGIT, and lost the ability to produce cytokines such as IFN $\gamma$ , TNF $\alpha$  and GM-CSF upon restimulation *ex vivo* compared with CAR T cells in the infusion product and that they exhibited a transcriptional profile consistent with exhausted T cells. These findings are consistent with the development of T cell exhaustion, and antitumor activity was limited (one partial remission in 14 treated patients). At the CAR T cell doses administered, no toxicity to normal tissues was observed in patients with solid tumors or CLL (despite the high levels of active circulating ROR1 CAR T cells) in this experiment.

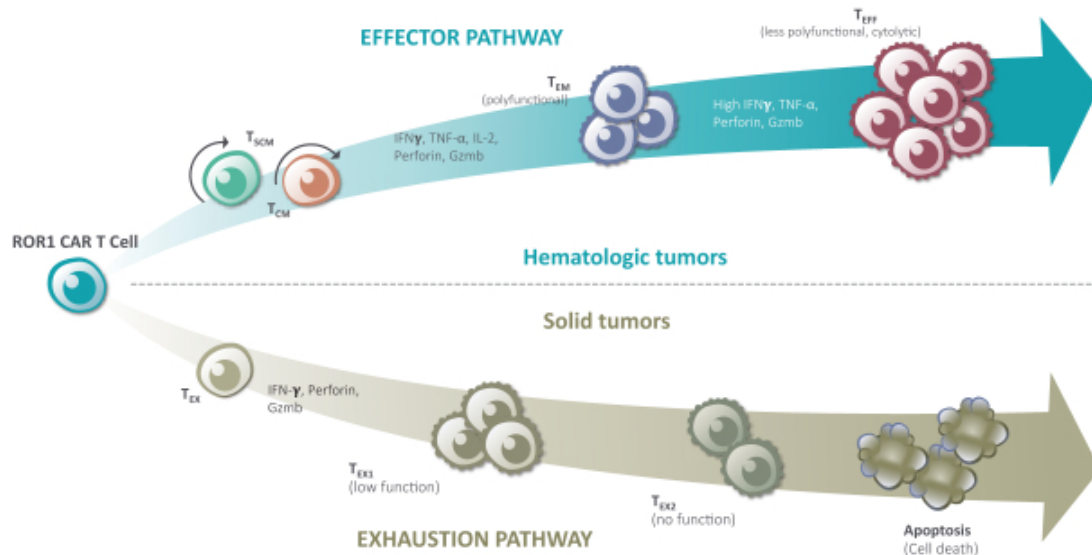
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*Figure 1: The same ROR1 CAR T cells exhaust in solid tumor patients but not in CLL patients. In both CLL and NSCLC/TNBC patients the CD4+ and CD8+ CAR T cells expand. The exhaustion markers TIGIT and LAG3 are greatly increased only in the solid tumor patients, suggest demonstrated loss of function of these exhausted cells.*



These findings indicated that whereas in a hematologic tumor CAR T cells differentiate along an effector pathway capable of eradicating cancer cells, in solid tumors the same CAR T cells differentiate along a distinct pathway leading to exhaustion, loss of function and lack of antitumor efficacy. By clinically testing the same CAR T cell, we conclude that the nature of the tumor (solid versus hematologic) is a major determinant of the fate of ACT T cells.

*Figure 2: In hematologic tumors, CAR T cells differentiate along the upper path towards functional effector cells, whereas in solid tumors, CAR T cells differentiate down the lower path into an exhausted state.*



**Lack of Stemness**

Patients with solid tumors can experience profound clinical responses to immunotherapy, albeit in a minority of cases. ACT and immune checkpoint blockade (ICB) both depend on the activities of T



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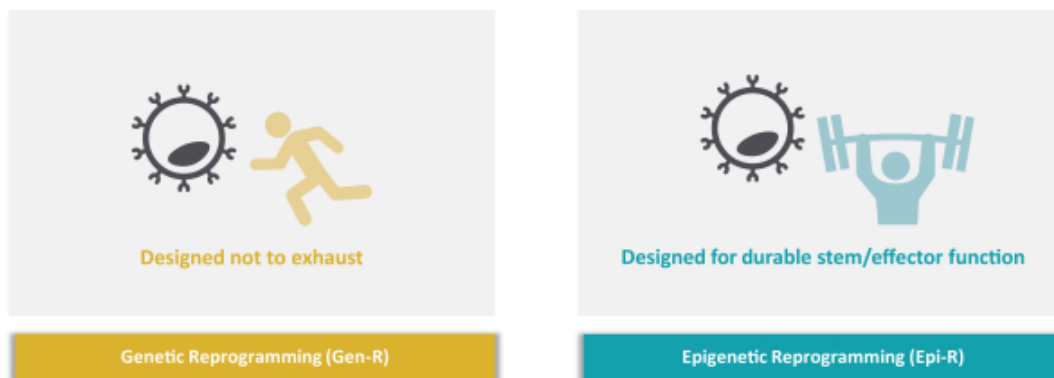
cells that react with neoantigens expressed by tumors. Until recently, the characteristics of clinically successful neoantigen-reactive T cells were unclear. However, researchers have recently identified T cell stemness – especially as driven by the hallmark transcription factor TCF7 – as a meaningful correlate of successful cancer immunotherapy in both ICB and ACT settings. Dr. Hacohen et. al. at the Broad Institute have correlated the presence of CD8<sup>+</sup> T cells expressing TCF7 predicted positive clinical outcomes to ICB. More recently, a study conducted by Drs. Steven Rosenberg and Sri Krishna at the NCI concluded that TIL-ACT responders exhibited a population of stem-like TILs positive for TCF7 in the infusion product. These data and others suggest that stem-like T cells capable of self-renewal, expansion and persistence are required for profound antitumor responses *in vivo*. Furthermore, they indicate an “active ingredient”: a component of the cell preparation that is responsible for the activity but only present in some preparations.

These clinical findings are consistent with our view of T cell development. Stem-like T cells are capable of self-renewal, expansion, persistence and superior antitumor response. These stem-like T cells also are capable of differentiation into effector states that are short-lived but required to kill cancer cells. However, effective, curative ACT must deliver a population of T cells with durable stemness, capable of continual self-renewal – generating more of themselves – while also generating progeny cells that can differentiate to polyfunctional effector cells.

Therefore, we seek to go beyond the clinical correlates of highly effective T cells to intentionally create cells with durable stemness, meaning that the living T cells have a quality which allows them to “durably” self-renew in the face of continued persistent signals from the tumor driving activation, proliferation and differentiation, and continue to do so *in vivo* until the cancer is eradicated. What durable stemness enables is that even with these persistent signals, the T cells do not lose their stem-like properties. We believe that a major barrier to effective solid tumor ACT is that most cell preparations *lack* this level of stemness. It is durable stemness which we believe will be required to address the burden of cancer in patients with solid tumors, and we aim to reliably and intentionally achieve durable stemness with our Epi-R technology.

### Our Technology Platforms

We have developed two technology platforms to address two major barriers to effective solid tumor ACT. Gen-R overcomes loss of T cell function attributable to an exhausted state, and Epi-R creates T cell populations with properties of durable stemness, while also maintaining polyclonality, an advantage of TIL ACT.



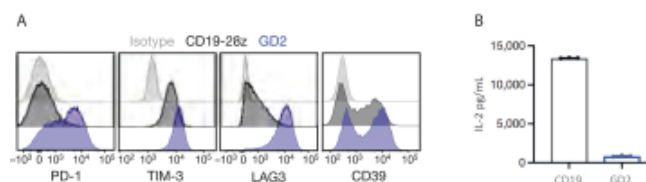
### Gen-R for Overcoming T Cell Exhaustion

T cell exhaustion is an important mechanism of ACT failure, illustrated by the inability of CAR T cells to treat solid tumors, as opposed to hematologic tumors. T cell exhaustion results from transcriptional and epigenetic changes that occur as T cells differentiate into a dysfunctional state. A strategy to prevent T cells from becoming exhausted would be ideal for improving the effectiveness of ACT against solid tumors. Our scientific co-founder Dr. Mackall identified such a strategy to utilize *ex vivo* genetic reprogramming to overcome the problem of T cell exhaustion.

Dr. Mackall demonstrated that genetically modifying T cells to overexpress the c-JUN protein prevented them from losing function. c-JUN combines with another protein, FOS, to form an AP1 protein complex. This protein complex works in cooperation with NFAT to direct the transcription of genes required for T cell effector function. Overexpression of c-JUN in CAR T cells restores their antitumor activity in preclinical solid tumor models where the same CAR T cells that do not overexpress c-JUN exhaust and fail to eliminate the tumor. We have further advanced the optimization, construct design, models and data related to Dr. Mackall's work, and as applied in our product candidates, we term the optimized overexpression of c-JUN our Gen-R technology.

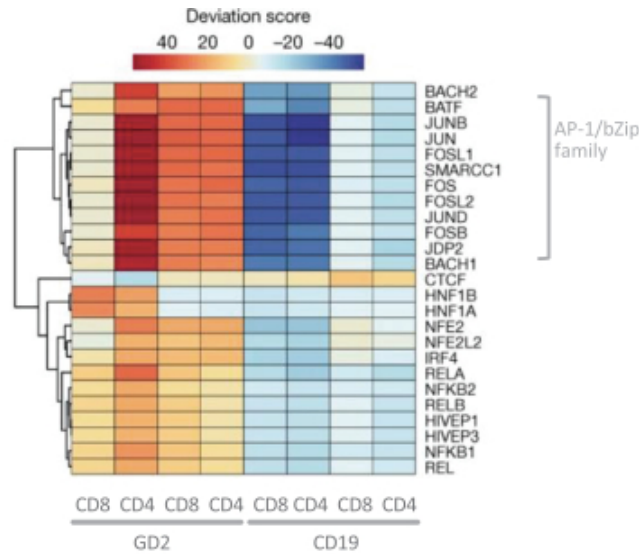
The discovery of Gen-R came from the realization that chronic stimulation of a T cell by an antigen (the T cell is always turned "on") combined with an immunosuppressive solid tumor TME likely promotes the development of T cell exhaustion. Dr. Mackall developed a GD2-targeted CAR T cell that is always turned on and quickly develops exhaustion. This model system drove the CAR T cells to have the hallmark phenotypic, functional, transcriptomic and epigenetic abnormalities described in cancer and chronic viral infections where T cells become exhausted. Compared to normal CD19-targeted CAR T cells that are not always "on," the GD2 CAR T cells demonstrated elevated expression of cell surface exhaustion-associated markers such as PD-1, TIM-3, LAG3 and CD39 (Panel A in Figure 3), and these T cells had decreased function as measured by secretion of IL-2 compared with T cells expressing the CD19 CAR (Panel B in Figure 3).

*Figure 3: The GD2 CAR T cell is a model for exhaustion. These T cells exhibit elevated expression of cell surface exhaustion-associated markers, including PD-1, TIM-3, LAG3 and CD39 (left). When compared to CD19 CAR T cells, which are not exhausted, the GD2 CAR T cells fail to produce IL-2, which is a characteristic of exhausted cells (right).*



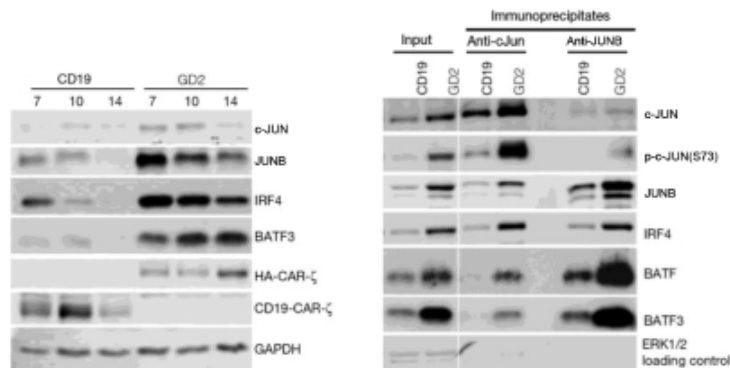
All T cell differentiation states, including exhaustion, are characterized by distinct chromatin structure (open versus closed). Generally, open chromatin structures allow for transcription factor binding while closed structures inhibit transcription factor binding. To determine if the GD2 model could enable the understanding of the biology of exhaustion, the GD2 and CD19 CAR T cells were examined for their chromatin structure to evaluate which transcription factor binding sites were accessible in the functional versus the exhausted states. The exhausted GD2 CAR T cells had a genome-wide restructuring of chromatin accessibility compared to the CD19 CAR T cells, and the greatest change was the increased availability of binding sites to the AP-1/ bZIP family and IRF4 transcription factors. These transcription factors include JUNB, JUND, BATF, BATF3, FOSL1, FOSL2 and IRF4.

Figure 4: Chromatin structure access of GD2 versus CD19 CAR T cells revealed increased access to AP-1 transcription factor binding sites, represented by red. This illustrated that the binding sites are more accessible to their transcription factors.



It is notable that c-JUN can bind directly to inhibitory bZIP members, potentially limiting its availability for binding to FOS, which is the necessary AP-1 complex for T cell effector function. Dr. Mackall then evaluated the levels of each of these transcription factors to see whether there were differences between CD19 and GD2 CAR T cells. What was seen was an increase in the level of several of these proteins including JUNB, BATF3 and IRF4 in GD2 CAR T cells compared to CD19 CAR T cells (Figure 5; Left panel). Furthermore, in the GD2 CAR T cells c-JUN was shown to be complexed with inhibitory factors such as JUNB, IRF4, BATF and BATF3 (Figure 5: Right panel). We believe these data are suggestive of reduced availability of c-JUN to bind to FOS (its activating partner) which is required for T cell activation.

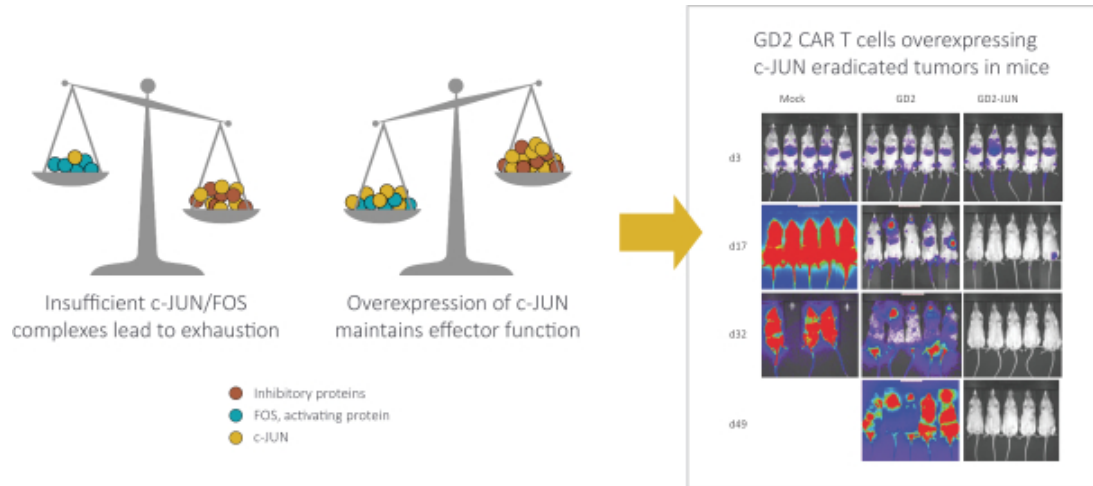
Figure 5: Left panel: inhibitory proteins that associate with c-JUN, including BATF, JUNB and IRF4 are increased in the exhausted GD2 versus CD19 CAR T cells. Right panel: in the exhausted GD2 cells, immunoprecipitation with c-JUN pulled down its inhibitory partners, demonstrating greater association of c-JUN with JUNB, IRF4, BATF and BATF3 in exhausted GD2 CAR T cells.



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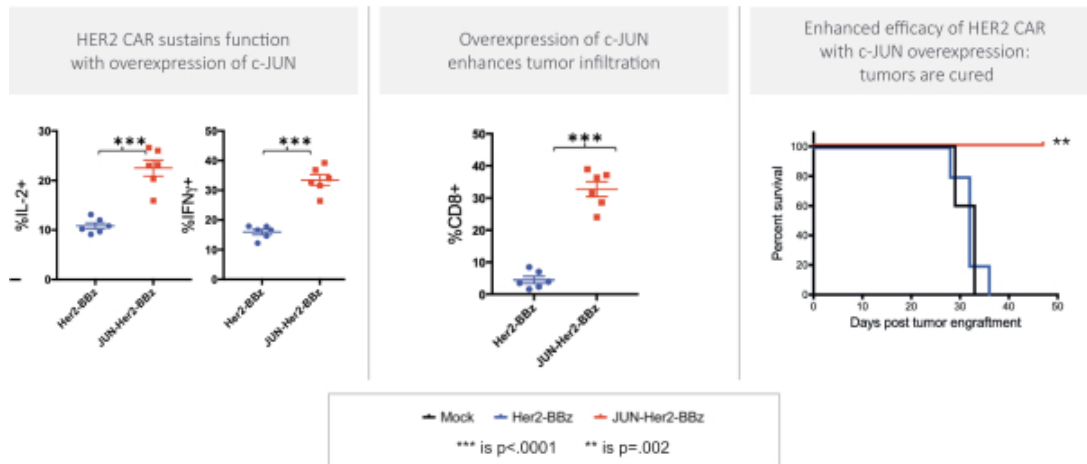
Dr. Mackall then hypothesized that overexpression of c-JUN in the GD2 CAR T cell, would enable the reconstitution of activating c-JUN/FOS heterodimers and shift the balance to activating versus suppressive protein complexes, and prevent the T cells from becoming exhausted. Indeed, overexpression of c-JUN in the GD2 CAR T cells led to tumor eradication *in vivo* in preclinical models as compared to the mice treated with GD2 CAR T cells that did not overexpress c-JUN. (Figure 6).

Figure 6: Left scale – in exhausted T cells, there is insufficient c-JUN to bind with FOS, because c-JUN is bound in overexpressed inhibitory complexes. Right scale – overexpression of c-JUN provides sufficient JUN protein to form activating c-JUN/FOS pairs, required for maintaining active T cell function. On the far right, *in vivo* models demonstrated only GD2 CAR T cells overexpressing c-JUN eradicated GD2<sup>+</sup> tumors, the GD2 CAR T cells lacking c-JUN failed to eliminate the tumors.



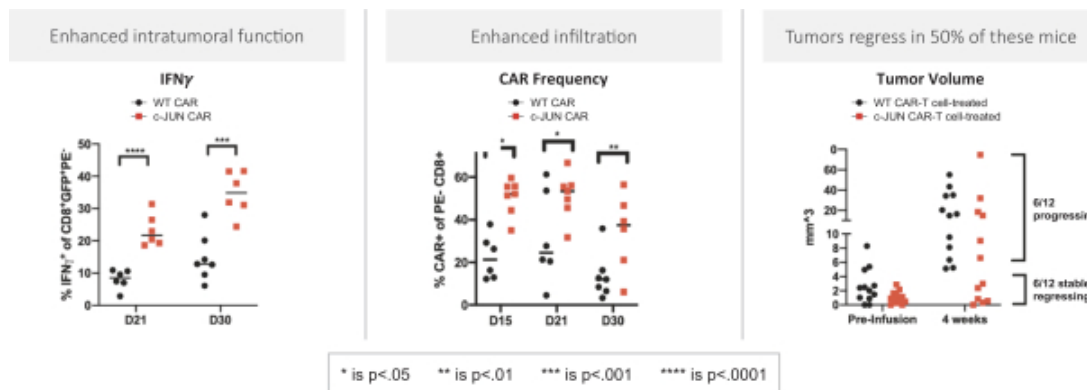
Dr. Mackall then investigated if the hypothesis would prove generalizable and be effective in solid tumor models where it was observed that the tumors caused the CAR T cells to exhaust. In a highly resistant human solid tumor model of osteogenic sarcoma in NSG mice, c-JUN overexpression augmented the antitumor activity of T cells engineered with a human epidermal growth factor receptor 2 (HER2) CAR whereas the control HER2 CAR T cells that function normally *in vitro* exhibited features of exhaustion *in vivo* and were ineffective in eradicating the tumor (Figure 7). Thus, the counter-exhaustion effect of c-JUN resulted in complete tumor eradication in contrast to the absence of efficacy in the mice treated with unmodified CAR T cells which exhausted. Importantly, this model recapitulates what is observed in human solid tumors, which demonstrates that T cells enter the tumors, exhaust and do not accumulate at the tumor site.

Figure 7: HER2 CAR T cells overexpressing c-JUN infiltrated into tumors, demonstrated higher T cell function and cured osteogenic sarcoma tumors in mice.



Dr. Riddell tested the hypothesis in another, even more rigorous solid tumor model of NSCLC. He utilized a mouse model which recapitulates the oncogenic driver mutations and immunosuppressive TME of human NSCLC. It has been difficult if not impossible to treat the tumors in these mice with chemotherapy or immunotherapy and this “model” is in all respects representative of murine NSCLC. This model was further designed so that the tumors express ROR1 and, perhaps not surprisingly proved to be resistant to therapy with ROR1 CAR T cells, just as was observed in treating human NSCLC with ROR1 CAR T cells. In contrast, tumor-bearing mice treated with ROR1 CAR T cells that overexpressed c-JUN demonstrated greater infiltration by the T cells into the tumor, enhanced function of those T cells and tumor regression in 50% of the mice, further confirming the results obtained by Dr. Mackall in HER2 and other cancer models. These results are in contrast to the 100% tumor progression observed in mice treated with ROR1 CAR without overexpression of c-JUN. (Figure 8). Once again, this model illustrated that when T cells enter solid tumors, they exhaust and become ineffective unless the T cells resist exhaustion with Gen-R.

Figure 8: ROR1 CAR T cell overexpressing c-JUN demonstrated efficacy in mice with NSCLC



In summary, Gen-R demonstrated improved CAR T cell function and antitumor efficacy in multiple models of T cell therapy for solid tumors using human and murine T cells. These data show that

preventing exhaustion with Gen-R can result in improved and sustained infiltration of functional T cells at the tumor site and supports the clinical translation of Gen-R for CAR T cell therapy of human solid tumors. We are poised to test Gen-R in our ROR1 (LYL797) and NY-ESO-1 clinical ACT programs in a number of solid tumor indications.

### ***Epi-R: Reprogramming Cells to Create Durable Stemness***

Emerging research has made clear that a key requirement of effective cellular immunotherapy is the presence of a population of T cells with specific characteristics of stemness as well as activation of effector functions to produce clinical responses. The frequency of this T cell population correlates with responses to cancer immunotherapy, including TIL ACT and ICB therapy.

Epi-R is our *ex vivo* epigenetic reprogramming technology designed to generate populations of T cells which have the properties of durable stemness. Durable stemness describes the ability of a population of T cells to maintain the sustained ability to self-renew and proliferate, even after being subjected to demands of activation and proliferation upon encountering target antigens expressed by tumor cells. In other words, we believe that a population of T cells with durable stemness are continually replenished, allowing them to generate all memory and effector T cell differentiation states that are required for meaningful long-term clinical responses.

We believe our scientists have been able to intentionally and reproducibly produce T cell populations with durable stemness using Epi-R. The resulting Epi-R T cell populations have *in vitro* and preclinical *in vivo* properties which suggest that they are significantly more potent than those generated by standard approaches to manufacturing T cells for ACT. Standard approaches likely generate ill-defined mixes of cells in various states of differentiation, most of which lack the properties to be effective against solid tumors. To be curative, we believe T cells with durable stemness properties are needed.

Our work has built upon the groundbreaking science of Dr. Restifo spanning over thirty years at the NCI, and then actuated by him and his colleagues at Lyell. We believe that we can reliably produce a population of T cells that have the requisite properties to be effective against tumor cells, that can be characterized by genomic, proteomic and transcriptomic features, and that may ultimately be responsible for clinical effectiveness in ACT. These T cells have enhanced proliferative capacities, as well as ability to engraft, persist and destroy tumor masses. Our ultimate goal is to characterize, identify, optimize and consistently produce these cells through our proprietary Epi-R technology, which comprises a protocol involving proprietary media, and well-defined cell activation and expansion protocols. We expect to develop other versions of the protocol in the future to further advance this technology.

Epi-R triggers metabolic pathways that cause T cells to have properties of durable stemness. The origins of Epi-R came from Dr. Restifo's work at the NCI, where he demonstrated that T cells grown in media with high concentrations of potassium were more stem-like and functional. These were the first clues that it might be possible to reprogram cells to be more stem-like and functional. In fact, Dr. Restifo and his team were able to demonstrate that cells grown with high potassium in the media were 40-100x more potent *in vivo* against established tumors compared with controls. They also demonstrated significantly enhanced abilities to infiltrate tumors, with tumor-infiltrating T cells exhibiting enhanced resistance to exhaustion as measured by markers such as TIM3. This work demonstrated that the high potassium resulted in changes in the epigenome of the T cells and that this epigenetic reprogramming was likely responsible for the persistence of functional changes in the T cell population, even after return to standard media or infusion *in vivo*.

At Lyell, Dr. Restifo and his team have continued the work and have further advanced and optimized these epigenetic reprogramming strategies to produce the Epi-R T cell populations with the

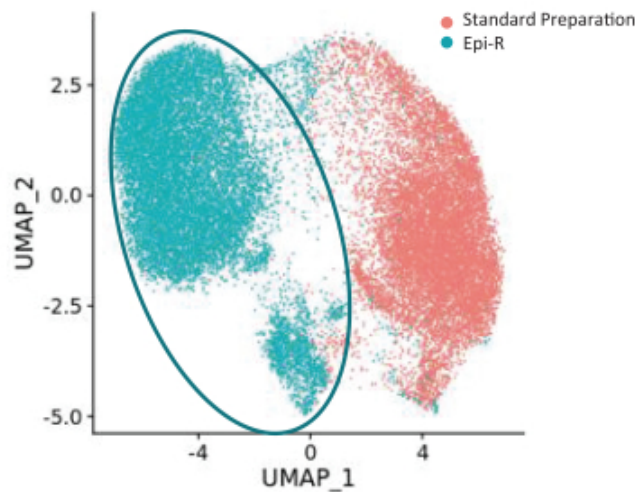
properties we seek, measured both phenotypically and functionally. We have expanded beyond Dr. Restifo's work at the NCI on hyperkalemia to execute multivariate, high dimensional experiments that improve upon what was previously published to create Epi-R protocols. Most importantly, in addition to elevated potassium, we have extensively reformulated the media, and optimized cytokines, growth factors, activation methods and other components related to cell culture, activation and expansion. These modifications were required to optimize phenotypic and *in vitro* and *in vivo* functions of the resulting T cell populations. In addition, we have advanced these research scale efforts and developed clinical scale production capabilities for Epi-R.

#### Creating Epi-R T cell populations

Epi-R creates populations of cells with phenotypic and *in vitro* and *in vivo* functional properties that we believe are needed for effective ACT. In single cell genome-wide RNA-Seq gene expression analysis, unsupervised clustering of single cells similar to each other reveal that Epi-R T cell populations have a distinct transcriptional profile when compared to the T cells found in a Standard Preparation (Figure 9). Standard Preparation, as used throughout this document refers to a typical cell preparation that includes TransAct beads, OpTmizer media and IL-2, IL-7 and IL-15 cytokines.

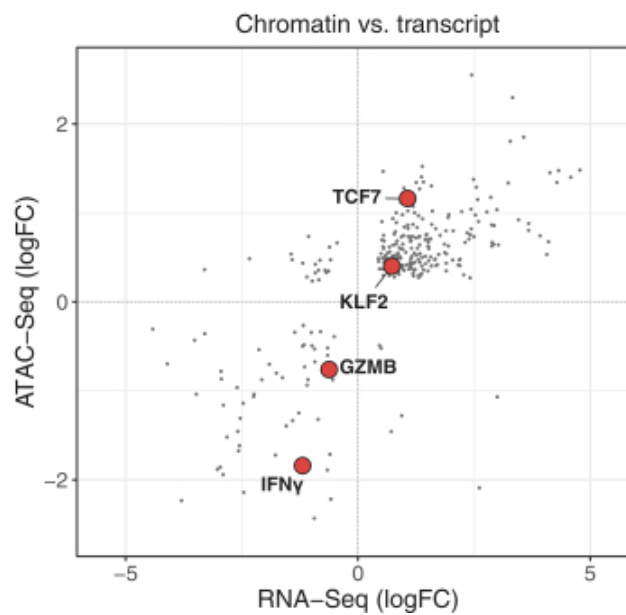
Figure 9:  
*Epi-R treatment generated T cells with a unique transcriptional profile. Each dot represents a single cell whose complex gene expression profile has been compressed to two dimensions; the teal population are cells treated with Epi-R and they exhibit a distinct gene expression profile from Standard Preparation, plotted in salmon color. Note that there is minimal intermingling of teal and salmon cell populations. UMAP=Uniform Manifold Approximation and Projection for Dimension Reduction.*

Global gene expression analysis demonstrates distinct gene expression profile of Epi-R expanded cells vs. Standard Preparation



The transcriptomic changes are associated with alterations of chromatin structures and the quantitative changes in transcription can be correlated with similar fold-change alterations in gene-specific chromatin accessibility as determined by ATAC-seq (Assay for Transposase-Accessible Chromatin using sequencing). Increased chromatin accessibility can be correlated with increased gene expression; conversely decreased chromatin accessibility can be associated with decreased gene expression. We observed that there was increased chromatin accessibility and gene transcription of stemness-associated genes including TCF7 and KLF2. Conversely, there was decreased accessibility and gene expression of hallmark effector genes such as IFN $\gamma$  and GZMB for effector-function priming. The increases and decreases in chromatin accessibility and gene expression are consistent with observations that Epi-R programs cells for stemness rather than immediate effector function (Figure 10).

*Figure 10: Epi-R treatment promoted chromatin accessibility and expression of genes associated with T cell stemness (for example, TCF7 and KLF2) and reduced expression of genes associated with effector differentiation (for example, GZMB and IFN $\gamma$ ). The impact of Epi-R treatment on chromatin accessibility (as profiled by ATAC-Seq) and gene expression (as measured by RNA-sequencing) as compared with Standard Preparation was measured. Individual genes with positive x-axis values have increased expression after Epi-R treatment, while genes with negative x-axis values have decreased expression. Genes with positive y-axis values have increased chromatin accessibility after Epi-R treatment compared with Standard Preparation, while genes with negative y-axis values have reduced chromatin accessibility after Epi-R. These changes are in accordance with the T cell properties that we seek.*



When we analyzed the gene expression of the Epi-R T cells together as a population, we showed that their epigenetic reprogramming resulted in an enrichment of the Wnt signaling pathway genes which functionalize stemness, as well as effector memory gene expression. This approach results in populations of cells that have the stemness we are looking for and cells that have a strong signature of tissue resident effector memory cells, in contrast to the populations produced by Standard Preparation. As stated above, recent literature supports the presence of such stem-like cells correlating with responsiveness to immune therapies, including ICB and ACT, which noted that patients who respond



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to ICB have a unique signature of endogenous TIL. The single cell RNAseq data showed a unique CD8<sup>+</sup> gene signature associated with memory, activation and cell survival in patients who respond to ICB. In addition, the literature supports the notion that stem-like CD8<sup>+</sup> T cells correlate with efficacy of ACT in human melanoma. Specifically, the expression levels of the genes encoding CD27, KLF2, TCF7, LEF1, IL7R and SELL predict effectiveness of ACT in solid tumors.

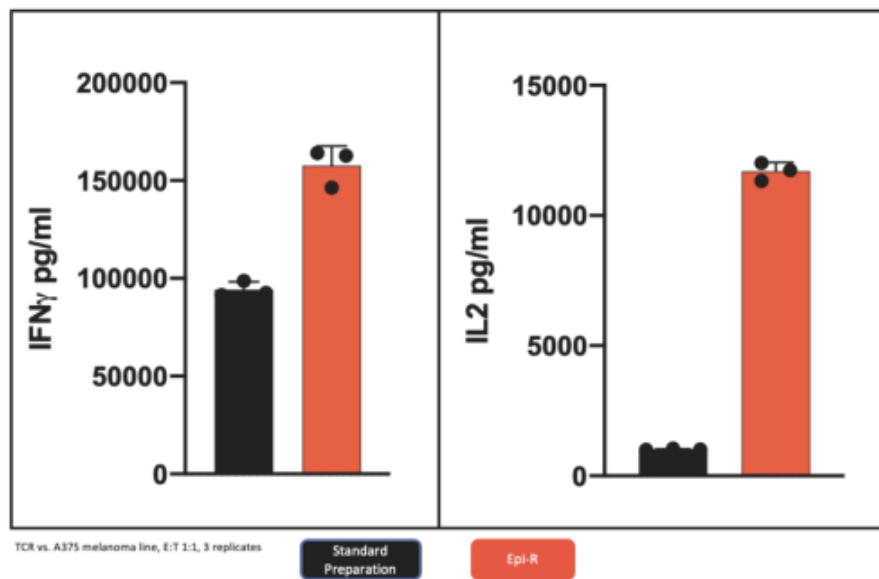
The T cell molecular signatures and genes reported in these correlative studies closely resemble the gene signatures seen in our Epi-R T cell populations and are selectively highlighted by red arrows in the volcano plots below. Each volcano plot illustrates the ratio of gene expression of Epi-R T cells versus those expanded in the Standard Preparation, plotted on a log scale which means that the difference in distance between data points are much smaller than if they were plotted on a linear scale. What is illustrated by the fact that all of the genes of interest are on one side of each respective volcano plot, the Epi-R side, showing that the genes of interest are uniformly expressed at greater levels in Epi-R T cells. These similarities suggest that with Epi-R, we are able to intentionally produce cell populations with the qualities predicted to be the “active ingredient” cells in immunotherapy that drive efficacy.

*Figure 11: Enhanced expression of T cell stemness and effector memory related genes in Epi-R treated T cells. Gene transcriptional profiling demonstrated that Epi-R T cells had increased expression of genes in the Wnt signaling pathway (a key promoter of T cell stemness, left panel) and of effector memory associated genes (key drivers of antitumor function, right panel). These findings are consistent with the recent literature and our own data indicating that T cell populations of stem-like T cells are responsible for ACT response.*



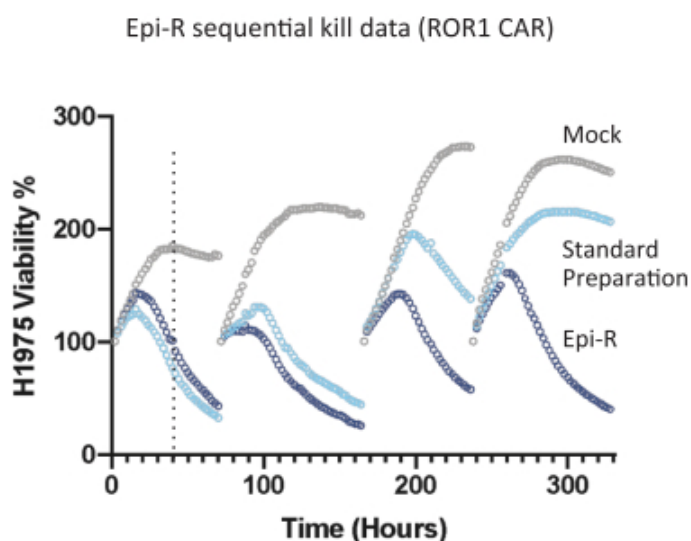
When Epi-R T cells are activated, they secrete cytokines required for tumor reactivity in significantly higher amounts versus Standard Preparation. IFN $\gamma$  and IL-2 cytokine secretion by Epi-R T cells indicate greater effector activity and polyfunctionality, required for antitumor activity (Figure 12).

Figure 12: Epi-R produced T cell populations exhibited greater effector activity and polyfunctionality, as measured by increased production and secretion of cytokines required for effective antitumor activity. T cells were co-cultured with target antigen-expressing tumor cell lines and T cell production of IFN $\gamma$  and IL-2 was measured in co-culture media.



Epi-R T cell populations resist the exhaustion of repetitive signaling which otherwise limits efficacy against solid tumors. We observed that Epi-R T cell populations maintain significantly greater ability to eliminate target tumor cells *in vitro* after multiple sequential exposures to tumor cells. They appear to “remember” their reprogramming and ability to kill tumor cells. In this experiment, cells were initially reprogrammed and expanded in Epi-R, and then transferred to Standard Preparation for the re-stimulation assay, which was repeated four times with consistent cell numbers. A low number on the y-axis indicates that the tumor cells are being killed. Epi-R T cells continued to kill tumor cells with sustained efficacy while by the third restimulation mock and Standard Preparation cells had exhausted and lost their ability to kill cells.

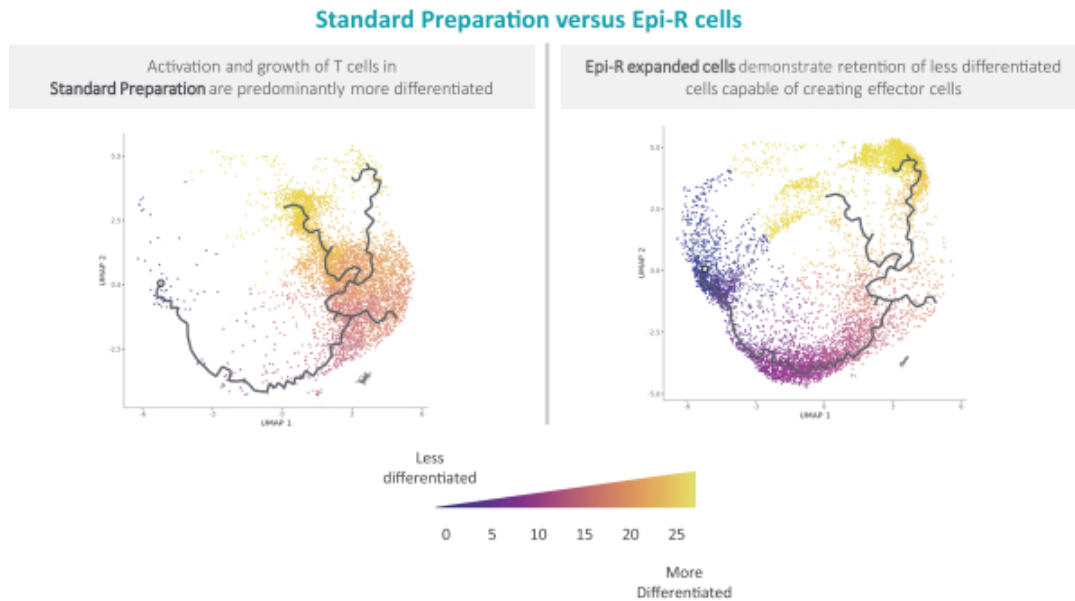
Figure 13: Epi-R produced T cells with enhanced long-term tumor killing potency. In a sequential restimulation assay, where T cells were repeatedly exposed to new tumors cells *in vitro*, Epi-R increased the ability of T cells to kill fresh additions of tumor cells over time (the dark blue dots show that tumor cells (the H1975 cell line) were killed even as the control and T cells grown in Standard Preparation conditions lost their ability after the second and third stimulations).



In addition to the sequential restimulation assay described above, which tested for a given population of T cells' continued ability to kill cancer cells on multiple exposures without controlling the T cell to tumor ratio, we also performed experiments where we serially restimulated T cells by adding new cancer cells while resetting the ratio of T cells to cancer cells to 1:1 at each stimulation. This latter assay tested for each individual T cells' potency against cancer cells over multiple rounds of exposure. These cells must also resist exhaustion and maintain their stemness in order to be effective. We performed a serial restimulation assay on cloned TCR T cells in Epi-R conditions, and then utilized trajectory analyses in order to illustrate the "durable stemness" of the T cell populations. In our definition of durable stemness, we posit that a T cell population can continue to both re-populate the stem cell population and differentiate to produce effector cells, even after prolonged and repetitive challenges with tumor cells. Based on the changes that we have observed between Epi-R T cells and T cells generated using Standard Preparation, we sought to understand what have become known as 'cell trajectories.' We know that T cells transition from one epigenetic state to another in response to stimuli, including recognition of tumor cells. Single cell RNA-Seq can enable the visualization of T cell transition states but to do so we must utilize machine learning algorithms to determine gene expression changes that occur in 'pseudotime,' a measure of how much progress an individual cell has made during its differentiation.

Pseudotime cell trajectories revealed an abundance of less-differentiated stem-like CD8<sup>+</sup> T cells even after repetitive stimulation with tumor cells under Standard Preparation using T cells previously expanded in Epi-R, whereas the growth of T cells previously expanded in Standard Preparation were predominantly more differentiated. The characteristics of resultant effector cells were also different, with Epi-R T cells generating effector cells resembling highly cytotoxic cells best able to engage in effector function.

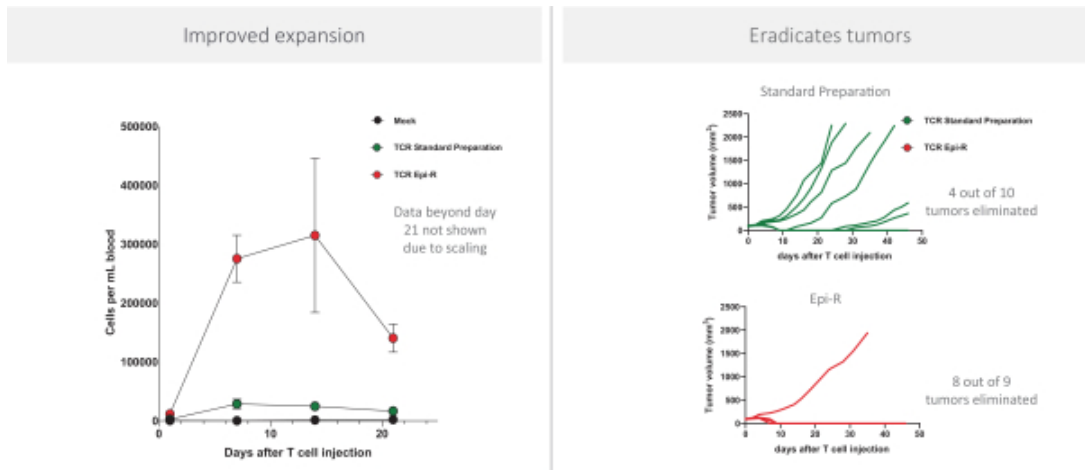
Figure 14: To understand the maturational differences in the reactions of T cells to tumor after having been programmed in Epi-R or Standard Preparation. T cells were placed in Standard Preparation and serially re-exposed to tumor cells every 3-4 days (x4) for 14 days (336 hours). We then used machine learning to create unsupervised cell trajectories using cells derived from both Epi-R T cells and T cells expanded in Standard Preparation then plotted the cell trajectories. The resulting Epi-R T cells were less differentiated and more functional than T cells generated from the Standard Preparation.



The greater functional activity of Epi-R T cell populations translated to enhanced activity in *in vivo* mouse antitumor experiments. The Epi-R T cell populations had superior expansion *in vivo* mouse models. We measured the number of T cells in the mice at various time points and observed as many as 50-fold more Epi-R T cells in the mice as compared to Standard Preparation T cells. Furthermore, in this experiment, treating mice with established tumors, the Epi-R T cells eradicated tumors in 8 out of 9 mice versus eradication in only 4 out of 10 mice treated with standard T cell preparations after 40 days. It is important to note that these Epi-R T cells were taken out of Epi-R conditions and injected *in vivo*, and by expanding and killing tumors over time, they are “remembering” their new properties after the *in vitro* epigenetic reprogramming.

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Figure 15: Epi-R T cells had improved expansion in vivo as shown in the left panel and had greatly improved antitumor function in mouse models of cancer, as shown on the right. Epi-R T cells eliminated tumors in 8 out of 9 treated mice (note overlapping red lines in Epi-R tumor killing along the x-axis), compared to 4 out of 10 mice treated with Standard Preparation T cells.

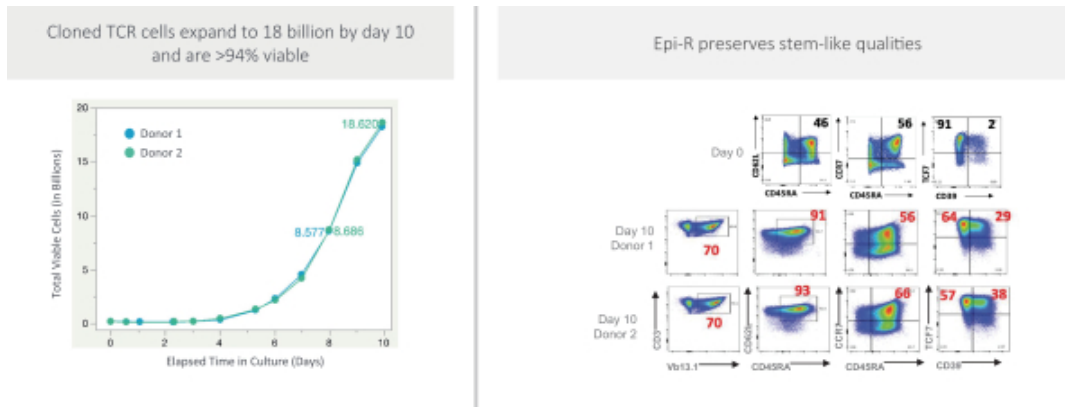


*Epi-R and Addressing the Expansion/Quality Paradox*

To treat patients, ACT needs to be produced at clinical scale, which means that the cells can be expanded to hundreds of millions of cells in the case of CAR, and billions of cells in the case of TCR and TIL based on current approaches. Typically, the more the cells expand during manufacturing, the worse the properties of the resulting cells, particularly their stem-like phenotype. We refer to this as the Expansion/Quality Paradox, and the ability solve this paradox could greatly improve the quality and reduce the time and expense of manufacturing ACT.

With Epi-R, we believe that we can generate engineered TCR cells to clinical scale with the desired phenotype and function. We show below that we expanded TCR cells up to 18 billion by day 10, which exceeds currently administered clinical doses; in addition, these cells are >94% viable. Furthermore, these cells maintained their stem-like qualities. (Figure 16)

Figure 16: representative data shows that engineered TCRs expanded to the billions and maintained their stemness in Epi-R.



*Epi-R applied to TILs*

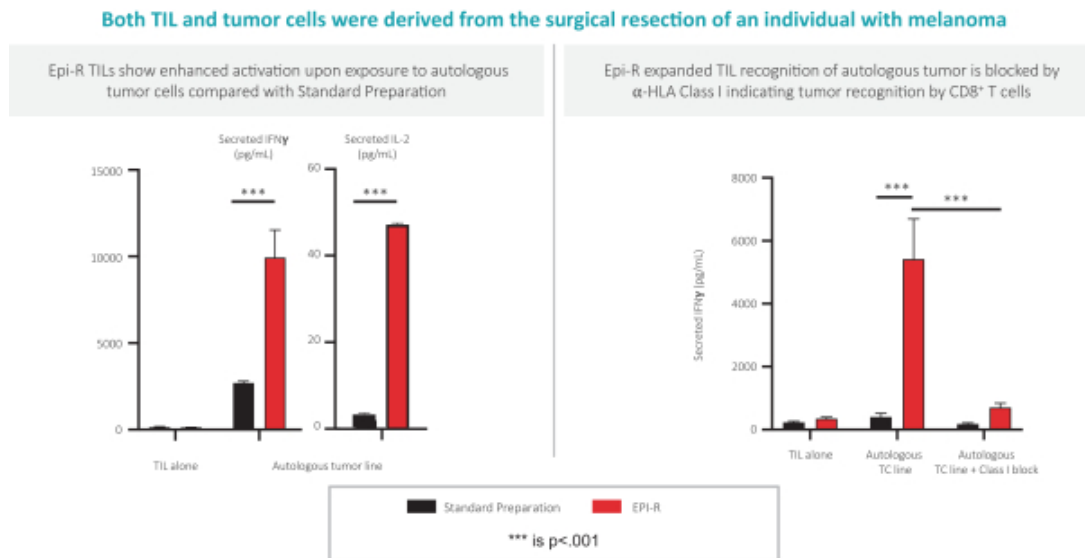
TIL ACT has been shown to be curative in a minority of cases of melanoma and occasionally in other cancers, demonstrating their potential in the treatment of solid tumors. We believe TILs have the potential to be more broadly and reliably effective against many tumor histologies, and that we can address the following requirements for TIL to achieve its potential as highly effective therapy against solid tumors.

- First, the infused TIL cells must have the property of durable stemness and be able to differentiate into effector cells for function, which we believe we achieve with Epi-R and have demonstrated with autologous *in vitro* experiments.
- Second, TIL must maintain their polyclonality during expansion, and preserve their ability to target a diversity of tumor neoantigens. Current standard TIL expansion causes a significant loss of TCR diversity, leading to skewed preparations with reduced clonotype representation. We have demonstrated that Epi-R can preserve the polyclonality of TIL preparations; for example, Epi-R T cells have ~30x more representation of the top dominant tumor TCRs in an autologous TIL experiment from a colon tumor.
- Third, stem-like and highly diverse TIL must be reliably extracted and expanded from multiple histologies. Specialized skills are required for this; while many have been able to consistently extract and expand TIL from melanoma specimens, other tissue histologies have proven more challenging. Our scientists are highly experienced in this art, and we have successfully extracted and expanded Epi-R TIL from melanoma, colorectal, NSCLC, pancreatic, renal cell, breast, prostate and liver cancers with a 95% success rate. This capability facilitates clinical trial designs that test our TIL product candidates in multiple solid tumor histologies.
- Finally, we must be able to expand TIL cell preparations to clinical scale, while maintaining their stem-like and clonally diverse properties. We have been able to expand, at clinical scale in the lab, TIL cell preparations to 13 billion cells (a clinically relevant dose) while maintaining their stem-like properties.

*Epi-R TIL cell preparations reacted to autologous tumors and eradicated them*

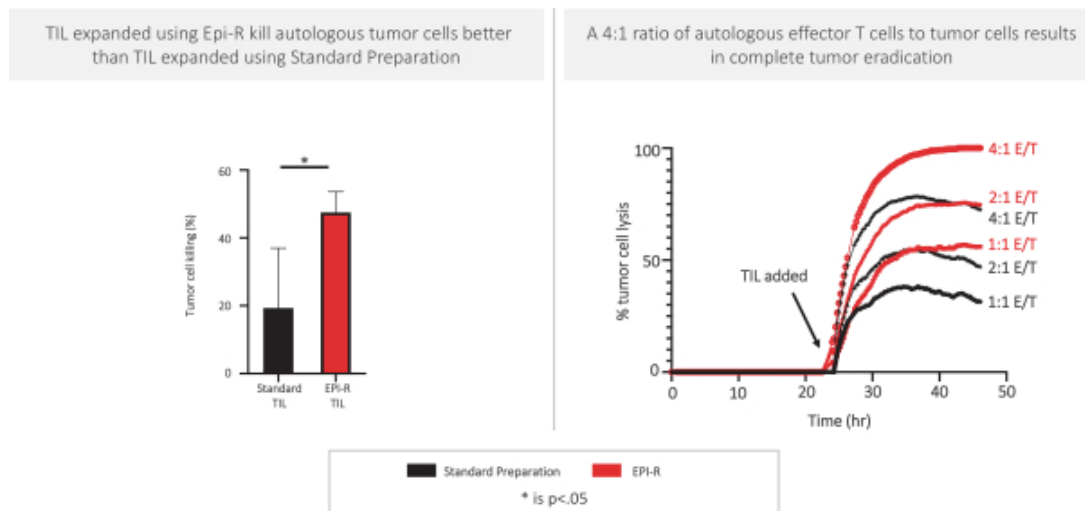
We performed experiments to evaluate Epi-R expanded TIL recognition of *autologous* melanoma cancer cells. We took a patient melanoma tumor excision, and both extracted and expanded TIL from that specimen in either Standard Preparation or Epi-R, as well as created a cancer cell line from the cancer cells from the tumor. By doing so, we could evaluate whether the expanded TIL from that tumor recognized and reacted to *that patient's own tumor*. We were able to demonstrate that Epi-R TIL exhibited enhanced activation, the response was mediated by activated killer CD8<sup>+</sup> cells, and they had significantly enhanced tumor cell killing capacity when compared to Standard Preparation. The higher secretion of IL-2, the critical T cell growth factor, is notable.

Figure 17: Epi-R TIL had enhanced recognition and activity against autologous melanoma tumor cell line. Asterisks denote significant  $p$ -values between groups. The red bars in the graph on the left show that Epi-R T cells from TIL secreted increased levels of IFN $\gamma$  and IL-2 cytokines as compared to Standard Preparation after co-culture with autologous melanoma tumor cells, indicating greater activation and cytotoxicity potential. As a control, when TIL alone were measured without the presence of autologous tumor cells, they did not activate and did not secrete the cytokines. In the bar chart on the right, we demonstrate that production of IFN $\gamma$  secretion dropped significantly when target cells were coated with an antibody to HLA Class I, indicating that the tumor cell recognition was mediated by CD8 $^+$  T cells.



These cells were also shown to be more effective at tumor cell killing. In the graph below on the left, we show that Epi-R TIL T cells killed autologous tumor cells at approximately a 50% rate, whereas those TIL grown in Standard Preparation only killed at approximately a 20% rate. When we then performed an experiment to titrate different levels of Epi-R effector T cells against tumor cells, we showed, on the right graph below, that a 4:1 effector T cell to tumor cell ratio resulted in complete tumor eradication.

Figure 18: Epi-R TIL had improved ability to kill autologous tumor cells. Standard and Epi-R TIL were co-cultured with autologous melanoma tumor cells and their ability to kill tumor was measured after 24 hours (left panel). Altering the ratio of TIL:tumor cells (E/T ratio) can impact TIL ability to kill tumor. Epi-R TIL exhibited increased tumor killing at all E/T ratios, and at a 4:1 ratio Epi-R TIL successfully killed all tumor cells.

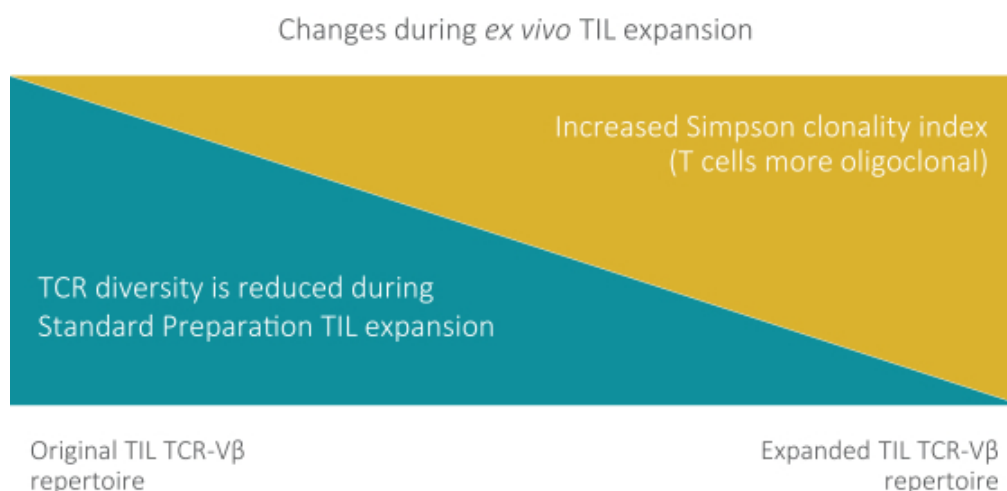


### Epi-R and retention of polyclonality

Epi-R has also demonstrated the ability to preserve the polyclonality of TIL preparations, one of the key advantages of this ACT modality. The figure below depicts a conceptual representation of what happens during typical TIL expansion in standard preparations: the expansion protocols result in loss of tumor-specific clones and significantly reduces the polyclonality of the cell preparations. We have shown with Epi-R that we can maintain the clonal diversity in TIL preparations with respect to the original repertoire of the TIL when first extracted out of the tumor.



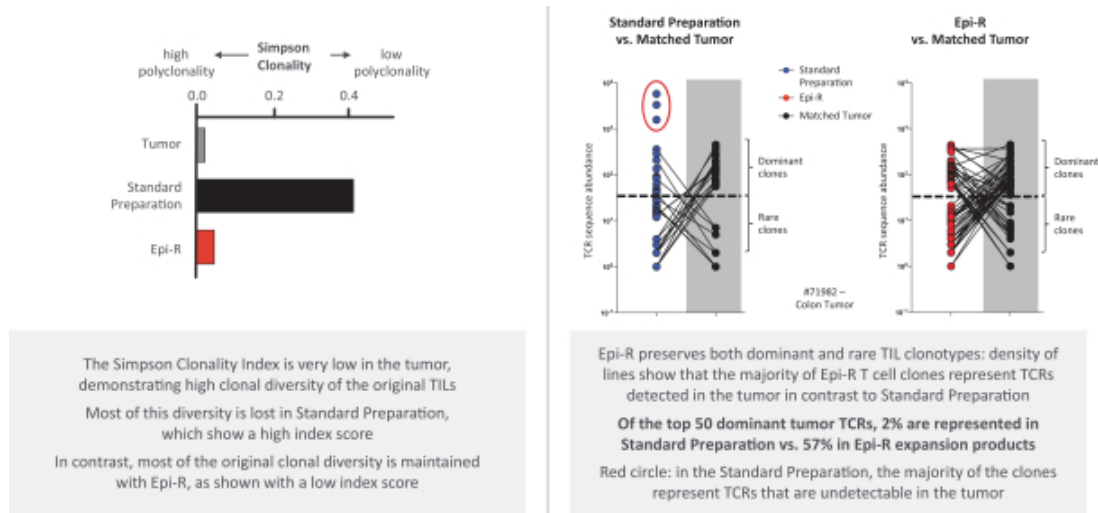
Figure 19: Standard TIL expansion preparations result in progressive loss of T cell polyclonality, resulting in reduced ability to recognize and respond to many tumor antigens. Epi-R preserves TIL polyclonality, increasing the ability of cell products to recognize and destroy tumor cells.



Quantitatively, we can measure polyclonality by the Simpson Diversity Index (or, in our use, the Simpson Clonality Index), shown below on the left (Figure 20). The Simpson Clonality Index is a quantitative tool that reflects diversity within a dataset; a low number represents high diversity, while a high number represents low diversity. An index value of 1 would represent a monoclonal population. The Simpson Clonality Index of TIL in the tumor is very low, demonstrating high clonal diversity of the original TILs. In standard TIL preparations, the majority of clones giving rise to the desired clonal diversity are lost upon stimulation and expansion as shown by the high Simpson Clonality Index. In contrast, most of the original tumor clonal diversity is maintained in TIL expanded with Epi-R, as shown with a low index score.

It is known that T cells migrating through tissues experience arrested migration upon recognition of their target tumor antigen, resulting in their activation and expansion, which is followed by their exhaustion. We quantified the TCRs from TILs and ranked them by the frequency of the clonotypes found. We compared the frequencies of individual TCRs after expansion in Standard Preparation or Epi-R conditions. On the right in the graph below, we show that Epi-R preserved both dominant and rare TIL clonotypes found amplified in the tumor; 57% of the TCR V $\beta$  sequences corresponded to the top 50 TCRs represented in the original TIL. By sharp contrast, only 2% of the TCR clonotypes expanded in the Standard Preparation were represented in the top 50 TCRs found in TIL.

Figure 20: Epi-R TIL exhibited increased T cell polyclonality and retention of original T cell clones. TCR sequencing was performed on Standard Preparation and Epi-R TIL and Simpson Clonality Index (a measure of polyclonality, with high Simpson values indicating low polyclonality) was measured. Epi-R TIL exhibited a low Simpson Clonality Index (left panel) that reflects increased diversity of T cell TCR repertoire. The relative abundance of TCRs that were observed in starting tumor T cell population was compared with standard and Epi-R expanded TILs. Epi-R TILs retained greater proportions of starting TCR repertoire after expansion.



We can further demonstrate that preserved polyclonality of the Epi-R preparations are specific to tumor neoantigens by counting the numbers of productive TCR rearrangements. In one study of TIL from a pancreatic cancer, we modeled predicted KRAS mutant-reactive T cells and evaluated the ability of Standard Preparation versus Epi-R expanded TILs to preserve KRAS mutant reactivity. KRAS is one of the most common and important mutations in human cancer, present in NSCLC, pancreatic, colorectal and other cancers. We observed that only Epi-R expanded TILs had all predicted KRAS mutant reactive clones present, indicating that those TILs preserved a broader TCR repertoire that is more reflective of the clonal diversity of T cells found in tumor; in other words, the more varied clonotypes of the TIL preparations were specific to predicted cancer neoantigens. In contrast, TILs expanded in Standard Preparation led to the loss of the tumor specific TCR clonotypes; in fact, the zeroes in the Standard Preparation column indicate that there are no T cells which can detect these predicted KRAS neoantigens (Figure 21).

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Figure 21: Epi-R expanded T cells contained increased proportions of TCRs predicted to recognize hotspot KRAS tumor driver mutations. In contrast, Standard Preparation TILs did not retain these tumor target-reactive TCRs.

AMINO ACID	SUM (Productive Frequency)	PRESENT IN	Standard Preparation	EPI-R	70703-TUMOR_TCRB
CASSLGTDTQYF	0.000273449	3	2.85193E-05	0.000215095	2.98347E-05
CASSRGLGNTIYF	0.000316628	2	0	0.000286793	2.98347E-05
CASSQNYGYTF	5.37341E-05	2	0	2.38994E-05	2.98347E-05
CASSLVGTEAFF	0.000286635	2	0	0.000167296	0.000119339
CASSLRGTEAFF	0.001272605	2	0	0.00124277	2.98347E-05
CASSGDSYGYTF	5.37341E-05	2	0	2.38994E-05	2.98347E-05
CASGETQYF	5.37341E-05	2	0	2.38994E-05	2.98347E-05

### Epi-R Summary

Our Epi-R technology allows us to generate T cell therapy products that retain increased characteristics of stemness that have been clinically linked with effective antitumor immunotherapies. These qualities preserve stemness while also enhancing the functional ability of our cells to recognize and destroy tumor cells, what we term durable stemness. Epi-R fine-tunes the chromatin structure of the T cells which results in a new transcriptional profiles of T cells to yield a novel cell population that is distinct from those produced by standard expansion processes, with increased expression of a distinct population of cells expressing key genes linked with T cell engraftment, expansion, *in vivo* persistence and function. Trajectory analyses of Epi-R T cell populations demonstrate that both stem-like and effector populations are maintained in the face of persistent activation, proliferation and multiple cycles of tumor killing, supporting a durable ability to self-renew. As predicted, clinical scale production of Epi-R cells show that they maintain all of these properties, thus addressing one of the challenges in ACT product production – how to maintain functionality of T cells during expansion. Our Epi-R T cell populations have increased durable functionality against tumors *in vitro* and *in vivo*, with increased ability to eradicate established tumors in realistic animal models of human cancer. Applying Epi-R to TIL expansion, we have been able to generate TIL products that exhibit increased polyclonality and retention of key TCR clonotypes in cells grown to clinically meaningful numbers. Our Epi-R TIL are able to effectively recognize and respond to autologous tumor cell lines by secreting key inflammatory cytokines and displaying increased ability to kill cancer on a per-cell basis. In utilizing Epi-R to create T cells with the qualities associated with clinical antitumor effectiveness, we believe that we have generated an opportunity to eradicate solid cancers.

### The Next Frontier: Epigenetic Rejuvenation of T Cells

We believe that Epi-R – the epigenetic reprogramming of T cells to create Epi-R cell populations with durable stemness – holds great potential. However, new science is emerging that provides insight into additional opportunities to capture the potential of T cells enhanced with the required properties to cure cancer. We can think of two cellular parameters as cells develop and differentiate over the life of an organism: cellular identity and age. The decline in function with aging is stereotypical in many cells; it has been well characterized in T cells. Aging of adult stem cells is thought to play a central role in determining the effect of aging on organismal function. Each T cell clonotype can be renewed from a stem cell-like state, but self-renewal, proliferation, function, persistence and antitumor activity are thought to be impacted by aging. We and others have documented the impact of aging on T cell function, which begins to decline after puberty, and at an increasingly accelerated rate after age 65. Morbidity and mortality from cancer also increases with age.

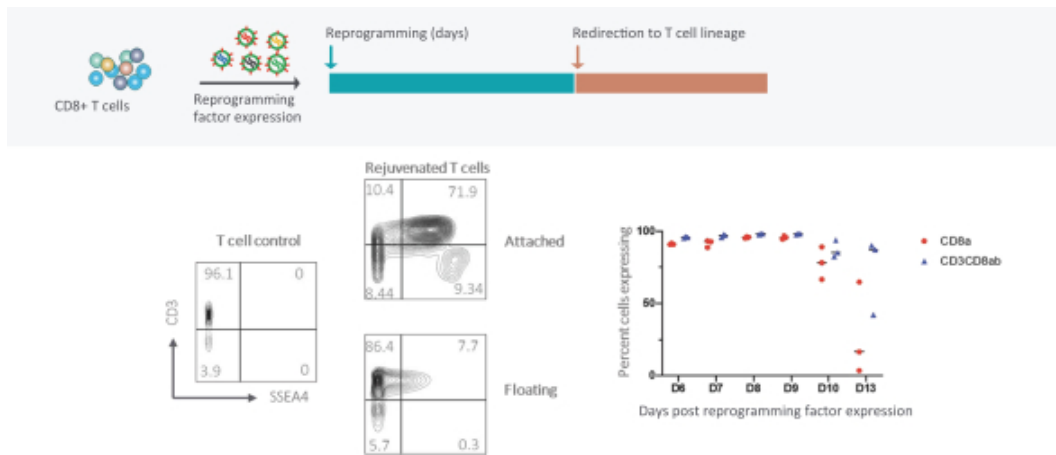
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We therefore sought to rejuvenate antitumor T cells. The most transformative examples of cell reprogramming have been demonstrated by Shinya Yamanaka, who proved through his Nobel Prize-winning work the ability to reprogram and dedifferentiate somatic cells into induced pluripotent stem cells utilizing four transcription factors (OCT3/4, SOX2, KLF4 and c-MYC; or OSKM), termed the Yamanaka factors. These factors regulate the developmental signaling network necessary for embryonic cell pluripotency. These iPSCs are remarkable in two ways: they are fully de-differentiated and they are rejuvenated to age zero, the age of cells immediately post-fertilization.

Recently, numerous labs have made a leap in cellular reprogramming, called partial reprogramming. By carefully controlling cell exposure to OSKM, scientists have been able to retain the functionality of cells while avoiding the impacts of aging. Rejuvenation can be measured by the reacquisition of youthful properties like enhanced stem cell proliferation and by newly discovered molecular clocks, which measure the intrinsic cellular epigenetic changes associated with aging. These intrinsic 'clocks' can be measured by DNA methylation patterns. We have early data for the first time with T cells illustrating the ability to "turn back" the epigenetic clock in a process called cell rejuvenation, without changing the cell's identity as would occur in de-differentiation. This cell rejuvenation process utilizes transient expression of OSKM, and/or other reprogramming factors.

Our data illustrates that when we express the reprogramming factors in a T cell population for a prolonged amount of time, T cells lose their identity and start to acquire markers associated with mesenchymal and embryonic stem cells. During this process, cells acquire the expression of stage-specific embryonic antigen-4 (SSEA-4) and begin to attach to the cell culture substrate. We are developing a method to revert the initial changes caused by reprogramming to regenerate T cell identity while reducing the epigenetic age of the cells.

*Figure 22: CD8<sup>+</sup> T cells were isolated from a normal donor and transiently exposed to reprogramming factors. Transient exposure to reprogramming factors enabled a change of behavior of cells – which included attachment to the cell culture substrate and the expression of SSEA-4. Cells retained expression of T cell lineage markers if the redirection step is started before approximately 9 days; longer exposure to classical iPSC reprogramming resulted in loss of cell identity as measured by the inability to recover hallmark cell identity markers CD8 and CD3.*

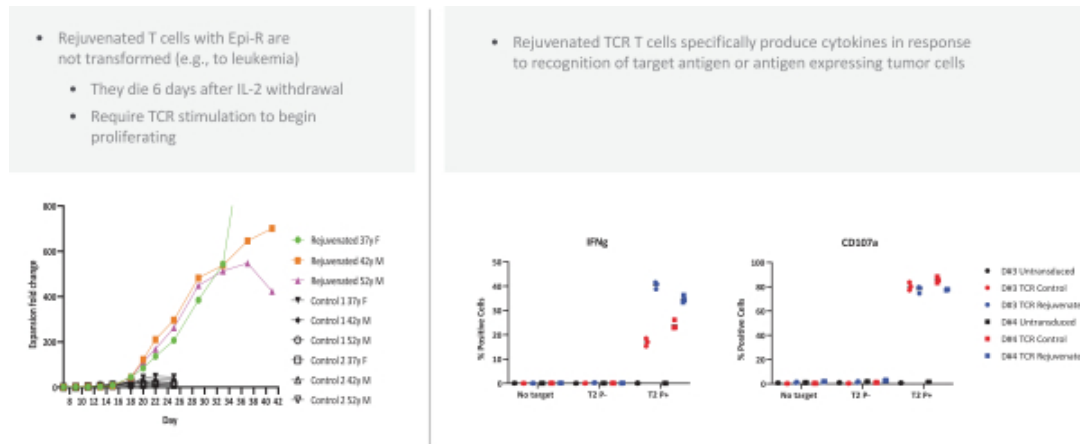


When the age of these cells were measured with the epigenetic clock, we observed that treating donor cells from individuals aged 21 and 43 (and the epigenetic clock measurement is consistent with

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the donor information) with transient expression of reprogramming factors, resulted in rejuvenated cell populations with clock measurements of 9-16 year-olds. These treated cells exhibit markedly enhanced and sustained proliferation *in vitro* and recognize tumor antigen. They retain their T cell identity and are not transformed; specifically, they are not proliferating uncontrollably as cancer cells do, and they require typical T cell activating signals such as IL-2 and TCR stimulation. Upon such stimulation, they behave as T cells and produce the expected cytokines in response to cancer antigen or antigen-expressing tumor cells.

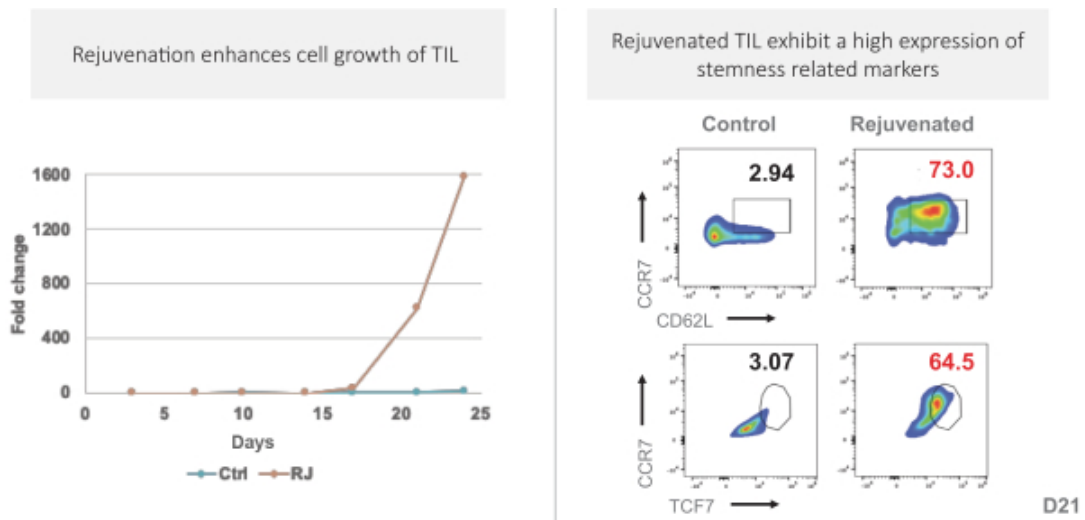
Figure 23: Partially reprogrammed T cells were rejuvenated, showing marked proliferation while retaining T cell identity and exhibiting enhanced function



We have also performed experiments involving the rejuvenation of TILs. Rejuvenation on TILs extracted from solid tumors shows dramatic improvements in cell growth and increases in the populations of T cells expressing stemness-associated markers such as CD62L, CCR7 and TCF7, which are closely associated with better and prolonged antitumor activity.

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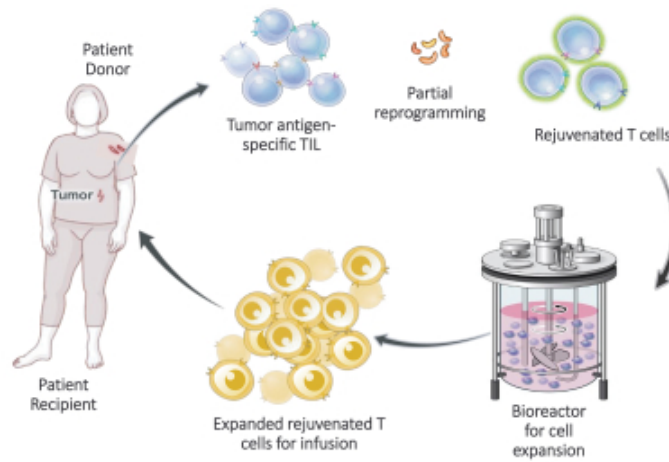
Figure 24: Rejuvenation of lung TILs of a 66-year-old patient. When compared to control conditions, cells exposed to reprogramming factors showed enhanced proliferative capacity and expression of cell phenotypes expressing CCR7, CD62L and TCF7, hallmarks of T cell populations with stem-like properties.



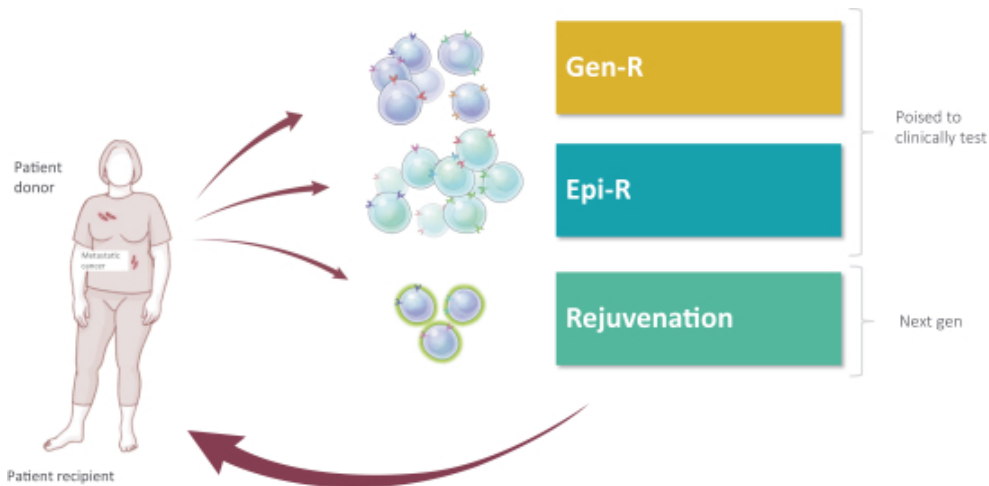
We believe T cell rejuvenation has the potential to be the next disruptive technology in cell-based therapy. Rejuvenated cells would be epigenetically younger and have higher proliferative potential and stemness properties. In the setting of tumor treatment using CAR, TCR-transduced, or naturally occurring TILs, T cells may have the ability to engraft and destroy solid tumors long term. Although T cell rejuvenation offers a revolutionary path to new treatments in the area of cancer, we believe that in the longer-term, this technology has potential application in non-oncology indications such as autoimmune and infectious diseases.

Building upon our work with Epi-R cell populations, we expect that the future production for next generation TIL could involve a partial reprogramming step, as illustrated in Figure 25.

Figure 25: potential next generation ACT including cell rejuvenation



**Summary: Our Technology Platforms**










We are a T cell reprogramming company focused on the goal of curing solid tumors. We are poised to advance four programs to the clinic across multiple modalities, targets and indications with both our Gen-R and Epi-R technology platforms beginning in 2022, and have next generation efforts ongoing in cell rejuvenation.

**Our Programs**

The application of our platform has generated several promising living cell product candidates across multiple ACT modalities in a wide range of solid tumor settings. We are utilizing our Gen-R and Epi-R technology platforms to develop a multi-modality product pipeline with four IND submissions expected by the end of 2022. Each of our programs provide opportunities to expand into additional

indications beyond the patient populations we are initially targeting. Our product candidates are summarized in the table below:

	TECHNOLOGY	TARGET	COMMERCIAL RIGHTS	INDICATION	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT MILESTONE
CAR	Gen-R & Epi-R	ROR-1 (LYL797)		<ul style="list-style-type: none"> <li>• NSCLC</li> <li>• TNBC</li> <li>• Other solid tumors</li> </ul>					Submit IND in Q1 2022
TIL	Epi-R	Polyclonal (LYL845)		<ul style="list-style-type: none"> <li>• Multiple solid tumor histologies</li> </ul>					Submit IND in 2H 2022
TCR	Gen-R	NY-ESO-1*		<ul style="list-style-type: none"> <li>• Synovial sarcoma</li> <li>• Other solid tumors</li> </ul>					Submit INDs in 1H 2022
	Epi-R								

\* Our collaborator, GlaxoSmithKline (GSK), is developing an NY-ESO-1 TCR T cell product candidate, currently in pivotal development. While we are currently evaluating Gen-R and Epi-R in separate preclinical programs for this product candidate, together these programs could represent a single future product opportunity for GSK utilizing one or both of our technology platforms.

**LYL797: Our CAR T Cell Program Targeting ROR1 in Multiple Solid Tumors**

We are applying our Gen-R and Epi-R technology platforms to our lead CAR program, LYL797, which is expected to be an IV administered CAR T cell product candidate targeting ROR1 with a single-chain variable fragment derived from rabbit anti-R12 antibody that recognizes and binds to ROR1 and a proprietary optimized EGFRopt safety switch. We are initially developing LYL797 for the treatment of ROR1+ NSCLC and TNBC. ROR1 expression is associated with poor prognosis and significant subsets of patients with common cancers express ROR1, including TNBC (~60%) and NSCLC (~40%), two of the highest ROR1 expressing indications. If successful, we anticipate expanding into other ROR1+ cancers with a lower incidence of ROR1 expression, including HR+ breast cancer, ovarian cancer and other solid tumors. We expect to submit an IND for LYL797 in the first quarter of 2022.

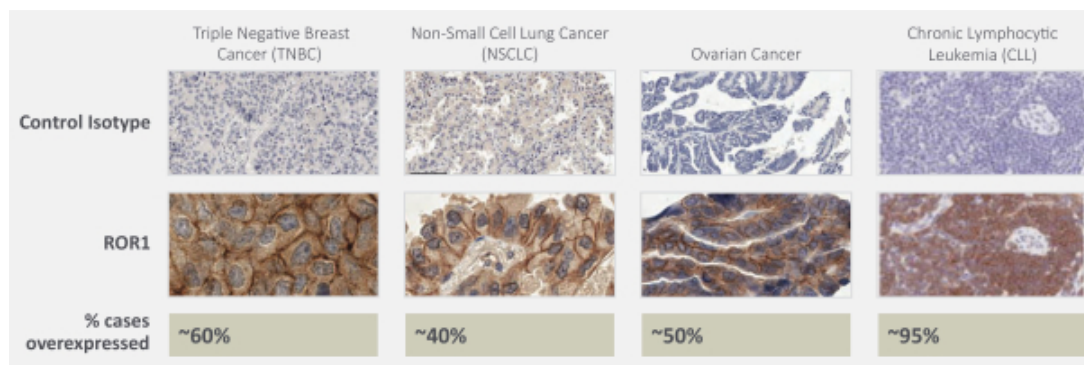
*Rationale for ROR1*

We have selected ROR1 as our initial target because it is highly expressed in certain solid tumor types and clinical data has been generated using ROR1 CAR T cells that demonstrate exhaustion and thus serve as a good vehicle to test our Gen-R technology. Data from multiple third-party clinical trials of ROR1 targeted therapies in hematologic and solid tumor cancers suggest that targeting ROR1 at currently evaluated dose levels was well tolerated with no on-target, off-tumor toxicity observed despite ROR1 expression in a number of normal tissues.

Figure 26 below shows pathological immunohistochemistry (IHC) staining of ROR1 in TNBC, NSCLC, ovarian cancer and CLL against control, and the approximate epidemiological frequencies of ROR1 overexpression. This pattern of ROR1 overexpression provided an opportunity to test a ROR1 CAR in both solid and hematological cancers to observe the impact of these different tumors on the T cells.



Figure 26: IHC staining of ROR1



### Background on Target Indications

Patients with solid tumors, including TNBC, NSCLC, ovarian cancer or HR+ breast cancer often face a poor prognosis and low rates of long-term survival. Although patients may benefit initially from radiation therapy, chemotherapy, surgery and more advanced alternatives such as ICB, immunotherapies or targeted therapies, most patients eventually relapse. After becoming resistant to initial lines of therapy, patients are limited to palliative care, experimental therapies in clinical trials, or chemotherapy regimens that often highly toxic and largely ineffective. Patients are further challenged by high rates of late-stage diagnosis, when tumors have metastasized. Despite recent advances in therapeutic development, for most patients diagnosed with solid tumors, a significant unmet medical need exists and long-term survival rates remain low.

#### Triple Negative Breast Cancer

Breast cancer is the second most common cancer in American women. Currently, the average risk for a woman in the United States to develop breast cancer is approximately 13%. The American Cancer Society estimates that about 43,600 women will die from breast cancer in the United States in 2021. Breast cancers that demonstrate the absence of estrogen receptor and progesterone receptor and no overexpression of HER2 are referred to as TNBC. Approximately 10-15% of patients with breast cancer have TNBC and TN status tends to be more common in women younger than age 40, who are African-American, or who have a BRCA1 mutation. In the United States, approximately 135,000 women suffered from TNBC in 2017 and the incidence rate was estimated to be 13.2 per 100,000 women. TNBCs present a high tendency to metastasize and patients are at a higher risk to relapse compared to other molecular types. TNBC differs from other types of invasive breast cancer in that they grow and spread faster, have limited treatment options, and a worse prognosis. Once TNBC has spread to distant parts of the body, the 5-year survival rate is only 11.5%. ROR1 is overexpressed in approximately 57% of patients with TNBC and ROR1 expression is correlated with poorer outcomes.

#### Non-Small Cell Lung Carcinoma

Lung cancer is the second most common cancer and is the leading cause of cancer mortality worldwide. It is estimated that 135,720 (72,500 men and 63,220 women) deaths from this disease occurred in 2020. NSCLC, defined as any type of epithelial lung cancer other than small-cell lung carcinoma (SCLC), accounts for about 84% of all lung cancers. In 2016, the incidence of NSCLC varied widely, ranging from 3 to 57 per 100,000 in Africa and North America respectively, with ~2 million cases diagnosed globally. For people with localized NSCLC, the overall 5-year survival rate is ~61%. For regional NSCLC, the 5-year survival rate is ~35%. Based on current data, when cancer metastasizes, the 5-year survival rate is 6%. ROR1 is overexpressed in approximately 42% of patients with NSCLC adenocarcinomas.

### Ovarian Cancer

Ovarian cancer is one of the most common gynecologic malignancies in women worldwide. Although ovarian cancer accounts for only ~4% of cancers in women worldwide, it is the eighth most common cause of cancer death, resulting in greater than 150,000 deaths per year, or ~4% of all cancer deaths. In the United States, approximately 235,000 women suffered from ovarian cancer in 2017 and the incidence rate was estimated to be 11.2 per 100,000 women. Only 30% of advanced stage ovarian cancer patients survive for five years after initial diagnosis and the majority of cases are detected in later stages. Late stage diagnosis is due in part to the largely asymptomatic nature of early stage disease and a lack of effective screening methods, coupled with the tumor's inherent aggressive biology. ROR1 is overexpressed in approximately 50% of patients with ovarian cancer.

### HR+ Breast Cancer

Breast cancer is categorized into subtypes based on the presence or absence of molecular markers for estrogen or progesterone receptors and HER2. Breast cancers that test positive for estrogen receptors, progesterone receptors, or both are HR+ breast cancers, with most cases testing positive for estrogen receptors. HR+ breast cancers account for the most common molecular subtypes of breast cancer, including Luminal A (HR+/HER2-) and Luminal B (HR+/HER2+), which together represent ~78% of all breast cancers. Luminal A is the most common type of breast cancer, representing ~68% of all breast cancer cases and tends to be slower-growing and less aggressive than other subtypes. In the United States, HR+ breast Cancer has an incidence rate of 100.3 per 100,000 women and it was estimated in 2017 that approximately 1,030,243 and 145,805 women had Luminal A and Luminal B breast cancer, respectively. Although prognosis for early stages is favorable, 5-year survival rates fall significantly in later stages. Once HR+ breast Cancer has spread to distant parts of the body, the 5-year survival rate is only 30.4% and 43.5% for Luminal A and Luminal B breast cancer, respectively. ROR1 is overexpressed in approximately 12% of patients with HR+ breast cancer.

### Additional Indications

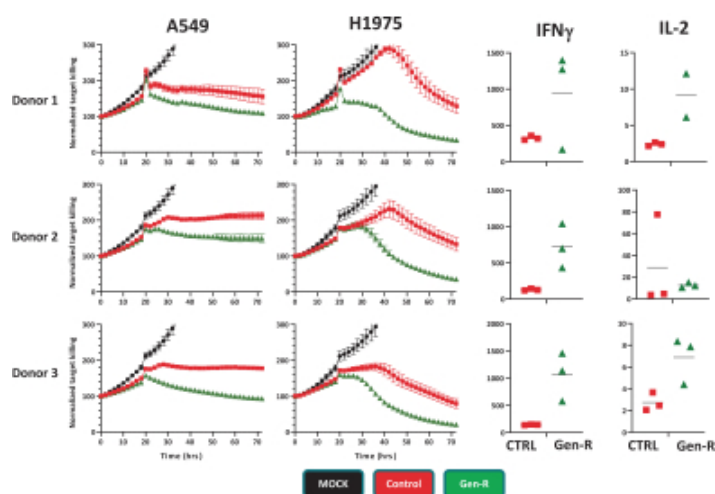
ROR1 has been reported to be expressed in many other solid tumors beyond breast, lung and ovarian, including prostate, stomach, endometrial and pancreatic, providing multiple opportunities for indication expansion. Many of these indications are unaddressed or under-addressed with currently approved therapeutics; further, patients with ROR1 expression tend to experience poorer outcomes on these treatments and poorer prognosis. These indications represent a significant unmet need and a substantial opportunity.

### *Preclinical Data*

We have conducted a number of preclinical *in vitro* and *in vivo* experiments of LYL797 against ROR1+ solid tumors. These studies have demonstrated that LYL797, which incorporates Gen-R and Epi-R, maintains stem-like phenotypes and can resist exhaustion while inhibiting tumor growth in models of tumor cells expressing ROR1.

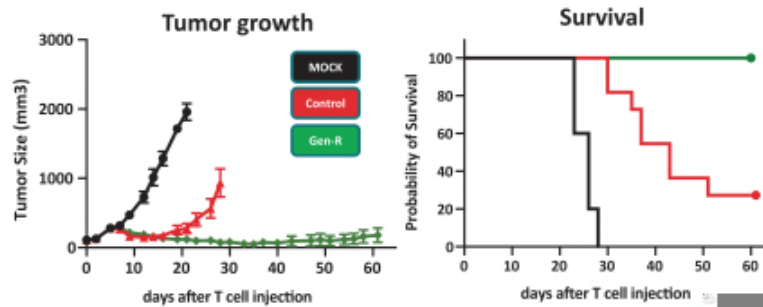
Gen-R and Epi-R, in combination with ROR1-targeted CAR T cells, have been evaluated preclinically in *in vitro* and *in vivo* models. In the studies depicted below, we exposed ROR1 + Gen-R CAR T cells (ROR-1 + Gen-R) and other ROR1 CAR T cells without Gen-R (the Control) to chronic stimulation by repeated exposure to ROR1+ NSCLC tumor cells, with fresh tumor cells introduced every two days. After seven days of chronic stimulation, we assessed cytolytic ability and cytokine release from the T cells. In all donors, the ROR1 + Gen-R T cells demonstrated improved maintenance of cytotoxicity against ROR1+ tumor cells while producing increased levels of cytotoxic cytokines, such as IFN $\gamma$ . This suggests persistence of activity and thus lack of exhaustion in ROR1 + Gen-R versus the Control T cells (Figure 27).

Figure 27: In vitro experiment demonstrated superior ability of ROR1 + Gen-R T cells to resist T cell exhaustion. In this experiment we repeatedly stimulated T cells from three different donors with ROR1+ lung cancer cells (cell lines A549 and H1975). After four rounds of stimulation over seven days, we tracked tumor killing kinetics by measuring reduction of tumor cells over time. Shown here are results comparing ROR1 + Gen-R T cells (Gen-R, in green), to the Control T cells (the Control, in red), and to T cells without a ROR1 CAR (Mock, in black). In both the left and middle columns (against two lung tumor cancer cell lines—A549 and H1975), the green line is below the red and black lines, indicating that more tumor killing occurred with ROR1 + Gen-R T cells. In addition, as shown in the right panel, at 24 hours after the fourth round of stimulation, the ROR1 + Gen-R T cells produced more of the killing-associated cytokines IFN $\gamma$  and IL-2.



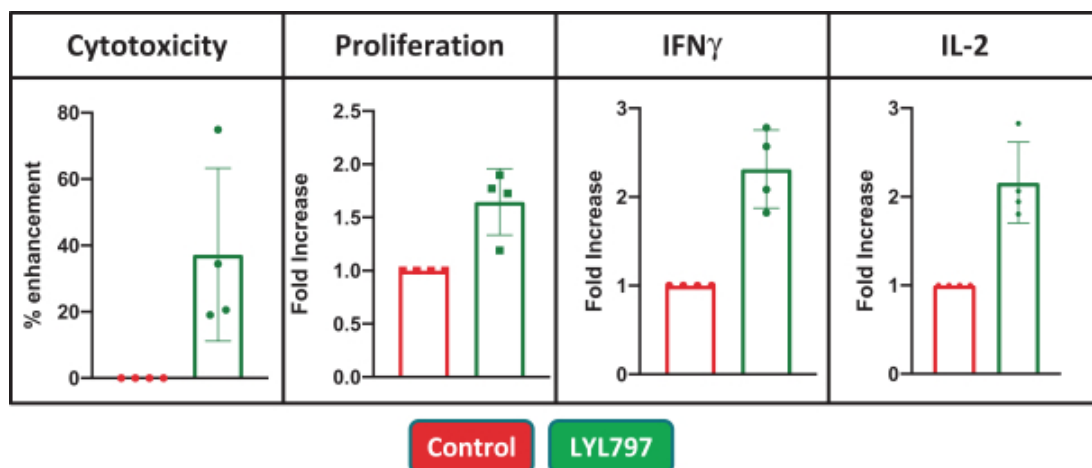
In *in vivo* experiments the ROR1 + Gen-R T cells achieved superior tumor growth inhibition relative to the Control in murine models of ROR1+ lung cancer. Importantly, as shown in the figure below, the Control T cells were administered at a sub-therapeutic dose and did not result in complete tumor eradication, while the ROR1 + Gen-R T cells, when administered intravenously at the same dose, demonstrated near complete inhibition of tumor growth.

Figure 28: In vivo study demonstrated inhibition of tumor using ROR1 + Gen-R T cells. In this study, tumor cells from a human ROR1+ lung cancer cell line were implanted into NSG mice. When tumors reached 100mm<sup>3</sup>, the mice were intravenously injected with ROR1 + Gen-R T cells (Gen-R, in green), the Control T cells (the Control, in red) or T cells without a ROR1 CAR (Mock, in black). The left panel shows results from tracking tumor growth. The black and red lines, Mock and the Control, go up over time, while the green line at the bottom, ROR1 + Gen-R, is nearly flat. At the end of the study (60 days post T cell injection) all of the mice treated with ROR1 + Gen-R T cells were alive and had no meaningful change in body weight.



Additional *in vitro* experiments demonstrate synergistic improvement of CAR T cells by implementing Epi-R in addition to Gen-R (LYL797). When repeatedly exposed to ROR1+ NSCLC tumor cells, with fresh tumor cells introduced every three days, LYL797 showed increases in cytotoxicity, proliferation and secretion of cytokines compared to ROR1 + Gen-R, across all donors.

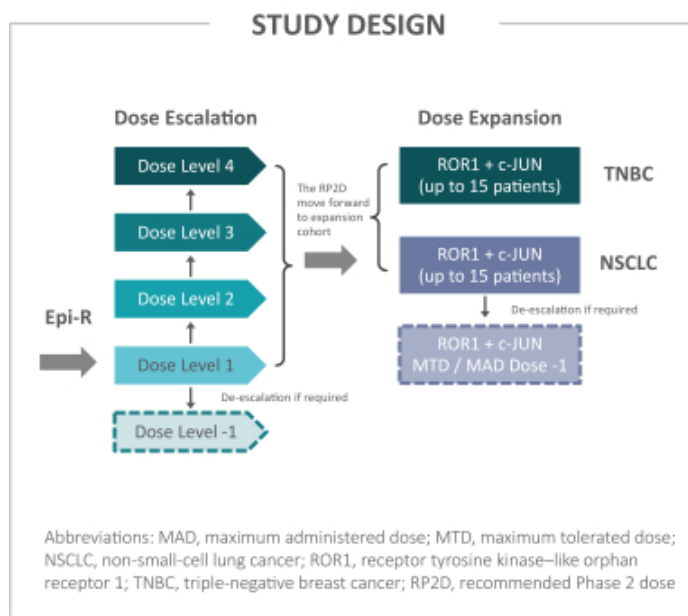
Figure 29: In vitro, application of Epi-R technology resulted in better functional activity of ROR1 + Gen-R T cells. LYL797 T cells (LYL797, in green) and ROR1 + Gen-R T cells (the Control, in red) were repeatedly stimulated every three days with tumor cells from a ROR1+ lung cancer cell line (A549). During the final stimulation, we measured the percent enhancement in tumor cell clearance (cytotoxicity) or the fold increase in proliferation and 24 hour cytokine production of LYL797 T cells compared to ROR1 + Gen-R T cells. Data from four donors is shown. LYL797 T cells showed increases in cytotoxicity, proliferation and secretion of cytokines compared to ROR1 + Gen-R T cells.



*Our Planned Phase 1 Trial*

We plan to submit an IND for LYL797 to the FDA in the first quarter of 2022. We are planning our Phase 1 clinical trial as a dose escalation and expansion study of LYL797 in approximately 40 patients with relapsed/refractory TNBC or NSCLC who have failed at least two lines of therapy. The primary endpoint of our Phase 1 trial is expected to be the safety and tolerability of LYL797. Additionally, we will investigate whether LYL797 T cells resist exhaustion. Patients will be monitored for cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), as well as tissue specific toxicities in ROR1-expressing organs. As a safety measure, we have included our EGFRopt safety switch in our construct. Thus, cetuximab may be used as a safety intervention. Secondary endpoints are clinical activity based on the evaluation of antitumor activity as evaluated by Response Evaluation Criteria in Solid Tumors (RECIST) criteria and characterization of the pharmacokinetic profile of LYL797. We plan to include exploratory biomarkers of T cell stemness and function to explore the impact of Gen-R and Epi-R in this trial. Once a safe dose is identified during dose escalation in TNBC, we plan to enroll a total of 15 patients with TNBC and 15 patients with NSCLC at the recommended Phase 2 dose (RP2D) of LYL797. We expect to submit an IND for LYL797 in the first quarter of 2022.

Figure 30: LYL797 Phase 1 study design



**LYL845: Our TIL Program Targeting Multiple Solid Tumor Indications**

We are applying our Epi-R technology to develop our product candidate, LYL845, which is expected to be an IV administered autologous TIL therapy in multiple solid tumors. TILs have previously shown clinical benefit in patients with melanoma and other solid tumors with high mutation burdens. Published data from third-party TIL trials show that treating metastatic melanoma patients with TILs results in a 50% or greater response rate, with up to half of those responses complete and durable. TIL therapy has also been shown to result in responses in patients with advanced cervical, lung, breast and gastrointestinal cancers, although response rates in these tumor histologies are much lower than that observed in the melanoma setting. TILs target a variety of tumor antigens, but it is thought that the clinical efficacy of TILs is largely driven by specific recognition of mutated tumor

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neoantigens. Further, broad TIL efficacy has been limited by poor enrichment of tumor-reactive T cells, poor quality and growth potential of expanded T cells, and failure to maintain polyclonality of TILs during production. We have designed LYL845 to incorporate our Epi-R technology that has shown promising improvements in enhancing T cell potency, antitumor activity and increased polyclonality of TILs. We expect to submit an IND to test LYL845 in multiple solid tumor indications in the second half of 2022.

### *Background on Target Indications*

We are targeting cervical, pancreatic, non-small cell lung, breast and colorectal cancer as well as melanoma initially, which all have a high unmet need based on the current treatment landscapes. Although patients may benefit initially from radiation therapy, chemotherapy, surgery and more advanced alternatives such as checkpoint therapies, immunotherapies or targeted therapies, most patients with these types of cancers eventually relapse. After becoming resistant to initial lines of therapy, patients are limited to palliative care, experimental therapies in clinical trials, or chemotherapy regimens that often highly toxic and largely ineffective. Overall, despite recent advances in therapeutic development, for most patients diagnosed with solid tumors, a significant unmet medical need exists and long-term survival rates remain low.

#### Melanoma

Melanoma arises due to genetic mutations in melanocytes, the pigment producing cells, which can be found in the skin, eye, inner ear and leptomeninges, and represents the most aggressive and the deadliest form of skin cancer. Although melanoma accounts for only ~1% of all dermatologic cancers, it is responsible for ~80% of deaths from skin cancer and only ~14% of patients with metastatic melanoma survive for five years. It is estimated that there are over 105,000 new cases of melanoma diagnosed in the United States per year, and over 7,000 deaths per year.

#### Cervical Cancer

While increased use of Pap tests has improved the death rates from cervical cancer in recent years, it is still a common cancer diagnosed in women in the United States. It is estimated that there are approximately 15,000 new cases of cervical cancer a year, resulting in about 4,000 deaths. Patients diagnosed with metastatic disease generally have significantly poorer prognosis and fewer treatment options. For patients with localized cervical cancer, the overall 5-year survival rate is ~92%. For regional cervical cancer, the 5-year survival rate is ~58%. When the cancer has metastasized, the 5-year survival rate is 17%.

#### Head and Neck Cancer

Cancers that are known collectively as head and neck cancers usually begin in the squamous cells that line the moist, mucosal surfaces inside the head and neck, otherwise known as squamous cell carcinomas. Cancers of the head and neck are further categorized by the area of the head or neck in which they begin: oral cavity, pharynx, larynx, paranasal sinuses and nasal cavity and salivary glands. Head and neck cancers account for approximately 4% of all cancers in the United States and are more than twice as common among men as they are among women. In 2021, an estimated 67,000 people will develop head and neck cancer. Additionally, it is estimated that nearly 15,000 deaths from head and neck cancer will occur in 2021. Approximately one out of five head and neck cancer cases will be metastatic, with tumors spreading past the squamous cells into deeper layers of tissue, past the epithelium layer into the mucosa. Five-year survival rates for head and neck vary based on the subtype of cancer. For people with oral cavity and pharynx cancer, a common type of head and neck cancer, that is local, the overall 5-year survival rate is 85%. When cancer has metastasized, the 5-year survival rate is 40%. For another prevalent type of head and neck tumors, laryngeal cancer, localized cancers

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have a 78% 5-year survival rate. For regional laryngeal cancer, the 5-year survival rate is 45%. When cancer has metastasized, the 5-year survival rate is 34%. Across other head and neck cancers, 5-year survival rates fall in a similar range.

### Pancreatic Cancer

Pancreatic cancer is an aggressive form of cancer that develops largely in the exocrine cells of the pancreas. Pancreatic cancer represents roughly 3% of all cancers, but due to poor prognosis associated with pancreatic cancer, it represents 7% of all cancer deaths. It is estimated that there are approximately 60,000 new cases of pancreatic cancer in the United States per year, and 50,000 deaths from this disease a year, making it the fourth leading cause of cancer death. For patients diagnosed with localized pancreatic cancer, the overall 5-year survival rate is ~39%, but 5-year survival rates drop to as low as 3% when patients are diagnosed with metastatic disease. At the time of diagnosis, a majority, or 52%, of pancreatic cancer cases have progressed to metastatic disease.

### Non-Small Cell Lung Cancer

Lung cancer is the second most common cancer and is the leading cause of cancer mortality worldwide. It is estimated that 135,720 (72,500 men and 63,220 women) deaths from this disease occurred in 2020. NSCLC accounts for about 84% of all lung cancers. In 2016, the incidence of NSCLC varied widely, ranging from 3 to 57 per 100,000 in Africa and North America respectively, with ~2 million cases diagnosed globally. For people with localized NSCLC, the overall 5-year survival rate is ~61%. For regional NSCLC, the 5-year survival rate is ~35%. Based on current data, when cancer metastasizes, the 5-year survival rate is 6%.

### Breast Cancer

Breast cancer is the most common cancer in American women, except for skin cancers. Approximately, 13% of women will be diagnosed with breast cancer at some point during their lifetime, with a current estimated 3.5 million women living with breast cancer in the United States as of 2017. It is estimated that there are approximately 282,000 new cases of breast cancer diagnosed in the United States per year, representing about 15% of all new cancer cases in the United States with a 90% 5-year relative survival. When cancer has metastasized, the 5-year survival rate drops to 6%. Over 40,000 deaths in the United States are expected to occur annually from breast cancer.

### Colorectal Cancer

Colorectal cancer is the fourth most common cancer diagnosed in the United States. Most colorectal cancers are a type of tumor called adenocarcinoma, which is cancer of the cells that line the inside tissue of the colon and rectum, but other types of less frequently arising colorectal tumors include neuroendocrine tumor of the gastrointestinal tract, gastrointestinal stromal tumor, small cell carcinoma and lymphoma. It is estimated that there are approximately 100,000 new cases of colon cancer and 45,000 new cases of rectal cancer in the United States per year. Further, it is the second most common cause of cancer deaths in the United States, estimated to cause over 50,000 deaths a year. For patients with localized colorectal cancer, the overall 5-year survival rate is ~90%. For regional colorectal cancer, the 5-year survival rate is ~72%. For patients diagnosed with metastatic disease, the 5-year survival rate is 14%. Approximately 25% of patients have metastatic disease at diagnosis, and about 50% of patients with colorectal cancer will eventually develop metastases. Over 35% of the patients with a new diagnosis of CRC will die within five years.

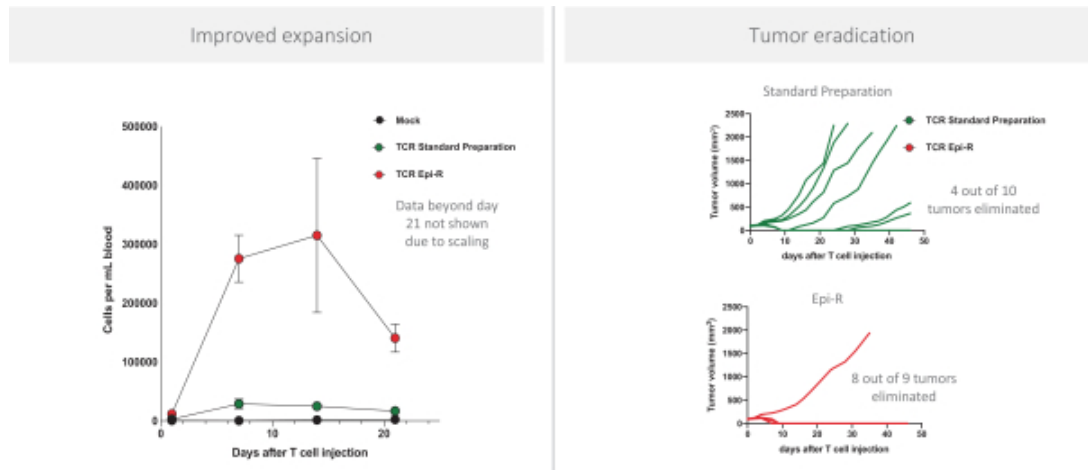
### *Our Preclinical Data*

We have conducted a number of preclinical *in vitro* and *in vivo* studies of LYL845 which suggest TILs enhanced with Epi-R maintain properties of durable stemness, including superior expansion and tumor eradication in both animal studies and autologous experiments, as well as polyclonality.

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Our Epi-R T cell populations have demonstrated superior expansion in *in vivo* mouse models. We measured the number of T cells in the mice at various time points and observed as many as 50-fold more T cells in mice injected with Epi-R T cells, as compared to mice injected with T cells expanded in Standard Preparation. We also observed, after 40 days, tumor eradication in 4 out of 10 mice treated with Epi-R T cells versus eradication in only 1 out of 9 mice treated with Standard Preparation. These observations may not be repeated in clinical trials and the safety of our product candidates is a determination solely within the authority of the FDA and comparable foreign regulators.

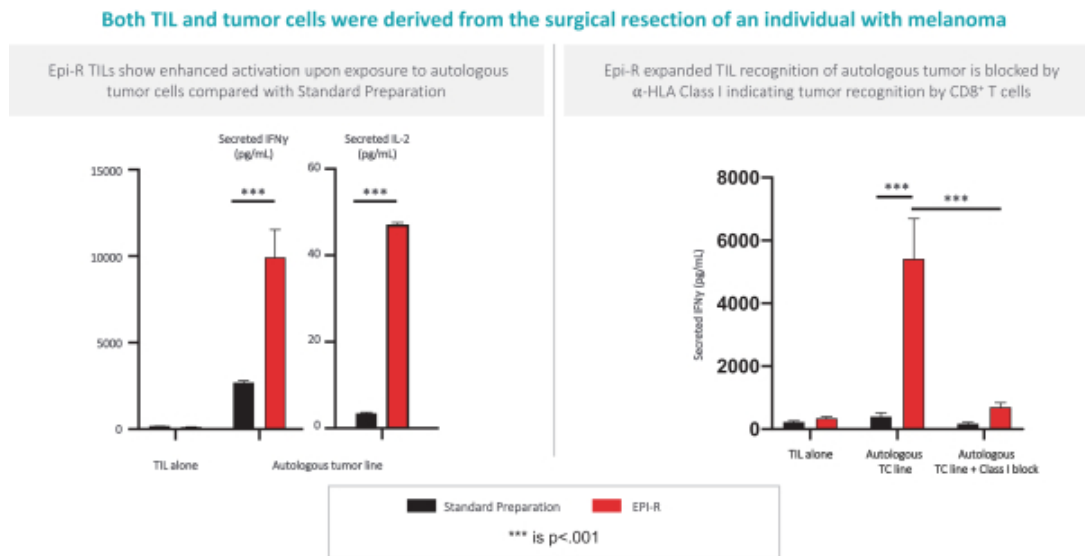
Figure 31: Epi-R T cells had improved expansion *in vivo* as shown in the left panel and had greatly improved antitumor function in mouse models of cancer, as shown on the right. Epi-R T cells eliminated tumors in 8 out of 9 treated mice (note overlapping red lines in Epi-R tumor killing along the x-axis), compared to 4 out of 10 mice treated with Standard Preparation T cells.



In *in vitro* studies we evaluated Epi-R expanded TIL recognition of autologous melanoma cancer cells. Utilizing a patient melanoma tumor excision, we both extracted and expanded TIL from that specimen in either Standard Preparation or Epi-R, and created a cancer cell line in order to evaluate whether the expanded TIL from that tumor recognize and react to that patient's own cancer cells. We were able to demonstrate that Epi-R TIL do exhibit enhanced activation, the response is mediated by activated killer CD8<sup>+</sup> cells, and they have significantly enhanced tumor cell killing capacity when compared to Standard Preparation. The higher secretion of IL-2, the critical T cell growth factor, is notable.

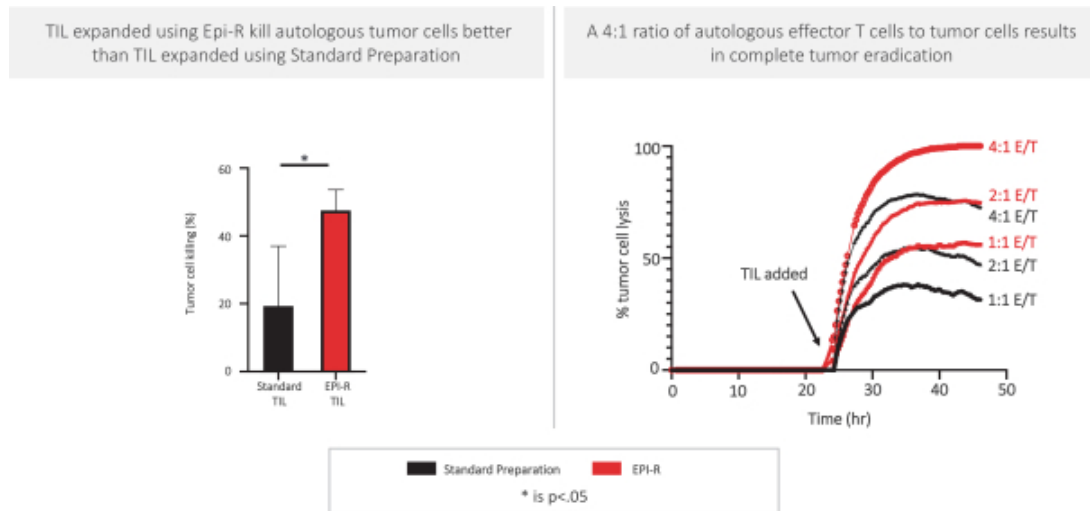


Figure 32: Epi-R TIL had enhanced recognition and activity against autologous melanoma tumor cell line. Asterisks denote significant p-values between groups. The red bars in the graph on the left show that Epi-R T cells from TIL secreted increased levels of IFN $\gamma$  and IL-2 cytokines as compared to Standard Preparation after co-culture with autologous melanoma tumor cells, indicating greater activation and cytotoxicity potential. As a control, when TIL alone were measured without the presence of autologous tumor cells, they did not activate and did not secrete the cytokines. In the bar chart on the right, we demonstrate that production of IFN $\gamma$  secretion dropped significantly when target cells were coated with an antibody to HLA Class I, indicating that the tumor cell recognition was mediated by CD8 $^+$  T cells.



These cells were also shown to be more effective at tumor cell killing. In the graph below on the left, we show that Epi-R TIL T cells killed autologous tumor cells at a rate of approximately 50% whereas those TIL grown in Standard Preparation killed at a rate of approximately 20%. We also observed, in an experiment to titrate different levels of Epi-R TIL T cells against tumor cells, that a 4:1 effector T cell to tumor cell ratio resulted in complete tumor eradication.

**Figure 33: Epi-R TIL had improved ability to kill autologous tumor cells. Standard and Epi-R TIL were co-cultured with autologous melanoma tumor cells and their ability to kill tumor was measured after 24 hours (left panel). Altering the ratio of TIL:tumor cells (E/T ratio) can impact TIL ability to kill tumor. Epi-R TIL exhibited increased tumor killing at all E/T ratios, and at a 4:1 ratio Epi-R TIL successfully killed all tumor cells.**

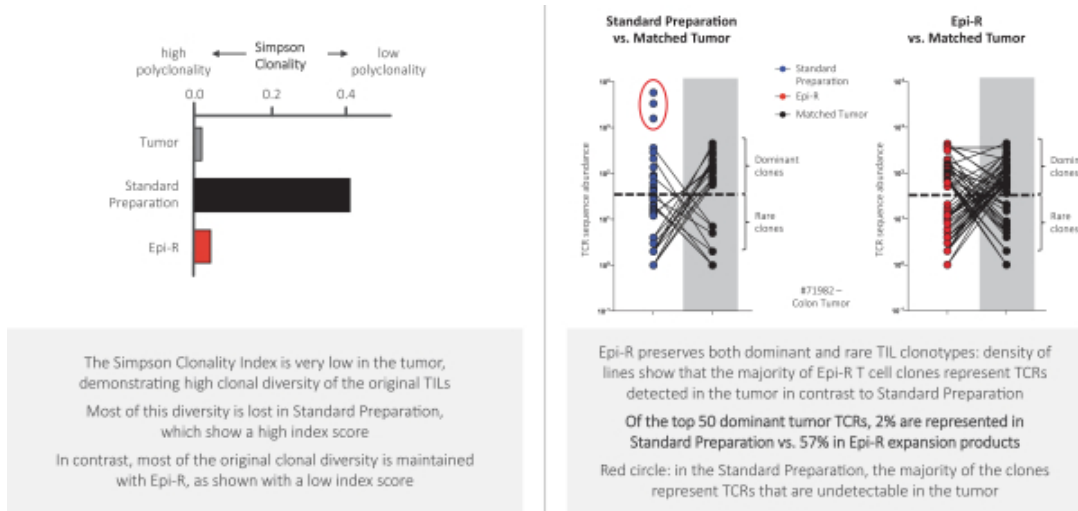


Epi-R has also demonstrated the ability to preserve the polyclonality of TIL preparations, one of the key advantages of this ACT modality.

Quantitatively, polyclonality can be measured by the Simpson Clonality index, shown below on the left (Figure 34). The Simpson Clonality Index is a quantitative tool that reflects diversity within a dataset; a low number represents high diversity, while a high number represents low diversity. An index value of 1 would represent a monoclonal population. The Simpson Clonality Index of TIL in the tumor is very low, demonstrating high clonal diversity of the original TILs. In Standard Preparation, the majority of clones giving rise to the desired clonal diversity are lost upon stimulation and expansion as shown by the high Simpson Clonality Index. In contrast, most of the original tumor clonal diversity is maintained in TIL expanded with Epi-R, as shown with a low index score.

It is known that T cells migrating through tissues experience arrested migration upon recognition of their target tumor antigen, resulting in their activation and expansion, which is followed by their exhaustion. We quantified the TCRs from TILs and ranked them by the frequency of the clonotypes found. We compared the frequencies of individual TCRs after expansion in Standard Preparation or Epi-R conditions. On the right in the graph below, we show that Epi-R preserved both dominant and rare TIL clonotypes found amplified in the tumor; 57% of the TCR Vβ sequences corresponded to the top 50 TCRs represented in the original TIL. By sharp contrast, only 2% of the TCR clonotypes expanded in Standard Preparation were represented in the top 50 TCRs found in TIL.

**Figure 34: Epi-R TIL exhibited increased T cell polyclonality and retention of original T cell clones. TCR sequencing was performed on Standard Preparation and Epi-R TIL and Simpson Clonality Index (a measure of polyclonality, with high Simpson values indicating low polyclonality) was measured. Epi-R TIL exhibited a low Simpson Clonality Index (left panel) that reflects increased diversity of T cell TCR repertoire. The relative abundance of TCRs that were observed in starting tumor T cell population was compared with Standard Preparation and Epi-R expanded TILs. Epi-R TILs retained greater proportions of starting TCR repertoire after expansion.**



**Our Planned Phase 1 Trial**

We plan to submit an IND for LYL845 to the FDA in the second half of 2022. We are planning our Phase 1 clinical trial as a dose escalation and expansion study of LYL845 in multiple solid tumor indications. The primary endpoint of our Phase 1 trial is expected to be the safety and tolerability of LYL854 in melanoma and other solid tumor indications. Eventually we hope to expand our development program to pancreatic, head and neck SCC, breast, colorectal and other solid tumors. We plan to monitor patients for CRS and auto-immunity. We plan to monitor clinical efficacy based on antitumor activity as evaluated by RECIST criteria and characterization of the pharmacokinetic profile of LYL845. We expect to submit an IND for LYL845 in the second half of 2022.

**NY-ESO-1 TCR: Our Lead Program with GSK**

Our collaborator, GSK, is developing an NY-ESO-1 TCR T cell product candidate, NY-ESO-1c259, currently in pivotal development. Our collaboration explores the potential enhancement of that product candidate through the application of our Gen-R and Epi-R platform technologies, with a goal to improve the depth and durability of clinical responses. While we are currently evaluating Gen-R and Epi-R in separate preclinical programs, together these programs could represent a single future product opportunity for GSK utilizing one or both of our platform technologies.

We are responsible for preclinical activities for both programs and, for NY-ESO-1 with Epi-R, we intend to conduct manufacturing and hold the product IND. GSK is responsible for executing the clinical trials and commercialization of the future product. We anticipate that initial clinical trials will be conducted in synovial sarcoma and multiple other solid tumors. Positive results from these trials could support additional combinations and expansions into additional tumor types, including those with lower levels of target antigen, such as NSCLC. We anticipate an IND submission in the first half of 2022.

**Rationale for NY-ESO-1**

NY-ESO-1 is a known cancer testis antigen target that has been previously validated in clinical trials. It is expressed in a wide range of solid tumors, including at high levels in some indications; however, it has low or no expression in healthy adult tissues. It is expressed in approximately 80% of synovial sarcomas, neuroblastomas and myxoid and round cell liposarcomas, more than 40% of

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melanomas and ovarian cancers, and between 20% to 40% of multiple other cancers including bladder, esophageal, hepatocellular, head and neck, ovarian, prostate, myeloma, breast and NSCLC. Patients who could benefit from treatment with NY-ESO-1-targeted therapies are further limited because the NY-ESO-1-antigen is HLA A2-restricted and the therapeutic T cells recognize only certain protein sequences.

### *Background on Target Indications*

We are initially targeting synovial sarcoma, NSCLC and myxoid round cell liposarcoma (MRCLS), which all have a high unmet need based on the current treatment landscapes. Synovial sarcoma and MRCLS, in particular, have limited treatment alternatives, and are largely treated with a combination of surgery and chemotherapy, but with significant rates of metastases and low 5-year survival rates in metastatic cases. While NSCLC has more treatment alternatives, it still has low five-year survival rates and due to its prevalence causes upwards of 130,000 deaths in the United States per year. In addition to the unmet need in these cancers, NY-ESO-1 expression is high in all three, 80+% in MRCLRS and synovial sarcoma as well as up to 25% in NSCLC, further supporting our development plans.

#### Synovial Sarcoma

Synovial sarcoma is a rare, yet highly malignant tumor occurring in soft tissue and accounts for approximately 5–10% of all soft tissue sarcomas. It is estimated that there are over 13,000 new cases of soft tissue sarcomas diagnosed in the United States per year, and over 5,000 deaths per year. This would translate to approximately 650-1,300 cases of synovial sarcoma per year. Synovial sarcoma is more common in adolescents and young adults than in older individuals, and it typically affects the extremities. Patients often develop metastases, particularly to the lungs, resulting in 10-year survival rates of <50%.

#### Non-Small Cell Lung Cancer

Lung cancer is the second most common cancer and is the leading cause of cancer mortality worldwide. It is estimated that 135,720 (72,500 men and 63,220 women) deaths from this disease occurred in 2020. NSCLC accounts for about 84% of all lung cancers. In 2016, the incidence of NSCLC varied widely, ranging from 3 to 57 per 100,000 in Africa and North America respectively, with ~2 million cases diagnosed globally. For people with localized NSCLC, the overall 5-year survival rate is ~61%. For regional NSCLC, the 5-year survival rate is ~35%. Based on current data, when cancer metastasizes, the 5-year survival rate is 6%.

#### Myxoid Round Cell Liposarcoma

MRCLS is a type of rare soft, connective tissue tumor that grows in cells that store fat in the body, typically in the arms and legs. While liposarcomas are rare, MRCLS is one of the most common types of liposarcoma and makes up approximately 30% of all cases, with 2,000 diagnosed occurrences in the United States each year. Other categories of liposarcomas include well-differentiated (~50%) and pleomorphic (10%) liposarcomas. MRCLS is specifically characterized by tumors in the extremities with prevalence in a younger population than other liposarcoma subtypes, as well as high risk of recurrence in other soft tissue sites or bones. One third of MRCLS cases will become metastatic with tumors spreading to unusual bone and soft tissue locations with multifocal synchronous or metachronous spread to fat pad areas in the retroperitoneum, trunk, pericardium and axilla. For people with localized soft tissue tumors, the overall 5-year survival rate is ~93%. When cancer has metastasized, the 5-year survival rate is 41%. Additionally, outcomes for patients with significant (5% or greater) round cell component is associated with a poorer prognosis, 74% 5-year survival rate vs. 92% in low grade myxoid liposarcomas.

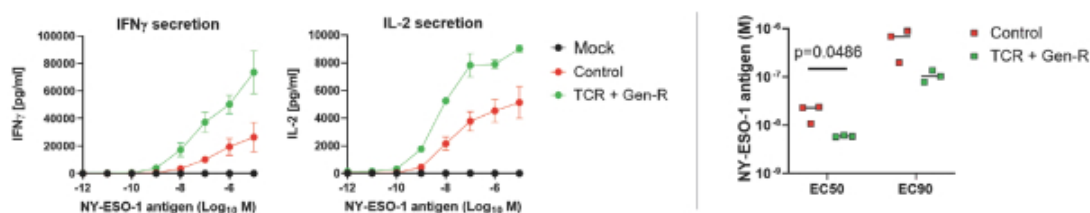
Preclinical Data

We have separately tested both platform technologies with GSK's NY-ESO-1 TCR. We are currently conducting preclinical studies for NY-ESO-1 TCR with Gen-R (NY-ESO-1 + Gen-R) and NY-ESO-1 TCR with Epi-R (NY-ESO-1 + Epi-R), compared to GSK's baseline NY-ESO-1 TCR (the Control). NY-ESO-1 + Gen-R data is discussed below; data is pending for NY-ESO-1 + Epi-R.

We have conducted a series of *in vitro* and *in vivo* experiments that show NY-ESO-1 + Gen-R T cells resisted exhaustion and had increased production of cytokines associated with tumor killing, improved sensitivity to lower levels of NY-ESO-1 surface expression and improved tumor cell killing compared to the Control, both initially and after persistent exposure to NY-ESO-1+ tumor cells. We believe these findings could translate into improved outcomes in the clinical setting.

We exposed NY-ESO-1 + Gen-R T cells to NY-ESO-1+ solid tumor cell lines and measured IFN $\gamma$  and IL-2, cytokines associated with tumor killing. We observed a more than two-fold increase in secretion of those cytokines with NY-ESO-1 + Gen-R compared to the Control in two of three donors. We also exposed T cells to increasing concentrations of NY-ESO-1 on solid tumor cells and showed that NY-ESO-1 + Gen-R were significantly more sensitive than the Control to low levels of NY-ESO-1 (Figure 35).

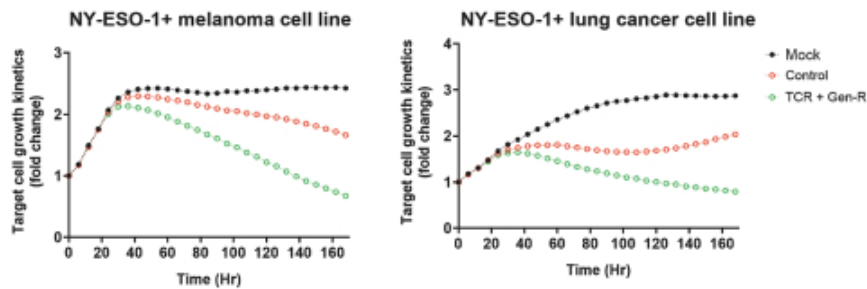
Figure 35: *In vitro* experiments showed that NY-ESO-1 + Gen-R had increased antitumor cytokines (left panel) and increased antigen sensitivity (right panel) compared to the Control. In the experiment on the left, T cells were exposed to NY-ESO-1+ tumor cells and IFN $\gamma$  and IL-2 production were measured. The figure shows that NY-ESO-1 + Gen-R (TCR + Gen-R, green curves) produced higher and increasing amounts of those cytokines compared to the Control (red curves). In the experiment on the right, T cells were exposed to increasing concentrations of NY-ESO-1 peptide presented by T2 cells, where EC50 and EC90 are measures of maximal antigen concentration needed for response. The right panel shows that NY-ESO-1 + Gen-R (green dots) were more sensitive to low levels of NY-ESO-1 compared to the Control (red dots). Mock T cells, without NY-ESO-1 TCR or Gen-R, are shown in the black curves. Results for EC50 were significant, with p values between groups shown.



Additionally, NY-ESO-1 + Gen-R T cells demonstrated a stronger, faster and sustained durability to kill solid tumor cells versus the Control (Figure 36). This result was observed across five donors and two NY-ESO-1+ solid tumor cell lines.

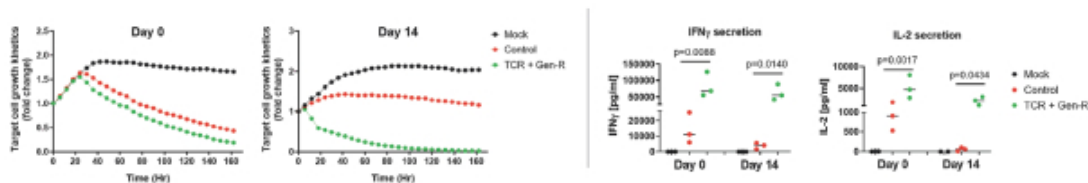
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Figure 36: NY-ESO-1 + Gen-R T cells (TCR + Gen-R, green curves) demonstrated superior ability to kill NY-ESO-1+ solid tumor cells compared to the Control. The figure shows T cell killing efficiency against two different NY-ESO-1+ cell lines, measured by tracking kinetics of tumor cell clearance over time. The green curves illustrate the clearance of tumor cells by the NY-ESO-1 + Gen-R; the red curves illustrate the same for the Control. Mock T cells, without NY-ESO-1 TCR or Gen-R, are shown in the black curves. In the right panel, the red curve goes upward over time as the TCR T cells without Gen-R lost their antitumor activity, while the green curve goes downward, showing that NY-ESO-1 + Gen-R T cells maintained their antitumor activity. Experiment performed with five donors; representative donor shown.



To test for T cell exhaustion, we exposed NY-ESO-1 + Gen-R to NY-ESO-1+ solid tumor cells repetitively. After persistent antigen exposure, NY-ESO-1 + Gen-R continued to kill NY-ESO-1+ tumor cells and secrete cytokines associated with tumor killing, while the Control T cells lost this ability (Figure 37). In addition, a significantly lower proportion of NY-ESO-1 + Gen-R expressed markers of exhaustion. These results suggest that NY-ESO-1 + Gen-R T cells resisted exhaustion after persistent antigen exposure compared to the Control.

Figure 37: NY-ESO-1 + Gen-R T cells (TCR + Gen-R, green line) showed enhanced long-term tumor killing activity. In a serial re-stimulation assay, where the T cells were exposed to fresh NY-ESO-1+ tumor cells four times, NY-ESO-1 + Gen-R T cells maintained the ability to kill NY-ESO-1+ tumor cells and to secrete cytokines over time, whereas the Control cells (red line) exhibited signs of exhaustion, as illustrated by loss of killing activity and cytokine secretion. The green curves in the left panel and the green dots in the right panel show that the NY-ESO-1 + Gen-R T cells were able to kill NY-ESO-1+ tumor cells and secrete high amounts of cytokines before (Day 0) and after (Day 14) four rounds of NY-ESO-1 antigen exposure, whereas the Control T cells showed signs of exhaustion, as illustrated by loss of ability to kill and secrete cytokines (red curves and red dots). Mock T cells, without NY-ESO-1 TCR or Gen-R, are shown in the black curves. Significant p values between groups are shown.



**Planned Phase 1 Trial**

The initial clinical trial for our NY-ESO-1 TCR program, conducted by GSK, is expected to test this product candidate in patients with synovial sarcoma and multiple other solid tumors for tolerability and preliminary efficacy. Positive results from such a trial could support additional combinations and

expansions, including expansion to additional patient populations with lower levels of target antigen, such as NSCLC.

### **Manufacturing and Digital Infrastructure**

We believe it is critically important to own, control and continuously monitor all aspects of the cell therapy manufacturing process in order to mitigate risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. 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, cost and quality, and have the ability to rapidly incorporate disruptive advancements and new innovations. Controlling manufacturing also enables us to protect proprietary aspects of our Gen-R and Epi-R technology platforms. We view our manufacturing team and capabilities as a significant competitive advantage.

Our LyFE manufacturing center is approximately 73,000 square feet and comprises laboratories, offices and manufacturing suites. LyFE has a flexible and modular design allowing us to produce plasmid, viral vector and T cell product to control and de-risk the sequence and timing of production of the major components of our supply chain related to our product candidates. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. We believe this capacity is sufficient to support our pipeline programs through pivotal trials and, if approved, early commercialization. We anticipate the facility to be cGMP qualified by the end of 2021.

LyFE is a paperless facility that integrates advanced data and analytics approaches to enable a completely digital manufacturing process. Our adaptive manufacturing capabilities allow us to track every step of the process and instantly manage any deviations or alerts. We believe the ability to capture and analyze data in real time will ultimately lead to more effective and safe cell therapy products for patients. Upon receipt of a patient specimen, the subsequent application of Gen-R and Epi-R is conducted within our integrated manufacturing center to generate reprogrammed T cells to be infused back into the patient. This integrated manufacturing capability, further enhanced with our sophisticated information science and real-time monitoring capabilities, should enable us to improve yield and success rates, which could result in a more favorable cost structure, while at the same time expanding our knowledge base for each product candidate from each manufacturing run.

To support our digital manufacturing capabilities, we worked with AWS. Our LyFE manufacturing center is one of the first cell therapy manufacturing facilities to benefit from AWS's extensive experience with cloud computing, Internet of Things (IoT) and advanced analytics. Our digital strategy is spearheaded by our Information Sciences team, comprising experts in cloud computing, security, software development, automation, robotics and advanced analytics, including artificial intelligence. Our digital analytics platform is designed to allow us to rapidly and continuously acquire, manage and analyze data to accelerate and enhance our science and operations and inform our next generation cell therapies. The key benefits of our digital manufacturing strategy include:

- Real-time data acquisition: allows for monitoring, alerting, rapid decision making;
- Workflow automation: reduces variability, manual oversight, data entry and calculations;
- Cloud computing: unlimited compute and storage, accelerated innovation, security, compliance;
- Agility: rapidly adapts to changing needs while ensuring compliance; and
- Analytics and insights: enables trending, process optimization, data-driven decision making.

Our Information Sciences infrastructure is built on a "data lake and control tower" approach to managing data arising from our scientific and manufacturing operations. A data lake is a platform which

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stores and allows access to integrated data from many sources, eventually to rapidly interconnect research, clinical and manufacturing data sources with patient outcomes. The control tower creates dashboards and real-time business metrics to allow us to understand, prioritize and resolve critical issues as they happen, end-to-end across our processes. Our goal is to learn and maximize the insights from each experiment, patient and manufacturing run, and apply those to continuous learning and process improvements to our product candidates.

### **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.

We are aware of a number of companies using *ex vivo* cell therapy approaches to treat solid tumors. Some of these companies may have substantially greater financial and other resources than we have, such as larger research and development staff and well-established marketing and sales forces, or may operate in jurisdictions where lower standards of evidence are required to bring products to market. There are a number of companies developing CAR T cells, TCR T cells or TIL-based immune-oncology therapies for the treatment of solid tumors including Achilles Therapeutics plc, Allogene Inc., BioNTech SE., bluebird bio Inc., Bristol Myers Squibb Co., Gilead Sciences Inc., GlaxoSmithKline Plc., Instil Bio Inc., Iovance Biotherapeutics Inc., Nanjing Legend Biotech and Tmunity Therapeutics Inc. Among companies developing cell therapies for solid tumors, we believe we are substantially differentiated by our technology platforms, knowledge, experience, scientific personnel and robust intellectual property portfolio. We believe the key competitive factors affecting the success of any of our product candidates will include efficacy, safety, accessibility, price and cost of manufacturing.

### **Collaboration, License and Success Payment Agreements**

#### ***Fred Hutch License Agreement and Success Payment Agreement***

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

We also entered into a letter agreement with Fred Hutch in December 2018 under which we agreed to make success payments to Fred Hutch, payable in cash or publicly traded equity at our discretion. These success payments are based on increases in the per share fair market value of our Series A convertible preferred stock or any security into which such stock has been converted or for which it has been exchanged during the success payment period, which is a period of time that begins on the date of our letter agreement with Fred Hutch and ends on the earlier of: (a) the ninth anniversary of that date and (b) the earlier of (i) the date on which we sell, lease, transfer, or exclusively license all or substantially all of our assets to another company and (ii) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger



stockholders own a majority of the shares of the surviving entity). Success payments will be owed (if applicable) after measurement of the value of our common stock in connection with the following valuation dates during the success payment period: (1) the first anniversary of the date on which we complete an initial public offering of our common stock, or our shares otherwise become publicly traded; (2) the second anniversary of such; (3) each two year anniversary thereafter (i.e., the four year anniversary, six year anniversary, etc. of such date); (4) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company; (5) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity); (6) the last day of the nine year period. Any success payment will generally be made within 45 days after the applicable valuation date, except that in the case of a merger or sale of all of our company's assets, the success payment will be made on the earlier of the 90th day following the transaction or the first date that transaction proceeds are paid to any of our stockholders. In the case of (1), (2) and (3), the value of our common stock will be determined by the average trading price of a share of our common stock over the consecutive 90-day period preceding the date the success payment is made; the value will otherwise be determined either, in the case of a merger or stock sale, by the consideration paid in the transaction for each share of our stock or the stock of the acquiring entity (or their parent or affiliate). The amount of a success payment is determined based on whether the value of our common stock meets or exceeds certain specified threshold values ascending from \$18.29 per share to \$91.44 per share, in each case subject to adjustment for any stock dividend, stock split, combination of shares, or other similar events. Each threshold is associated with a success payment, ascending from \$10.0 million at \$18.29 per share to \$200.0 million at \$91.44 per share, payable if such threshold is reached. Any previous success payments made to Fred Hutch are credited against the success payment owed as of any valuation date, so that Fred Hutch does not receive multiple success payments in connection with the same threshold. The success payments paid to Fred Hutch will not exceed, in aggregate, \$200.0 million, which would be owed only when the value of the common stock reaches \$91.44 per share.

#### ***Stanford License Agreement and Success Payment Agreement***

In January 2019, we entered into a license agreement with Stanford that grants us an exclusive, worldwide, sublicensable license under certain patent rights, and a non-exclusive, worldwide, sublicensable license under certain other patent rights and technology, to make, have made, use, offer to sell, sell, import, or otherwise offer to dispose of products and processes covered by such patent rights or incorporating such technology for all fields of use utilizing CARs and/or TCRs. The patents and patent applications covered by this agreement are directed to compositions and methods of treating related to preventing, reversing, inhibiting, reducing or modulating T cell exhaustion and compositions and methods related to engineered cell surface receptors including CARs. We also have the right to add certain Stanford patent applications covering certain inventions which are improvements to the existing patents and patent applications, as well as a right of first negotiation for other patent applications covering inventions made in the principal investigator's lab which relate to and are necessary or useful for utilizing CARs and/or TCRs.

We are obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and to develop markets for licensed products.

We paid to Stanford an upfront payment of \$400,000. We are required to pay to Stanford an annual maintenance fee in the mid tens of thousands on the second anniversary of entering into this agreement, and each anniversary thereafter until the date of the first commercial sale of a licensed product. We are obligated to pay Stanford up to a maximum of \$3.7 million per target upon achievement of certain specified clinical and regulatory milestones. We are also obligated to pay to Stanford \$2.5 million collectively for all licensed products upon our achievement of a certain commercial milestone. In addition,

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the license agreement provides that we are required to pay to Stanford low single-digit tiered royalties based on annual net sales of the licensed products by us and by our sublicensees. If we seek to challenge the validity of any of the licensed patents, during the pendency of such action our royalty rate will increase, and if the outcome of such challenge finds that patent is both valid and infringed our royalty rate will increase further. We are also required to pay Stanford (a) royalties in the mid-teens percentage of the payments that we receive from sublicensees of the rights solely licensed to us by Stanford, or (b) if sublicensed with other intellectual property, on a tiered basis in the low six figures up to \$300,000.

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

In connection with the license agreement, we entered into a letter agreement in January 2019 with Stanford pursuant to which we issued to Stanford 910,000 shares of our common stock.

We also entered into a letter agreement with Stanford in October 2020, under which we agreed to make success payments to Stanford, payable in cash or publicly traded equity at our discretion. These success payments are based on increases in the per share fair market value of our Series A convertible preferred stock or any security into which such stock has been converted or for which it has been exchanged during the success payment period, which is a period of time that begins on the date of our letter agreement with Stanford and ends on the earlier of: (a) the ninth anniversary of that date and (b) the earlier of (i) the date on which we sell, lease, transfer, or exclusively license all or substantially all of our assets to another company and (ii) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity). Success payments will be owed (if applicable) after measurement of the value of our common stock in connection with the following valuation dates during the success payment period: (1) the first anniversary of the date on which we complete an initial public offering of our common stock, or our shares otherwise become publicly traded; (2) the second anniversary of such; (3) each two year anniversary thereafter (i.e., the four year anniversary, six year anniversary, etc. of such date); (4) the date on which we sell, lease, transfer or exclusively license all or substantially all of our assets to another company; (5) the date on which we merge or consolidate with or into another entity (other than a merger in which our pre-merger stockholders own a majority of the shares of the surviving entity); (6) the last day of the nine year period. Any success payment will generally be made within 45 days after the applicable valuation date, except that in the case of a merger or sale of all of our company's assets, the success payment will be made on the earlier of the 90th day following the transaction or the first date that transaction proceeds are paid to any of our stockholders. In the case of (1), (2) and (3), the value of our common stock will be determined by the average trading price of a share of our common stock over the consecutive 90-day period preceding the date the success payment is made; the value will otherwise be determined either, in the case of a merger or stock sale, by the consideration paid in the transaction for each share of our stock or the stock of the acquiring entity (or their parent or affiliate). The amount of a success payment is determined based on whether the value of our common stock meets or exceeds certain specified threshold values ascending from \$18.29 per share to \$91.44 per share, in each case subject to adjustment for any stock dividend, stock split, combination of shares, or other similar events. Each threshold is associated with a success payment, ascending from \$10.0 million at \$18.29 per share to \$200.0 million at \$91.44 per share, payable if such threshold is reached. Any previous success payments made to Stanford are credited against the success payment owed as of any valuation date, so that Stanford does not receive multiple success payments in connection with the same threshold. The success payments paid to Stanford will not exceed, in aggregate, \$200.0 million, which would be owed only when the value of the common stock reaches \$91.44 per share.

### ***GSK Collaboration and License Agreement***

In May 2019, we entered into a collaboration and license agreement with GSK which became effective on July 7, 2019 and was amended in June 2020. Under the GSK Agreement, we agreed to work collaboratively with GSK to research and develop certain T cell therapies incorporating our technology platforms or other cell therapy innovations as applied to CARs or TCRs under distinct collaboration programs. The GSK Agreement could include T cell therapies for up to a total of nine CAR or TCR targets, and GSK may select these CAR or TCR targets for collaboration during a specified period, subject to certain restrictions.

Under the GSK Agreement, we granted GSK an option, for each Lyell cell therapy innovation that was the subject of a collaboration program under the GSK Agreement, to obtain an exclusive, worldwide license to develop and commercialize that Lyell cell therapy innovations as part of a TCR or CAR cell therapy for the specific target, for human diagnostic and therapeutic uses, except that we retain rights for the China territory for T cell therapies directed to targets that were within GSK's pipeline and met certain criteria prior to inclusion in the GSK Agreement. We also retain rights to the Lyell cell therapy innovations for other products and targets.

For potential T cell therapies that are the subject of collaboration programs under the GSK Agreement, we are responsible for certain research and development activities, at our cost, up to GSK's option point. The GSK option point is prior to IND filing for therapies to targets that were within GSK's pipeline and met certain criteria prior to inclusion in the GSK Agreement and, for other targets, the GSK option point is after results of a specific clinical trial. At the GSK option point, together with GSK we must engage in an option process for a specified period of time, at the end of which GSK may exercise its option. Generally, each party is responsible for its own cost and expense to conduct each collaboration program. Upon any such option exercise, GSK will be responsible for further development, at GSK's cost.

In April 2021, GSK exercised its option to the NY-ESO-1 TCR with Gen-R program. As a result of such option exercise, we will transition to GSK responsibility for future research and development of this program at its cost and expense.

For applications of our Epi-R technology to the NY-ESO-1 TCR, we have agreed with GSK to share responsibilities of development activities for the period between IND-enabling work and the GSK option point at the conclusion of initial clinical trials. During that period, we are responsible for ongoing research, process development and vector and cell manufacturing, while GSK is responsible for clinical trials. We share regulatory responsibilities with GSK; we are responsible for the product IND and GSK for the clinical protocol and associated regulatory filings.

For a specified time period, we are prohibited from working with third parties to develop or commercialize CAR or TCR T cell therapies, except (a) in China for non-GSK programs, (b) with entities such as research institutions, contractors and clinical sites that are not granted commercial rights, (c) for companies with supporting tools and (d) in programs for which the therapy targets one of the targets excluded from the GSK Agreement. Currently five targets are excluded, and we may exclude three additional targets during a specified period. In addition, there is a target-based exclusivity for so long as GSK is paying royalties on a product to that target.

We received an upfront payment of \$45.0 million from GSK under the GSK Agreement. In addition to the upfront payment, we are eligible to receive up to two one-time payments, totalling up to approximately \$200.0 million in aggregate for technology validation of Lyell's cell therapy innovations. For each cell therapy target for which there has been a joint collaboration program, Lyell also could receive up to approximately \$400.0 million in aggregate in development and sales milestones if the target is already within GSK's pipeline and meets certain criteria, up to approximately \$900.0 million in

aggregate in development and sales milestones for all other targets, and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK's pipeline and meet certain criteria, or from high single digit to low teens for all other targets. Royalties and milestones are paid once per target, even if there is more than one Lyell innovation applied to a T cell therapy directed to that target.

The GSK Agreement will expire on a product-by-product and country-by-country basis upon the latest of (a) the expiration of the last valid claim of the last to expire licensed patent covering such product in such country, (b) the expiration of all regulatory exclusivity for such product in such country, or (c) a specified period after the first commercial sale of such product in such country. GSK may terminate the GSK Agreement in its entirety or on a collaboration program-by-collaboration program basis for convenience or in its entirety upon a change of control of Lyell by a GSK competitor. Each party may terminate the GSK Agreement in its entirety or with respect to a collaboration program in the event of an uncured material breach by the other party or in its entirety for the other party's insolvency. We may terminate the GSK Agreement in the event of a patent challenge by GSK or specified third parties.

#### ***National Cancer Institute (NCI) License Agreement***

In December 2020, we entered into a license agreement with NCI that grants us a worldwide license to certain patent rights, and intellectual property rights related to certain know-how, to develop, make and commercialize licensed products and practice licensed processes for the treatment of human cancers, which license is (A) exclusive with respect to certain licensed patents for use in the field of (1) companion diagnostics for our T cell therapy products, (2) adoptive T cell therapy products generated from autologously derived, induced pluripotent stem cells, or (3) adoptive T cell therapy products isolated from autologously-derived and allogeneic-derived peripheral blood; (B) non-exclusive with respect to all licensed patents for use in the field of (4) autologous and allogeneic, adoptive T cell therapy products; and (C) non-exclusive with respect to the licensed know-how for use in the fields of (1) through (4). The licensed patents and licensed know-how covered are directed, in part, to thymic emigrant cells, hematopoietic progenitor cells, thymic organoid from human pluripotent stem cells, T cells, T memory stem cells, and their use for the treatment of cancer in humans. We may grant sublicenses under our license with NCI's written approval and, if the rights we are sublicensing are non-exclusive, they must be sublicensed in combination with certain other intellectual property. On or before the seventh anniversary of the agreement, it is the intention of NCI and us to enter into an amendment to the agreement, which amendment is intended to narrow our exclusive license for certain licensed patents to a defined list of cancer indications that meet certain criteria. Such amendment would also extend the term of our exclusive license to such licensed patents so that it would continue beyond such seventh anniversary until the expiration of the last to expire of such licensed patents.

We are obligated to use commercially reasonable efforts to develop, manufacture and sell licensed products and to adhere to an agreed-upon clinical development plan and performance milestones.

We paid to NCI an upfront payment of \$100,000. We have paid a prorated annual maintenance payment to NCI in the mid four figures and we also agreed to pay NCI future annual maintenance payments in the high five figures, which payments may be credited against earned royalties. We may be obligated to pay to NCI up to a maximum of \$3.1 million upon achievement of certain specified clinical and regulatory milestones. We may also be obligated to pay to NCI a maximum of \$12.0 million collectively for all licensed products upon our achievement of certain commercial milestones. In addition, the license agreement provides that we are required to pay to NCI low single-digit royalties on annual net sales of the licensed products.

The license agreement will expire on the expiration of the last to expire valid claim of the licensed patents. We may terminate the agreement at will, in its entirety, or on a patent-by-patent and country-by-country basis. NCI has the right to terminate the agreement in the event of our uncured breach or to terminate or modify the agreement, at NCI's option, for our failure to meet certain diligence obligations, in the event of certain false statements or omissions by us, for our violation of certain laws, for our material breach of a covenant in this agreement, if we fail to maintain reasonable availability of licensed products or licensed processes, if we cannot meet certain health and safety needs, or if we cannot reasonably justify a failure to comply with certain production requirements.

## **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 if appropriate, may seek 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.

As of April 30, 2021, our in-licensed and owned patent portfolio consists of approximately nine licensed U.S. issued patents, approximately 25 licensed U.S. pending patent applications, and approximately 27 owned U.S. pending patent applications (including two co-owned with collaboration partners), as well as approximately 19 licensed patents issued in jurisdictions outside of the United States, approximately 110 licensed patent applications pending in jurisdictions outside of the United States (including approximately five licensed pending Patent Cooperation Treaty (PCT) applications), and approximately two owned pending PCT application, that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. The patents and patent applications outside of the United States in our portfolio are held primarily in Europe, Canada, Japan and Australia. For information related to our in-licensed intellectual property, see the subsection titled under “—Collaboration, License and Success Payment Agreements.”

As for the product candidates and related manufacturing processes we develop and commercialize, in the normal course of business, we intend to pursue, when possible, composition, method of use, process, dosing and formulation patent protection. We may also pursue patent protection with respect to manufacturing and drug development processes and technology and with respect to our technology platform. When available to expand market exclusivity, our strategy is to obtain or license additional intellectual property related to current or contemplated development technology platforms, core elements of technology and/or product candidates.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest nonprovisional filing date. In the United States, a patent's term may be lengthened by patent term adjustment (PTA), which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In addition, in certain instances, the patent term of a U.S. patent that covers an FDA-approved drug may also be eligible for extension to recapture a portion of the term effectively lost as a result of clinical trials and the FDA regulatory review period, such extension is referred to as patent term extension (PTE). 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, 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. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug. 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.

In some instances, we submit patent applications directly to the USPTO as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding nonprovisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding nonprovisional application may be entitled to the benefit of the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs. Such delay may be useful in the event that we decide not to pursue prosecution of the application. While we intend to timely file nonprovisional patent applications relating to our provisional patent applications, we cannot predict whether any such nonprovisional patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. nonprovisional applications and PCT applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national or regional patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national or regional applications prior to having to incur the filing fees and prosecution costs. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national/regional-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organisation. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

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For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel, country-specific patent laws and our business model and needs are always considered. We may file patents containing claims for protection of all useful applications of our proprietary technology platforms and any products, as well as all new applications and/or uses we discover for existing technology platforms and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims, to help ensure that maximum coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including, for example, the extent of the prior art, the novelty and non-obviousness of the invention and the ability to satisfy the patent eligibility, written description and enablement or support requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and the scope of a patent can be reinterpreted or further altered even after issuance. Consequently, we may not ultimately obtain or maintain adequate patent protection for any of our product candidates or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection against competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. No consistent policy regarding the scope of claims allowable in patents in the field of cell and gene therapy has emerged in the United States. The patent situation outside of the United States is even more uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell, or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products, their use and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product candidates and practicing our proprietary technology. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. Our issued patents and those that may issue in the future may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates.

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Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. Patent disputes are sometimes interwoven into other business disputes.

As of March 31, 2021, our registered trademark portfolio currently contains approximately 27 registered trademarks and pending trademark applications, consisting of approximately four pending trademark applications in the United States, approximately two foreign pending trademark applications in Canada and India, and trademark registrations in the following countries through national filings: Australia, Brazil, China, European Union, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Republic of Korea, Switzerland and the United Kingdom.

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 this function to third parties. We intend to continue evaluating opportunities to work with partners that enhance our capabilities with respect to the development and commercialization of LYL797 or LYL845. In addition, we intend to commercialize our product candidates, if approved, in key markets either alone or with partners in order 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 preclinical, 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 preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements (GLP);
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an 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;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- 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 cGTPs requirements for the use of human cellular and tissue products, and of selected clinical investigation sites to assess compliance with GCPs;
- 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 preclinical testing stage. Preclinical tests, also referred to as nonclinical 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 preclinical 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.

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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 IBCs as set forth in the 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 independent 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 board, 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.

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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 preclinical 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 submitted 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 ten 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, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the 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 are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

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

#### ***Expedited Development and Review Programs***

The FDA offers a number of expedited development and review programs for qualifying product candidates. For example, the fast track program is intended to expedite or facilitate the process for reviewing new products that are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Specifically, new biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a fast track product at any time during the clinical development of the product. The sponsor of a fast track product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A fast track product may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete

application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

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

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

In 2017, the FDA established a new regenerative medicine advanced therapy (RMAT) designation, which is intended to facilitate an efficient development program for, and expedite review of, any drug or biologic that meets the following criteria: (i) the drug or biologic qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (ii) the drug or biologic is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (iii) preliminary clinical evidence indicates that the drug or biologic has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides all the benefits of breakthrough therapy designation, including more frequent meetings with the FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Product candidates granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical

benefit, or reliance upon data obtained from a meaningful number of clinical trial sites, including through expansion of trials to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through submission of clinical evidence, clinical trials, patient registries, or other sources of real-world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of such therapy. Fast track designation, breakthrough therapy 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 designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

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

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

### ***Post-Approval Requirements***

Biologics are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting,

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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 GMP 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 Affordable Care Act, signed into law in 2010, 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 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 preclinical 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 will 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.

In the European Union, for example, a clinical trial application (CTA) must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with the applicable requirements, clinical trial development may proceed. The requirements and process governing the conduct of clinical trials, are to a significant extent harmonized at the European Union-level but could vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. The way clinical trials are conducted in the European Union will undergo a major change when the Clinical Trial Regulation (Regulation (EU) 536/2014) comes into application, probably in 2022. The Regulation harmonizes the assessment and supervision processes for clinical trials throughout the European Union via a Clinical Trials Information System, which will contain a centralized European Union portal and database.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. Innovative products that target an unmet medical need may be eligible for a number of expedited development and review programs in the European Union, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the United States. Such products are generally eligible for accelerated assessment and may also benefit from different types of fast track approvals, such as a conditional marketing authorization or a marketing authorization under exceptional circumstances granted on the basis of less comprehensive clinical data than normally required (respectively in the likelihood that the sponsor will provide such data within an agreed timeframe or when comprehensive data cannot be obtained even after authorization).

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric trials. No extension to any supplementary protection certificate can be granted on the basis of pediatric trials for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than

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five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- The second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- The applicant consents to a second orphan medicinal product application; or
- The applicant cannot supply enough orphan medicinal product.

The medicinal products we are developing, which are based on genes, cells or tissues, may be considered advanced therapy medicinal products (ATMPs) in the European Union if they meet the scientific criteria for defining an ATMP. The principles of the aforementioned medicines legislation apply to ATMPs. All ATMPs must obtain a marketing authorization from the EMA and are regulated through the centralized authorization procedure. Regulation (EC) No 1394/2007 (the ATMP Regulation) provides specific incentives to accelerate the development of such products, including fee reductions for scientific advice, an ATMP classification procedure (for all developers) and a certification procedure for quality and preclinical data (for SMEs only).

If tissues and cells are being used as starting materials in a medicinal product we may also need to comply with the requirements of Directive 2004/23/EC (the European Tissues and Cells Directive) covering standards for donation, procurement and testing, processing, preservation, storage and distribution of human tissues and cells, as well as its technical implementing directives; and Directive 2015/566, as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.

In the European Union, early access mechanisms for innovative medicines (such as compassionate use programs and named patient supplies), pricing and reimbursement, and promotion and advertising are subject to national regulations and oversight by national competent authorities and therefore significantly vary from country to country.

Sanctions for non-compliance with the aforementioned requirements, which may include administrative and criminal penalties, are generally determined and enforced at national level. However, under the European Union financial penalties regime, the EMA can investigate and report on alleged breaches of the European Union pharmaceutical rules by holders of a marketing authorization for centrally authorized medicinal products and the European Commission could adopt decisions imposing significant financial penalties on infringing marketing authorization holders.

The United Kingdom left the European Union on January 31, 2020. Following the Transition Period which ended on December 31, 2020, Brexit could materially impact the regulatory regime with

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respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom in the coming years.

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

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

### ***Other Healthcare Laws***

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, sell, market and distribute any products for which we obtain marketing approval. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security, price reporting and physician and other health care provider transparency laws and regulations. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

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

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

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

HIPAA also created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) annually report information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and certain ownership and investment interests held by these healthcare providers and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

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. These third-party payors are increasingly reducing coverage and reimbursement for medical products, drugs and services. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

### **Healthcare Reform**

In the United States, in March 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations;
- required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell "branded prescription drugs" to specified federal government programs.
- expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, the Tax Act was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA and our business.

Other legislative changes have also been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers,

including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which has resulted in several Congressional inquiries and proposed federal legislation, as well as state efforts, designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The likelihood of success of these and other measures initiated by the former Trump administration is uncertain, particularly in light of the new Biden administration. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We anticipate that these new laws will result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products (if approved). In addition, it is possible that there will be further legislation or regulation that could harm our business, financial condition and results of operations. For example, it is possible that additional governmental action is taken in response to address the COVID-19 pandemic.

#### ***Other Privacy and Security Laws***

We may become subject to privacy laws in the jurisdictions in which we are established or in which we sell or market our products or run clinical trials. For example, in Europe we may be subject to Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) in relation to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). The GDPR is directly applicable in each European Union Member State, however, it provides that European Union Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business.

The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines pseudonymized (i.e., key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. We are subject to the supervision of local data protection authorities in those European Union jurisdictions where we are established or otherwise subject to the GDPR. Fines for certain breaches of the GDPR are significant: up to the greater of €20 million or 4% of total global annual turnover. Further, following the withdrawal of the United Kingdom from the European Union on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and the European Union, we will have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, each regime having the ability to fine up to the greater of €20 million/ £17 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, including how data transfers between European Union member states and the United Kingdom will be treated. These changes may lead to additional compliance costs and could increase our overall risk. In addition to the foregoing, a breach of the GDPR or other applicable privacy and data protection laws and regulations could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, or potential civil claims including class action type litigation.

In addition, the GDPR includes restrictions on cross-border data transfers. Certain aspects of cross-border data transfers under the GDPR are uncertain as the result of legal proceedings in the European Union, including a recent decision by the Court of Justice for the European Union that invalidated the EU-U.S. Privacy Shield and, to some extent, called into question the efficacy and legality of using standard contract clauses. This may increase the complexity of transferring personal data across borders. The GDPR will increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. We are also subject to European Union rules with respect to cross-border transfers of personal data out of the European Union and EEA. Recent legal developments in the European Union have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. On July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy, subject to certain conditions, of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism), future regulatory guidance could result in changes to the use of standard contractual clauses. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Further, the vote in the United Kingdom in favor of exiting the European Union, referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. Specifically, while the Data Protection Act of 2018, which “implements” and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, aspects of data protection in the United Kingdom, such as the transfer of data from the EEA to the United Kingdom, remain uncertain. During the period of “transition” (i.e., until December 31, 2020), European Union law



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will continue to apply in the United Kingdom, including the GDPR, after which the GDPR will be converted into United Kingdom law. Beginning in 2021, the United Kingdom will be a “third country” under the GDPR.

In addition, California recently enacted the California Consumer Privacy Act (CCPA) which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling certain personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt-out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA became effective on January 1, 2020, and (i) allows enforcement by the California Attorney General, with fines set at \$2,500 per violation (i.e., per person) or \$7,500 per intentional violation and (ii) authorizes private lawsuits to recover statutory damages for certain data breaches. In addition, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we would become subject if it is enacted. The CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Further, the California Privacy Rights Act (the CPRA) recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

### ***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 the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

### **Employees and Human Capital Resources**

As of March 31, 2021, we had 188 full-time employees and two part-time employees, consisting of clinical, research, operations, regulatory, finance and business development personnel. 53 of our employees hold Ph.D. or M.D. degrees. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our continued ability to attract, retain and motivate exceptional employees is vital to ensuring our long-term competitive advantage. Our employees are critical to our long-term

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success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- **Talent development, compensation and retention** – We strive to provide our employees with a rewarding work environment, including the opportunity for growth, success and professional development. We provide a competitive compensation and benefits package, including broad-based bonus and equity plans, a 401(k) plan and a multi-layered recognition program – all designed to attract and retain a skilled and diverse workforce.
- **Health and safety** – We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, wellness days and other additional benefits which are intended to assist employees to manage their well-being.
- **Inclusion and diversity** – We are committed to efforts to increase diversity and foster an inclusive work environment that supports our workforce.

One of our top priorities during the ongoing COVID-19 pandemic remains protecting the health and well-being of our employees, customers, partners and communities. We have closely monitored the COVID-19 pandemic and have strived to follow recommended containment and mitigation measures, including the guidance from the CDC, the states of California and Washington and applicable counties. For most of the pandemic, essential laboratory, manufacturing and support employees worked in our facilities to continue and progress experiments and manufacturing related activities. We implemented preventative measures at our facilities in order to minimize the risk of employees' exposure to the virus, including the following requirements: that each employee who entered a facility agreed to comply with social distancing, frequent hand washing and the requirement to wear masks. We also increased cleaning of high touch areas, provided hand sanitizing stations and implemented an employee questionnaire to ensure employee health status and to provide for limited on-site tracing if needed. Finally, commencing in early March 2020, we suspended all non-essential business travel and directed all employees who are not essential laboratory or manufacturing personnel to work from home. We expect to continue such measures for the near foreseeable future. We will continue to actively monitor the situation related to the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state, or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

### **Facilities**

#### **California**

Our current corporate headquarters are located in South San Francisco, California, where we lease approximately 40,000 square feet of office and laboratory space pursuant to a lease agreement which commenced on January 14, 2019 and expires on December 17, 2021. Additionally, we lease approximately 108,000 square feet of office and laboratory space in South San Francisco, California, which will be the site of our future corporate headquarters, pursuant to a lease agreement which commenced on February 1, 2020 and expires on March 31, 2031.

#### **Washington**

We lease approximately 34,000 square feet of office and laboratory space in Seattle, Washington, pursuant to a lease agreement which commenced on January 1, 2019 and expires on December 31, 2028. We lease approximately 73,000 square feet of manufacturing, office and laboratory space in Bothell, Washington, pursuant to a lease agreement which commenced on February 1, 2020 and expires on May 31, 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.

### ***COVID-19 Impact on Facilities***

We are partially operating virtually to align with local COVID-19 guidelines, which we believe meets our operational needs for the time being as a preclinical-stage organization. To date, we have not experienced any material impact on our ability to operate our business. We plan to periodically reassess our facility needs.

### **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. For example, although not material to our operations, in February 2021 we filed a demand for arbitration to, among other things, seek rescission of the agreements we entered into with PACT in June 2020 and recover the consideration paid to PACT thereunder. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm 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, such proceedings or claims 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.

**MANAGEMENT****Executive Officers, Management and Directors**

The following table sets forth information regarding our executive officers, management and directors as of June 9, 2021.

<b>Name</b>	<b>Age</b>	<b>Position</b>
<b>Executive Officers:</b>		
Richard D. Klausner, M.D.	69	Executive Chairman and Director
Elizabeth Homans	55	Chief Executive Officer and Director
Charles Newton	51	Chief Financial Officer
Stephen Hill	50	Chief Technical Operations Officer
Heather Turner	48	Chief General Counsel
<b>Management:</b>		
Nicholas Restifo, M.D.	60	Executive Vice President, Research
Tina Albertson, M.D., Ph.D.	48	Chief Medical Officer and Head of Development
Richard Goold, Ph.D.	61	Chief Information Officer
Lisa Ryan	54	Chief People Officer
<b>Non-Employee Directors:</b>		
Hans Bishop(2)	57	Director
Otis Brawley, M.D.(2)(4)	61	Director
Catherine Friedman(1)(3)	60	Director
Elizabeth Nabel, M.D.(3)(4)	69	Director
Robert Nelsen(1)	58	Director
William Rieflin(1)(3)	61	Director
Lynn Seely, M.D.(5)	62	Director

(1) Member of the compensation committee.

(2) Member of the nominating and corporate governance committee.

(3) Member of the audit committee.

(4) Appointed April 2021.

(5) Appointed May 2021.

**Executive Officers**

**Richard D. Klausner, M.D.** is our founder and current Executive Chairman and was previously our Chief Executive Officer from September 2018 to July 2020. He previously served on the board of directors of Juno Therapeutics, a Bristol-Myers Squibb company that he founded. Since January 2016, Dr. Klausner has served as a member of the board of directors of GRAIL, a private life sciences company that he founded. He is also the co-founder and Executive Chairman of Mindstrong, co-founder of Lifemine Therapeutics, Executive Chairman of Wisdo, Chairman of Sonoma Biotherapeutics and a member of the board of directors of X-Tremity Prosthetics. From September 2013 to February 2016, Dr. Klausner served in multiple senior leadership positions at Illumina Corporation, including as Senior Vice President, Chief Medical Officer and Chief Opportunity Officer. He currently chairs the Grand Challenges in Cancer program of Cancer Research UK. Previously he served as managing partner of the venture capital firm, The Column Group, was the Executive Director for Global Health of the Bill and Melinda Gates Foundation from 2002 to 2005 and was the eleventh director of the National Cancer Institute between 1995 and 2001. Dr. Klausner received an M.D. from Duke Medical School and a B.S. from Yale University. We believe that Dr. Klausner's scientific and medical expertise, particularly in cell biology, molecular biology and cancer, as well as his industry, academic and public service leadership roles, make him an appropriate member of our board of directors.

**Elizabeth Homans** has served as our Chief Executive Officer and member of our board of directors since August 2020. From September 2018 to August 2020, she served as our President and

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the operational lead as we grew in size, scope and ambition. From July 2009 to May 2018, Ms. Homans served in multiple senior leadership positions at Genentech, including Vice President, U.S. Sales and Marketing Leader for Breast Cancer, Vice President, U.S. Sales and Marketing Leader for Xolair, Vice President, Global Regulatory Operations Leader and Vice President, Global Product Strategy, HER2 Franchise. From May 2004 through November 2007, Ms. Homans served as Executive Director, Project Leadership and Portfolio Management at Jazz Pharmaceuticals, Inc. Ms. Homans received an M.B.A. from Columbia University in the City of New York and a B.A. in German and Economics from Bates University. We believe that Ms. Homans' extensive work in high-growth biotechnology companies makes her an appropriate member of our board of directors.

**Charles Newton** has served as our Chief Financial Officer since February 2021. From November 2015 to February 2021, he served as Managing Director & Co-Head of Healthcare Investment Banking in the Americas at Bank of America. From September 2010 to November 2015, Mr. Newton served as Managing Director at Credit Suisse where his last position was Co-Head of Healthcare Investment Banking in the Americas. From June 1996 to September 2010, he served in the investment banking division at Morgan Stanley where his last position was Managing Director and Head of Western Region Healthcare Investment Banking. Mr. Newton received an M.B.A. from The Tuck School at Dartmouth College and a B.S. in Finance from Miami University.

**Stephen Hill** has served as our Chief Technical Operations Officer since June 2019. From June 2018 to June 2019, he was Senior Vice President, Head of Global Biologics Operations and from March 2016 to June 2018 as Vice President, Site Head at AstraZeneca, a publicly-traded company. From December 2012 through February 2016, Mr. Hill served in multiple positions at Amgen, including as Vice President, Bulk Manufacturing, Executive Director, Plant Manager and Executive Director, Manufacturing Technologies. Mr. Hill received an M.B.A. and a B.S. in Microbiology and B.A. in Political Science from the University of Washington.

**Heather Turner** has served as our Chief General Counsel since December 2019 when she was promoted from our General Counsel, a position she served from April 2019 to December 2019. From February 2018 to March 2019, she served as Executive Vice President, General Counsel and Secretary of Sangamo Therapeutics, Inc., a publicly-traded biotechnology company. From July 2015 to February 2018, Ms. Turner served as Executive Vice President, General Counsel and Head of Portfolio Strategy at Atara Biotherapeutics, Inc., a publicly-traded cell therapy company. From June 2007 to June 2015, she served as General Counsel and Secretary of Orexigen Therapeutics, Inc., a publicly-traded small molecule company. Ms. Turner received a J.D. from UCLA School of Law and a B.A. in Environmental Studies from University of California, Santa Barbara.

## **Management**

**Nicholas Restifo, M.D.** has served as our Executive Vice President, Research since July 2019. From July 1989 to July 2019, Dr. Restifo served in multiple positions at the National Cancer Institute, including as Head of the Center of Excellence in Immunology and Director of the 'Cancer Moonshot' in Adoptive Cellular Therapy. Dr. Restifo received an M.D. from New York University and his B.S. in Natural Sciences from Johns Hopkins University.

**Tina Albertson, M.D., Ph.D.** has served as our Chief Medical Officer and Head of Development since July 2020. From January 2015 to April 2020, Dr. Albertson was Vice President of Global Drug Development at Juno Therapeutics, a Bristol-Myers Squibb company. From October 2010 to January 2015, Dr. Albertson served as Medical Director at Seagen, a publicly-traded biotechnology company. Dr. Albertson also completed a pediatric oncology fellowship at University of Washington. Dr. Albertson received a Ph.D. in Cancer Biology from University of Washington, an M.D. from Stanford University and a B.S. in Biology from University of Oregon.

**Richard Goold, Ph.D.** has served as our Chief Information Officer since April 2019. From January 2019 to April 2019, he served as our Senior Vice President of Information Sciences. From January 2010 to December 2018, Dr. Goold served as Chief Executive Officer of Station X, a human genome data analytics company that he founded and that was acquired by Roche. From November 2002 to April 2004, Dr. Goold was the Chief Genomics Officer at Incyte Corporation. From February 2000 to October 2002, Dr. Goold was Chief Executive Officer of Prospect Genomics, a computational genomics company that he founded and that was acquired by Structural GenomiX. Dr. Goold was also a founding scientist and Project Lead at the UCSF/Stanford Human Genome Center. Dr. Goold received a Ph.D. in Medical Biochemistry from the University of Cape Town and a M.Pharm. in Pharmacology and a B.Pharm. from Rhodes University.

**Lisa Ryan** has served as our Chief People Officer since December 2020. From December 2018 to December 2020, she served as our Vice President of People. From November 2008 through December 2018, Ms. Ryan served in multiple positions at Genentech, including Global Human Resources Director, Product Development, Clinical Operations; Director, Human Resources for Biologics; Associate Director, Human Resources, SSF Production and DS/DP Quality; Group Product Manager, Business Operations – Virology and Specialty Care and Senior Human Resources Business Partner, US Commercial. From July 2004 to January 2008, Ms. Ryan served as Vice President/Group Director of Talent Operations at Digitas, a digital and direct advertising agency that is part of the Publicis group. Lisa received an M.B.A. from Suffolk University and a B.A. in Psychology from Boston College.

#### **Non-Employee Directors**

**Hans Bishop** has served as a member of our board of directors since August 2018. Since 2019, Mr. Bishop has served as the Chief Executive Officer of GRAIL, Inc., a private life sciences company. From July 2013 to March 2018, Mr. Bishop served as President and Chief Executive Officer at Juno Therapeutics, a company that he founded and that was acquired by Celgene. From February 2012 through July 2013, Mr. Bishop served as Executive in Residence at Warburg Pincus, a multinational private equity firm. From January 2010 to September 2011, Mr. Bishop served as Executive Vice President and Chief Operating Officer at Dendreon, Inc., a publicly-traded cancer immunotherapy company. From December 2006 to January 2010, Mr. Bishop served as President of Specialty Medicine at Bayer Healthcare, a publicly-traded company. From January 2004 to August 2006, he served in multiple leadership positions at Chiron Corporation, a multinational biotechnology company, including as Senior Vice President of Global Commercial Operations and Vice President and General Manager of European Biopharmaceuticals. He currently serves as the Chairman of Sana Biotechnology since October 2018 and as a director of Agilent Technologies since July 2017 and JW Therapeutics, all of which are publicly-traded companies, and previously served as a director of Celgene from June 2018 to November 2019. Mr. Bishop received a B.A. in Chemistry from Brunel University in London. We believe that Mr. Bishop's more than 30 years of experience in the biotechnology industry and chemistry studies make him an appropriate member of our board of directors.

**Otis Brawley, M.D.** has served as a member of our board of directors since April 2021. Dr. Brawley has served as a Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University since January 2019 and as a member of the board of directors of PDS Biotechnology Corporation, a publicly-traded biotechnology company, since November 2020. From April 2007 to December 2018, he served as the Chief Medical and Scientific Officer of American Cancer Society. From January 2002 to August 2007, he was director of the Georgia Cancer Center at Grady Memorial Hospital. From April 2001 to December 2018, he served as professor of hematology, oncology, medicine and epidemiology at Emory University. Dr. Brawley received an M.D. from the University of Chicago, Pritzker School of Medicine and a B.S. in Chemistry from the University of

Chicago. He completed an internal medicine residency at Case-Western Reserve University and a fellowship in medical oncology at the National Cancer Institute. He is board certified in internal medicine and medical oncology. We believe that Dr. Brawley's education and work in oncology makes him an appropriate member of our board of directors.

**Catherine Friedman** has served as a member of our board of directors since August 2018. Ms. Friedman is an independent financial consultant who has been serving public and private companies in the life sciences industry since 2006. Previously, Ms. Friedman held numerous executive positions during a 23-year investment banking career with Morgan Stanley & Co., an investment bank, including managing director, head of West Coast Healthcare and co-head of the Biotechnology Practice. Ms. Friedman is the chair of the board of directors for GRAIL, Inc. since August 2017, and also serves as a member of the boards of Altaba Inc. (formerly Yahoo! Inc.) since March 2016, Radius Health, Inc. since August 2015, Seer, Inc. since September 2020, Vividion Therapeutics, Inc. since March 2021 and Revolution Healthcare Acquisition Corp since February 2021, and previously served on the board of directors of Innoviva, Inc., a publicly-traded company. Ms. Friedman is a trustee of The Darden School Foundation at the University of Virginia. Ms. Friedman holds a B.A. in economics from Harvard University and an MBA from The University of Virginia's Darden School of Business. We believe that Ms. Friedman's extensive financial experience and work for biotechnology companies make her an appropriate member of our board of directors.

**Elizabeth Nabel, M.D.** has served as a member of our board of directors since April 2021. Dr. Nabel served as a member of the board of directors of Moderna, Inc., a publicly-traded pharmaceutical company, from December 2015 to July 2020, and was reappointed to Moderna's board in March 2021. Since March 1, 2021, Dr. Nabel is Executive Vice President for Strategy at ModeX Therapeutics, a new biotechnology company focused on immunotherapies for cancer and viral diseases. Through February 2021, Dr. Nabel served as the President of Harvard University-affiliated Brigham Health, which includes Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, and the Brigham and Women's Physician Organization, a position she held from January 2010. Dr. Nabel was also a Professor of Medicine January 2010 to February 2021 and currently is a Professor of Medicine emeritus at Harvard Medical School. Prior to joining Brigham Health, Dr. Nabel held a variety of roles, including Director, at the National Heart, Lung and Blood Institute at the National Institutes of Health, a federal agency funding research, training and education programs to promote the prevention and treatment of heart, lung and blood diseases, from September 1999 to November 2009. She is an elected member of the National Academy of Medicine of the National Academy of Sciences. Dr. Nabel received an M.D. from Weill Cornell Medical College and a B.A. in psychology from St. Olaf College. We believe that Dr. Nabel's education and work in medicine makes her an appropriate member of our board of directors.

**Robert Nelsen** has served as a member of our board of directors since September 2018. Since 1986, Mr. Nelsen has served as Co-founder and Managing Director of ARCH Venture Partners, a venture capital firm focused on early-stage technology companies. Mr. Nelsen is a member of the board of directors of Beam Therapeutics, Denali Therapeutics, Hua Medicine, Karuna Pharmaceuticals, Sana Biotechnology, Revolution Healthcare Acquisition Corp. and Vir Biotechnology, all of which are publicly-traded companies, and serves as the Chairman of Hua Medicine. Previously, Mr. Nelsen served on the boards of Juno Therapeutics from August 2013 to March 2018, Syros Pharmaceuticals from August 2012 to June 2018, Sienna Biopharmaceuticals from August 2015 to October 2018, Agios Pharmaceuticals from December 2007 to June 2017, KYTHERA Biopharmaceuticals from January 2006 to December 2014, Adolor Corporation from November 1994 to May 2008, Illumina Corporation from June 1998 to August 2006, Fate Therapeutics from September 2007 to June 2014, deCODE genetics from August 1996 to November 2001, NeurogesX from July 2000 to May 2013, Bellerophon Therapeutics from February 2014 to February 2015, Sage Therapeutics from September 2013 to March 2016 and Caliper Life Sciences from April 1996 to

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December 1999. From 2004 to 2014, Mr. Nelsen served as trustee of the Fred Hutchinson Cancer Research Center. Mr. Nelsen received an M.B.A. from the University of Chicago and a B.S. degree with majors in Economics and Biology from the University of Puget Sound. We believe that Mr. Nelsen's experience as a venture capitalist building and serving on the boards of many public and private emerging companies, including multiple life sciences, biotechnology and pharmaceutical companies, makes him an appropriate member of our board of directors.

**William Rieflin** has served as a member of our board of directors since May 2020. From September 2010 to September 2018, he served as the Chief Executive Officer of NGM Biopharmaceuticals, Inc. Since April 2015, Mr. Rieflin has served on the Board, and has been Chairman of the Board since June 2019, at RAPT Therapeutics, Inc., a publicly-traded biopharmaceutical company and since September 2018 he has served as Executive Chairman of the Board at NGM Biopharmaceuticals, Inc., a publicly-traded biotechnology company where he also previously served as a member of the board since 2010. Mr. Rieflin previously served on the board of directors of Anacor Pharmaceuticals, Inc., a pharmaceutical company, from April 2011 to June 2016 and of XenoPort, Inc. from September 2010 to July 2016. Mr. Rieflin also served as a board member of Flexus Biosciences until its acquisition in 2015. From August 2004 until September 2010, he served as President of XenoPort, Inc., a publicly-traded company. He currently serves on the board of directors of Kallyope, Inc. and Lycia Therapeutics, Inc., both privately-held companies. Mr. Rieflin received an M.B.A. from the University of Chicago Booth Graduate School of Business, a J.D. from Stanford Law School and a B.S. in Industrial and Labor Relations from Cornell University. We believe that Mr. Rieflin's extensive experience in the biopharmaceutical industry, his industry expertise and financial knowledge and his experience as a member of the board of directors of other public companies makes him an appropriate member of our board of directors.

**Lynn Seely, M.D.** has served as a member of our board of directors since May 2021. Dr. Seely currently serves as a member of the board of directors of Blueprint Medicines Corp., a publicly-traded pharmaceutical company. From June 2016 to January 2021, Dr. Seely served as President, Chief Executive Officer and a member of the board of directors of Myovant Sciences, a biotechnology company. From March 2005 to October 2015, Dr. Seely served as Senior Vice President and Chief Medical Officer of Medivation, a biotechnology company. Dr. Seely received an M.D. from the University of Oklahoma College of Medicine and a B.A. in Journalism from the University of Oklahoma. Dr. Seely completed her residency and served as chief resident in internal medicine at Yale-New Haven Hospital, and she completed her fellowship in endocrinology and metabolism at the University of California, San Diego. We believe that Dr. Seely's education and work in healthcare and life sciences makes her an appropriate member of our board of directors.

### **Composition of Our Board of Directors**

Our business and affairs are organized under the direction of our board of directors, which currently consists of nine members with two vacancies. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Certain members of our board of directors were elected under the provisions of our Amended and Restated Voting Agreement entered into in April 2021 (the Voting Agreement), which will terminate upon the closing of this offering. Under the terms of our Voting Agreement, the stockholders who are party to the Voting Agreement have agreed to vote their respective shares to elect: (i) two directors designated by ARCH Venture Fund IX, L.P. and ARCH Venture Fund IX Overage, L.P., currently Hans Bishop and Robert Nelsen; (ii) one director who shall be our then-current Chief Executive Officer, currently Elizabeth Homans; (iii) one director who shall be our then-current Executive Chairman, currently Richard D. Klausner, M.D.; and (iv) five directors who are not our employees or affiliates, with such individuals to be designated by mutual agreement of our board of directors, currently Otis



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Brawley, Catherine Friedman, William Rieflin, Elizabeth Nabel and one vacancy. The Voting Agreement will terminate upon the closing of this offering, and upon the closing of the offering no stockholder will have any special rights regarding the election or designation of the members of our board of directors. Our current directors elected to our board of directors pursuant to the Voting Agreement will continue to serve as directors until their successors are duly elected and qualified by holders of our common stock.

Our board of directors may establish the authorized number of directors from time to time by resolution. In accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- the Class I directors will be Hans Bishop, Catherine Friedman and Robert Nelsen, and their terms will expire at the annual meeting of stockholders to be held in 2022;
- the Class II directors will be Richard Klausner, Otis Brawley and William Rieflin, and their terms will expire at the annual meeting of stockholders to be held in 2023; and
- the Class III directors will be Elizabeth Homans, Lynn Seely and Elizabeth Nabel, and their terms will expire at the annual meeting of stockholders to be held in 2024.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

### **Director Independence**

Under the Nasdaq Listing Rules independent directors must comprise a majority of our board of directors as a listed company within one year of the listing date.

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning her or his background, employment and affiliations, including family relationships, our board of directors has determined that none of our directors, other than Dr. Klausner and Ms. Homans, has any relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our board of directors has determined that Dr. Klausner and Ms. Homans, by virtue of their positions as our Executive Chairman and Chief Executive Officer, respectively, are not independent under applicable rules and regulations of the U.S. Securities and Exchange Commission (the SEC) and the Nasdaq Listing Rules. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director and the transactions described in the section titled "Certain Relationships and Related Person Transactions."

### **Committees of Our Board of Directors**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has adopted a

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written charter that satisfies the rules and regulation of the SEC and the Nasdaq Listing Rules, which we will post to our website at [www.lyell.com](http://www.lyell.com) upon the closing of this offering. Our board of directors may establish other committees as it deems necessary or appropriate from time to time.

### **Audit Committee**

Our audit committee currently consists of William Rieflin, Catherine Friedman and Elizabeth Nabel, each of whom our board of directors has determined satisfies the independence requirements under Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Securities Exchange Act of 1934, as amended (Exchange Act). The chair of our audit committee is William Rieflin, who our board of directors has determined is an "audit committee financial expert" within the meaning of SEC regulations. Each member of our audit committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the board of directors has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the audit committee is to discharge the responsibilities of our board of directors with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our audit committee include:

- helping our board of directors oversee our corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and
- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

### **Compensation Committee**

Our compensation committee currently consists of Catherine Friedman, Robert Nelsen and William Rieflin. The chair of our compensation committee is Catherine Friedman. Our board of directors has determined that each member of our compensation committee is independent under the Nasdaq Listing Rules and as a "non-employee director" as defined in Rule 16b-3 promulgated under the Exchange Act.

The primary purpose of our compensation committee is to discharge the responsibilities of our board of directors in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers, directors and other senior management, as appropriate. Specific responsibilities of our compensation committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management;

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- reviewing and recommending to our board of directors the compensation paid to our directors;
- reviewing and approving the compensation arrangements with our executive officers and other senior management;
- administering our equity incentive plans and other benefit programs;
- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;
- reviewing, evaluating and recommending to our board of directors succession plans for our executive officers; and
- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation strategy, including base salary, incentive compensation and equity-based grants, to assure that it promotes stockholder interests and supports our strategic and tactical objectives, and that it provides for appropriate rewards and incentives for our management and employees.

### ***Nominating and Corporate Governance Committee***

Our nominating and corporate governance committee consists of Otis Brawley and Hans Bishop. The chair of our nominating and corporate governance committee is Otis Brawley. Our board of directors has determined that each member of the nominating and corporate governance committee is independent under the Nasdaq Listing Rules, a non-employee director, and free from any relationship that would interfere with the exercise of his or her independent judgment.

Specific responsibilities of our nominating and corporate governance committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on our board of directors;
- considering and making recommendations to our board of directors regarding the composition and chairmanship of the committees of our board of directors;
- instituting plans or programs for the continuing education of our board of directors and orientation of new directors;
- developing and making recommendations to our board of directors regarding corporate governance guidelines and matters; and
- overseeing periodic evaluations of the board of directors' performance, including committees of the board of directors and management.

### **Code of Business Conduct and Ethics**

In connection with this offering, we adopted a written Code of Business Conduct and Ethics that applies to all 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 will be posted on our website at [www.lyell.com](http://www.lyell.com). We intend to disclose on our website any future amendments of our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics. Information contained on, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only an inactive textual reference.

## Compensation Committee Interlocks and Insider Participation

None of the members of the compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last calendar year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

## Non-Employee Director Compensation

During the year ended December 31, 2020, each of the following individuals served on our board of directors as non-employee directors: Hans Bishop, Catherine Friedman, Robert Nelsen and William Rieflin.

The following table presents all of the compensation awarded to or earned by or paid to our named non-employee directors during the fiscal year ended December 31, 2020.

Name	Fees Earned or Paid in Cash (\$)	Option Awards \$(1)	Total (\$)
Hans Bishop	—	—	—
Catherine Friedman	125,842	\$2,363,999(2)	\$2,489,841
Robert Nelsen	—	—	—
William Rieflin(3)	30,935	\$1,479,796(4)	\$1,510,731

(1) All of the option awards were granted under the 2018 Plan, the terms of which plan are described below under “Executive Compensation—Equity Benefit Plans—2018 Equity Incentive Plan.” The amounts shown represent the grant date fair values of option awards granted in 2020 as computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) Topic 718. See Note 12, *Stock-Based Compensation*, to our audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumption used in the calculation. As of December 31, 2020, Mr. Bishop, Ms. Friedman and Mr. Rieflin held options to purchase 1,163,038, 650,000 and 400,000 shares of common stock, respectively. As of December 31, 2020, Mr. Bishop and Ms. Friedman held 1,250,000 and 41,667 shares of common stock, respectively, that were subject to a right of repurchase in favor of the company at \$0.0001 per share that becomes exercisable in the event the non-employee director terminates service with the company for any reason. No other non-employee director held any option or stock awards as of December 31, 2020.

(2) In accordance with our non-employee director compensation policy, Ms. Friedman was granted the option to purchase 400,000 shares of common stock on May 19, 2020. Ms. Friedman was also granted the option to purchase 250,000 shares of common stock on December 17, 2020 in connection with her services as a director and the chair of the compensation committee. Each grant vests monthly over three years.

(3) Mr. Rieflin was appointed to our board of directors effective as of May 19, 2020.

(4) In accordance with our non-employee director compensation policy, Mr. Rieflin was granted the option to purchase 400,000 shares of common stock on May 19, 2020 which vests monthly over three years.

Mr. Bishop and Mr. Nelsen were not compensated for their service on our board of directors during the year ended December 31, 2020. Ms. Homans and Dr. Klausner each also served on our board of directors during the year ended December 31, 2020, but neither received any additional compensation for their service as a director. See the section titled “Executive Compensation” for more information regarding the compensation earned by Ms. Homans and Dr. Klausner.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

In November 2019, our board of directors adopted our Director Compensation Policy for our nonemployee directors (the Policy). In April 2021, our board of directors adopted an amended and restated form of the Policy, to be effective in connection with the consummation of this offering (the Amended Policy). The Policy

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provides, and the Amended Policy will provide, that our non-employee directors will receive the following compensation for service on our board of directors:

- an annual cash retainer of \$50,000 (which is the same in the case of the Amended Policy) for all non-employee directors other than the lead director/chair of our board of directors;
- an annual cash retainer of \$10,000 (or \$30,000 in the case of the Amended Policy) for the chair of our board of directors (in addition to the annual cash retainer above);
- an additional annual cash retainer of \$7,500, \$5,000 and \$2,500 (or \$15,000, \$12,000 and \$10,000 in the case of the Amended Policy) or service as chair of the audit committee, compensation committee and the nominating and corporate governance committee, respectively (other than for the chair of any such committee);
- an additional annual cash retainer of \$3,500, \$2,500 and \$1,500 (or \$7,500, \$6,000 and \$5,000 in the case of the Amended Policy) for service as a member of the audit committee, compensation committee and the nominating and corporate governance committee, respectively; and
- an appointment option grant, for new non-employee directors, to purchase 400,000 shares of our common stock (or 100,000 shares of our common stock in the case of our Amended Policy with an annual option grant of 50,000 shares of our common stock), vesting in 36 equal monthly installments measured from the date the non-employee director is first elected to our board of directors (or generally on the earlier of the next annual meeting or the first anniversary of the date of grant, in the case of annual grants), subject to the non-employee director's continued service on each applicable vesting date.

Each appointment option grant and annual option grant was or will be granted under our 2018 Equity Incentive Plan (2018 Plan), or following the completion of this offering, under our 2021 Plan, and our then current standard form of option agreement under such plan. These options have or will have a maximum term of 10 years from their grant date and a per share exercise price equal to at least 100% of the fair market value of a share of our common stock on the option's grant date. In the event of our acquisition (as defined in our 2018 Plan) or change in control (as defined in our 2021 Plan), each non-employee director's then-outstanding equity awards granted under the Policy (in the case of an acquisition) or the Amended Policy (in the case of a change in control) will become fully vested immediately prior to the closing of the acquisition or change in control, as applicable, provided that he or she remains in continuous service until immediately prior to the closing of the acquisition or change in control, as applicable.

## EXECUTIVE COMPENSATION

Our named executive officers for the year ended December 31, 2020 were:

- Richard Klausner, M.D., our Executive Chairman and former Chief Executive Officer;
- Elizabeth Homans, our Chief Executive Officer;
- Stephen Hill, our Chief Technical Operations Officer; and
- Heather Turner, our Chief General Counsel.

### Summary Compensation Table

The following table presents all of the compensation awarded to or earned by or paid to our named executive officers during the fiscal year ended December 31, 2020.

Name and Principal Position	Fiscal Year	Salary (\$)	Bonus (\$)(1)	Stock Awards (\$)	Option Awards (\$)(2)	Non-Equity Incentive Plan Compensation (\$)(3)	All Other Compensation (\$)(4)	Total (\$)
Richard Klausner, M.D. <i>Executive Chairman and former Chief Executive Officer</i> (5)	2020	427,147	738,712	20,799,288(6)	16,618,943(6)	261,288	6,858	38,852,236
Elizabeth Homans <i>Chief Executive Officer</i>	2020	493,981	327,250	—	17,730,122(7)	309,000	8,922	18,869,275
Stephen Hill <i>Chief Technical Operations Officer</i>	2020	441,343	54,984	—	2,139,150	219,938	6,317	2,861,732
Heather Turner <i>Chief General Counsel</i>	2020	441,343	254,984	—	2,526,150	219,938	810	3,443,225

- (1) The amounts shown represent discretionary bonuses earned by Dr. Klausner, Ms. Homans, Mr. Hill and Ms. Turner as recognition of accomplishing certain achievements as further described in detail below under the subsection titled “—Narrative to Summary Compensation Table—Bonus Compensation.”
- (2) Except as otherwise noted, the amounts shown represent the grant date fair values of option awards granted in 2020 as computed in accordance with FASB ASC Topic 718. See Note 12, *Stock-Based Compensation*, to our audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumption used in the calculation. All of the option awards were granted under the 2018 Plan, the terms of which plan are described below under “—Equity Benefit Plans—2018 Equity Incentive Plan.”
- (3) The amounts shown represent the annual performance-based cash bonus earned by our named executive officers based on the achievement of certain corporate performance objectives during 2020 as described further under the subsection titled “—Narrative to Summary Compensation Table—Bonus Compensation.” These amounts were paid in early 2021.
- (4) The amounts shown represent: (i) for Dr. Klausner, \$6,858 of life insurance premiums paid by us on his behalf, including \$2,143 for associated taxes (ii) for Ms. Homans, \$2,322 of life insurance premiums paid by us on her behalf, including \$315 for associated taxes and \$6,600 paid as reimbursement for certain legal fees, including \$1,600 for associated taxes; (iii) for Mr. Hill, \$1,242 of life insurance premiums paid by us on his behalf, including \$91 for associated taxes and \$5,075 paid as reimbursement for certain relocation expenses, including \$1,236 for associated taxes; and (iv) for Ms. Turner, \$810 of life insurance premiums paid by us on her behalf, including \$19 for associated taxes.
- (5) Dr. Klausner ceased serving as our Chief Executive Officer when Ms. Homans was appointed our Chief Executive Officer in August 2020. Dr. Klausner continues to be employed as our Executive Chairman.
- (6) The amounts shown also include the incremental fair value of stock award and option award modifications deemed to have occurred based on the continued vesting of Dr. Klausner’s restricted stock and option awards following his transition from Chief Executive Officer to Executive Chairman in 2020, calculated in accordance with FASB ASC Topic 718. See Note 12, *Stock-Based Compensation*, to our audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumption used in the calculation.
- (7) The amount shown also includes the incremental fair value of option awards modified to provide for service-based vesting as described further under the section titled “—Offer Letters”, calculated in accordance with FASB ASC Topic 718. See Note 12, *Stock-Based Compensation*, to our audited consolidated financial statements included elsewhere in this prospectus for a discussion of the assumption used in the calculation.

## **Narrative to the Summary Compensation Table**

Our board of directors or our compensation committee reviews compensation annually for all employees, including our named executive officers. In making compensation determinations, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company.

Our board of directors or our compensation committee has historically determined our executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our board of directors or our compensation committee then approved the compensation of each executive officer. Upon the closing of this offering, the compensation committee will determine our executive officers' compensation and follow this process, but generally the compensation committee itself, rather than our board of directors, will approve the compensation of each executive officer.

### ***Annual Base Salary***

Base salaries for our executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such executive officer's qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, typically in connection with our annual review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. In making decisions regarding salary increases, we may also draw upon the experience of members of our board of directors with executives at other companies. The 2020 base salaries for our named executive officers are reflected in the table above, as adjusted throughout the year, except for Dr. Klausner, whose annual base salary was reduced to \$275,000 when he ceased serving as our Chief Executive Officer and Ms. Homans, whose annual base salary was increased to \$515,000 when she began serving as our Chief Executive Officer.

### ***Bonus Compensation***

Our executive officers are eligible earn an annual incentive bonus of up to a percentage of his or her annual base salary, with such percentage set forth in his or her respective offer letter, based on the achievement of performance objectives to be determined by our board of directors. Additionally, from time to time, our board of directors or compensation committee, in its discretion, may approve bonuses for our executive officers based on individual performance, company performance or as otherwise determined to be appropriate.

For 2020, each of our named executive officers was eligible to receive an annual incentive bonus based on the achievement of certain 2020 corporate goals of the company. The target bonus amounts for Dr. Klausner, Ms. Homans, Mr. Hill and Ms. Turner were \$261,288, \$309,000, \$219,938 and \$219,938, respectively. In February 2021, our board of directors assessed company performance against our 2020 corporate goals and based on such performance, awarded a cash annual incentive bonus to each of our named executive officers equal to 100% of his or her target bonus amount for 2020. In addition, in February 2021, our board of directors also assessed additional company achievements in 2020 and based on such assessment awarded each of our named executive officers an additional cash bonus in the amount of \$738,712 for Dr. Klausner, \$77,250 for Ms. Homans, and \$54,984 for each of Mr. Hill and Ms. Turner. All of the bonus amounts described above were paid in early 2021. Ms. Turner and Ms. Homans also received additional cash bonuses in the amounts of

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\$200,000 and \$250,000, respectively, based on performance achievements of certain corporate goals which was approved by the board of directors in March 2020.

**Outstanding Equity Awards as of December 31, 2020**

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2020.

Name	Grant Date	Option Awards (1)				Stock Awards		
		Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price Per Share (\$)	Vesting Commencement Date	Option Expiration Date	Number of Shares or Units of Stock not yet Vested (#)(2)	Market Value of Shares or Units not yet Vested \$(3)
Richard Klausner, M.D.	8/6/2018	—	—	—	8/1/2018(6)	—	2,916,667	18,200,002
	11/6/2018	1,526,487(4)	1,187,269(5)	0.10	9/20/2018(6)	11/5/2028	—	—
	8/31/2019	1,655,868(4)	3,019,524(5)	3.65	7/9/2019(7)	8/30/2029	—	—
Elizabeth Homans	1/16/2020	135,416	514,584	3.65	2/1/2020(7)	1/15/2030	—	—
	11/6/2018	1,951,423(4)	1,517,775(5)	0.10	9/17/2018(6)	11/5/2028	—	—
	11/6/2018	361,375(4)	332,465(5)	0.10	11/6/2018(8)	11/5/2028	—	—
	1/16/2020	47,916	182,084	3.65	2/1/2020(7)	1/15/2030	—	—
Heather Turner	7/15/2020	279,358	3,072,942	5.81	8/1/2020(7)	7/14/2030	—	—
	4/23/2019	208,333	291,667	3.65	4/1/2019(6)	4/22/2029	—	—
	1/16/2020	34,375	130,625	3.65	2/1/2020(7)	1/15/2030	—	—
Stephen Hill	11/17/2020	—	550,000	5.96	12/1/2020(7)	11/16/2030	—	—
	7/10/2019	187,500	312,500	3.65	6/19/2019(6)	7/9/2029	—	—
	1/16/2020	34,375	130,625	3.65	2/1/2020(7)	1/15/2030	—	—
	11/17/2020	—	450,000	5.96	12/1/2020(7)	11/16/2030	—	—

- (1) All of the option awards were granted under the 2018 Plan, the terms of which plan are described below under “—Equity Benefit Plans—2018 Equity Incentive Plan.”
- (2) Constitutes restricted shares of common stock that are subject to repurchase at their original purchase price upon a termination of service. The repurchase right lapses over the vesting schedule, subject to continued service to us through the applicable vesting date.
- (3) Amount is calculated by multiplying the number of shares shown in the table by \$6.24, the estimated fair market value per share of our common stock as of December 31, 2020.
- (4) The option is early-exercisable, meaning that it can be exercised before it vests for restricted shares of our common stock subject to the same vesting provisions as the underlying options. Accordingly, the number of shares shown for the option in this column represent the number of shares that were exercisable and vested as of December 31, 2020.
- (5) The option is early-exercisable, meaning that it can be exercised before it vests for restricted shares of our common stock subject to the same vesting provisions as the underlying options. Accordingly, the number of shares shown for the option in this column represent the number of shares that were exercisable and unvested as of December 31, 2020.
- (6) The restricted stock award and options vest as to 25% of the shares or shares initially underlying the option on the first anniversary of the vesting commencement date and as to 1/48<sup>th</sup> of the shares initially underlying the option each month until fully vested on the fourth anniversary of the vesting commencement date, subject to continued service to us through the applicable vesting date.
- (7) Each option vests as to 1/48<sup>th</sup> of the shares initially underlying the option each month until fully vested on the fourth anniversary of the vesting commencement date, subject to continued service to us through the applicable vesting date.
- (8) The option initially vested based on the occurrence of certain milestones. The vesting was subsequently modified in 2020 to vest as to 25% of the shares initially underlying the option on the first anniversary of the vesting commencement date and as to 1/48<sup>th</sup> of the shares initially underlying the option each month until fully vested on the fourth anniversary of the vesting commencement date, subject to continued service to us through the applicable vesting date.

Options held by certain of our named executive officers are eligible for accelerated vesting under specified circumstances. Please see the subsection titled “—Offer Letters” below for a description of such potential acceleration.

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2021 Plan, the terms of which are described below under the section titled “—Equity Benefit Plans—2021 Equity Incentive Plan.”



## **Emerging Growth Company Status**

We are an “emerging growth company,” as defined in the JOBS Act. As an emerging growth company we will be exempt from certain requirements related to executive compensation, including the requirements to hold a nonbinding advisory vote on executive compensation and to provide information relating to the ratio of total compensation of our chief executive officer to the median of the annual total compensation of all of our employees, each as required by the Investor Protection and Securities Reform Act of 2010, which is part of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

## **Pension Benefits**

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the fiscal year ended December 31, 2020.

## **Nonqualified Deferred Compensation**

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2020.

## **Offer Letters**

Below are descriptions of our offer letters with our named executive officers. The offer letters with our executive officers generally provide for at-will employment and set forth the executive officer’s initial base salary, annual target bonus, and eligibility to participate in our employee benefit plans.

*Richard Klausner, M.D.*

In July 2020, we and Dr. Klausner entered into an amended offer of employment that governs the current terms of his employment in connection with his transition from Chief Executive Officer to Executive Chairman. The amended offer of employment provides that Dr. Klausner’s initial annual base salary was \$275,000. Effective March 1, 2021, Dr. Klausner’s annual base salary is \$284,625.

Dr. Klausner is eligible to earn an annual incentive bonus of up to 60% of his base salary, based on the achievement of performance objectives to be determined by our board of directors. The amended offer of employment provides that Dr. Klausner’s annual incentive bonus for 2020 was to be pro-rated based upon his salary and target bonus level provided for immediately before his transition from Chief Executive Officer to Executive Chairman (which salary was \$550,000 and annual target bonus was 60%) and the length of his employment from August 1, 2020 through the end of the 2020 fiscal year, which amount is disclosed in the “Bonus Compensation” and “Non-Equity Incentive Plan Compensation” columns in the “Summary Compensation Table” above.

Dr. Klausner’s amended offer of employment provides for severance payments upon certain qualifying terminations of his employment. In the event of a termination of his employment by us without Cause (as defined below) or resignation for Good Reason (as defined below), Dr. Klausner will receive severance in the form of 18 months of his then-current base salary, with such amount to be paid through our normally scheduled payroll date following the date on which his employment is terminated. Dr. Klausner will also be entitled to a pro-rated target annual incentive bonus for the year in which termination occurs and up to 18 months of COBRA premiums for Dr. Klausner and his dependents paid for by the company. In addition, the company’s repurchase option will lapse with respect to 100% of the shares of common stock previously purchased by Dr. Klausner. Dr. Klausner

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will also receive accelerated vesting of his then-outstanding and unvested options which would otherwise become vested solely on the passage of time and his continuous service. These severance benefits are conditioned upon Dr. Klausner executing a general release and waiver of all claims against the company.

“Cause” means (i) executive is indicted for, convicted of, or pleads guilty or nolo contendere to, a felony or crime involving moral turpitude; (ii) executive engages in conduct that constitutes willful gross negligence, willful misconduct, or unsatisfactory performance in carrying out the executive’s duties under the amended offer of employment, and, if curable, such breach remains uncured following fifteen (15) days prior written notice given by the company to the executive specifying such conduct; (iii) executive has breached any covenant or any material provision of any agreement with the company, including among other things, a willful and material breach of written company policy, and, if curable, such breach remains uncured following fifteen (15) days’ prior written notice specifying such breach given by the company to the executive; (iv) executive’s material violation of federal law or state law that the board reasonably determines has had or is reasonably likely to have a material detrimental effect on the company’s reputation or business; or (v) executive’s act of fraud or dishonesty in the performance of the executive’s job duties.

“Good Reason” means (i) that executive, without executive’s express, written consent, has incurred a material reduction in authority, title, duties or responsibilities at the company or a successor employer (with respect to a termination in connection with a change in control, relative to executive’s authority, title, duties or responsibilities immediately prior to the change in control); (ii) that executive, without executive’s express, written consent, has suffered a material breach of the amended offer of employment by the company or a successor employer; (iii) that executive, without executive’s express, written consent, has been required to relocate or travel more than fifty (50) miles from executive’s then current place of employment in order to continue to perform the duties and responsibilities of executive’s position (not including customary travel as may be required by the nature of executive’s position); or (iv) that executive, without executive’s express, written consent, has been directed by the board to violate knowingly and intentionally any material state, federal or foreign law, rule or regulation applicable to the company.

In the event of a Change in Control (as defined below), the repurchase option will lapse with respect to 100% of the shares that Dr. Klausner purchased on August 6, 2018 and all such unvested shares will immediately become fully vested, provided that Dr. Klausner is an employee of the company as of the time of the effective date of such Change in Control. Further, in the event of a Change of Control, all options held by Dr. Klausner shall immediately vest and become exercisable, provided that he is an employee of the company as of the time of the effective date of the Change in Control.

“Change in Control” means any transaction or series of related transactions pursuant to which any individual or entity acquires (i) more than fifty percent (50%) of the issued and outstanding equity securities of the company or (ii) all or substantially all of the assets of the company (in either case, whether by merger, consolidation, sale, exchange, issuance, transfer or redemption of the company’s equity securities by sale, exchange or transfer of the Company’s consolidated assets or otherwise), provided that, where applied to compensation subject to Section 409A, any acceleration of or change in payment shall only apply (if required by Section 409A) if the corporate transaction is also a change in control event described in Treasury Regulation 1.409A-3(i)(5).

### *Elizabeth Homans*

In July 2020, we and Ms. Homans entered into an amended offer of employment that governs the current terms of her employment in connection with her transition to the role of Chief Executive Officer.

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The offer letter provides that Ms. Homans' initial annual base salary was \$515,000. Effective as of March 1, 2021, Ms. Homans' annual base salary is \$556,200. Ms. Homans is eligible to earn an annual incentive bonus of up to 60% of her base salary, based on the achievement of performance objectives to be determined by our board of directors. The offer letter provides that Ms. Homans' annual incentive bonus for 2020 was to be pro-rated based upon her salary and target bonus level provided for in her original employment agreement (which salary was \$450,000 and annual target bonus was equal to 50% of her base salary) and the length of her employment from August 1, 2020 through the end of the 2020 fiscal year, which amount is disclosed in the "Bonus" and "Non-Equity Incentive Plan Compensation" columns in the "Summary Compensation Table" above.

Our board of directors previously granted Ms. Homans an option to purchase up to 3,699,198 shares of the company's common stock under our 2018 Plan and an option to purchase up to 693,840 shares of common stock that vested based on the occurrence of certain milestones, which was later amended in July 2020 by the board so that 25% of the shares subject to the option shall vest on the one-year anniversary of the vesting commencement date, and 1/48th of the total number of shares initially subject to the option shall vest each month thereafter on the same day of the month as the vesting commencement date. Pursuant to the amended offer of employment, Ms. Homans was granted an option to purchase up to 3,352,300 shares of our common stock. All such awards are reflected in the "Outstanding Equity Awards as of December 31, 2020" table above. If, after twelve months of Ms. Homans' employment in the role of Chief Executive Officer, our board of directors approves a corporate score of at least 90% based upon its review of performance against 2020 corporate goals, and determines that we have made reasonable progress towards achieving our 2021 corporate goals as approved by the board, Ms. Homans will be granted an additional option to bring her total equity ownership in us up to 3.4% of our fully-diluted outstanding shares of equity capital as of the date of the grant. In February 2021, Ms. Homans was granted an option to purchase 583,532 shares of common stock. In August 2020, our board of directors approved the extension of Ms. Homans' post-termination exercise period for all the options granted to Ms. Homans on November 6, 2018 and January 16, 2020.

Ms. Homans' amended offer of employment provides for severance payments upon certain qualifying terminations of her employment. In the event of a termination of her employment by us without Cause (as defined above) or resignation for Good Reason (as defined above), Ms. Homans will receive severance in the form of 18 months of her then-current base salary, with such amount to be paid through our normally scheduled payroll following the date on which her employment is terminated. Ms. Homans will also be entitled to a pro-rated target annual incentive bonus for the year in which termination occurs and up to 18 months of COBRA premiums for Ms. Homans and her dependents paid for by the company. These severance benefits are conditioned upon Ms. Homans executing a general release and waiver of all claims against the company. Additionally, Ms. Homans' amended offer letter provides that in the event of certain qualifying terminations, the post-termination exercise period applicable to certain of Ms. Homans' options will be extended.

In the event of a Change in Control (as defined above), Ms. Homans will also receive accelerated vesting of 100% of her then-outstanding and unvested options which would otherwise become vested solely on the passage of time and her continuous service, provided that Ms. Homans is an employee of the company as of the effective date of such Change in Control.

### *Stephen Hill*

In May 2019, we and Mr. Hill entered into an offer letter governing the terms of his employment. The offer letter provides that Mr. Hill's initial annual base salary was \$425,000. Effective March 1, 2021, Mr. Hill's annual base salary is \$455,271. Mr. Hill is eligible to earn an annual incentive bonus of up to 50% of his base salary, based on the achievement of performance objectives to be determined

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by our board of directors. In 2019, Mr. Hill also received an advance signing bonus of \$300,000, which will be considered earned in May 2022 following the completion of three years continuous service with the company. Mr. Hill received relocation reimbursement of \$100,000, 50% of which is subject to clawback by the company under certain circumstances. The company granted Mr. Hill a stock option to purchase up to 500,000 shares of the company's common stock under our 2018 Plan, which award is reflected in the "Outstanding Equity Awards as of December 31, 2020" table above.

Mr. Hill's offer letter provides for severance payments upon certain qualifying terminations of his employment. In the event of a termination of his employment by us without Cause (as defined above) or resignation for Good Reason (as defined immediately below), Mr. Hill will receive severance in the form of 12 months of his then-current base salary, such amount to be paid through our normally scheduled payroll date following the date on which his employment is terminated, and up to 12 months of COBRA premiums paid for by the company. These severance benefits are conditioned upon Mr. Hill executing a general release and waiver of all claims against the company.

For the purposes of Mr. Hill's offer letter, the following definition of "Good Reason," as set forth in his offer letter, applies:

"Good Reason" means (i) that executive, without executive's express, written consent, has incurred a material reduction in authority, title, duties or responsibilities at the company or a successor employer (with respect to a termination in connection with a change in control, relative to executive's authority, title, duties or responsibilities immediately prior to the change in control); (ii) that executive, without executive's express, written consent, has suffered a material breach of the offer of employment by the company or a successor employer; (iii) that executive, without executive's express, written consent, has been required to relocate or travel more than fifty (50) miles from executive's then current place of employment in order to continue to perform the duties and responsibilities of executive's position (not including customary travel as may be required by the nature of executive's position); (iv) that executive, without executive's express, written consent, has incurred a material reduction of work space designed to cause executive to resign, other than a reduction in work space generally applicable to all senior executives of the Company; or (v) that executive, without executive's express, written consent, has been directed by the board to violate knowingly and intentionally any material state, federal or foreign law, rule or regulation applicable to the company.

If Mr. Hill's employment is terminated by us without Cause, or Mr. Hill resigns for Good Reason, in each case within twelve (12) months after a Change in Control (as defined below), 100% of the then unvested shares subject to the option to purchase 500,000 shares granted to him on July 10, 2019 shall immediately vest. "Change in control" means any transaction or series of related transactions pursuant to which any individual or entity acquires (i) more than fifty percent (50%) of the issued and outstanding equity securities of the company or (ii) all or substantially all of the assets of the company (in either case, whether by merger, consolidation, sale, exchange, issuance, transfer or redemption of the company's equity securities by sale, exchange or transfer of the company's consolidated assets or otherwise).

### *Heather Turner*

In February 2019, we and Ms. Turner entered into an offer letter governing the terms of her employment. The offer letter provides that Ms. Turner's initial annual base salary was \$420,000. Effective as of March 1, 2021, Ms. Turner's annual base salary is \$455,271. Ms. Turner is eligible to earn an annual incentive bonus of up to 50% of her base salary, based on the achievement of performance objectives to be determined by our board of directors. The company granted Ms. Turner a stock option to purchase up to 500,000 shares of the company's common stock under our 2018 Plan, which award is reflected in the "Outstanding Equity Awards as of December 31, 2020" table above.

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Ms. Turner's offer letter provides for severance payments upon certain qualifying terminations of her employment. In the event of a termination of her employment by us without Cause (as defined above) or resignation for Good Reason (as defined above), Ms. Turner will receive severance in the form of 12 months of her then-current base salary, such amount to be paid through our normally scheduled payroll date following the date on which her employment is terminated, and up to 12 months of COBRA premiums paid for by the company. These severance benefits are conditioned upon Ms. Turner executing a general release and waiver of all claims against the company.

### **Potential Payments and Benefits upon Termination or Change in Control**

The offer letters we have entered into with our named executive officers provide for severance and/or change in control benefits as described above under "—Offer Letters."

### **Other Compensation and Benefits**

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision plans, in each case on the same basis as all of our other employees. We pay the premiums for the medical, disability, and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers.

### **401(k) Plan**

Our named executive officers are eligible to participate in our defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may elect to defer up to 90% of their eligible compensation into the plan on a pretax or after tax basis, up to annual limits prescribed by the Code.

### **Equity Benefit Plans**

We believe that our ability to grant equity-based awards is a valuable and necessary compensation tool that aligns the long-term financial interests of our employees, consultants and directors with the financial interests of our stockholders. In addition, we believe that our ability to grant options and other equity-based awards helps us to attract, retain and motivate employees, consultants and directors, and encourages them to devote their best efforts to our business and financial success. The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus forms a part.

#### ***2021 Equity Incentive Plan***

In June 2021, our board of directors adopted, and our stockholders approved, our 2021 Plan. Our 2021 Plan became effective on the date of the underwriting agreement related to this offering. Our 2021 Plan came into existence upon its adoption by our board of directors, but no grants will be made under our 2021 Plan prior to its effectiveness. No further grants will be made under our 2018 Plan.

**Awards.** Our 2021 Plan provides for the grant of incentive stock options (ISOs) within the meaning of Section 422 of the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options (NSOs), stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of awards to our employees, directors and consultants and any of our affiliates' employees and consultants.

**Authorized Shares.** The maximum number of shares of our common stock that may be issued under our 2021 Plan will not exceed 68,856,698 shares of our common stock, which is the sum of (i) 24,700,000 new shares, plus (ii) an additional number of shares not to exceed 44,156,698 shares, consisting of (a) shares that remain available for the issuance of awards under our 2018 Plan as of immediately prior to the time our 2021 Plan became effective and (b) any shares of our common stock subject to outstanding stock options or other stock awards granted under our 2018 Plan that, on or after our 2021 Plan became effective, terminated or expired prior to exercise or settlement; were not issued because the award is settled in cash; were forfeited because of the failure to vest; or were reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares of our common stock reserved for issuance under our 2021 Plan will automatically increase 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 our common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by our board of directors no later than December 31 of the immediately preceding year. The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan is 206,570,094 shares.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full or that are paid out in cash rather than in shares will not reduce the number of shares available for issuance under our 2021 Plan. Shares withheld under a stock award to satisfy the exercise, strike or purchase price of a stock award or to satisfy a tax withholding obligation will not reduce the number of shares available for issuance under our 2021 Plan. If any shares of our common stock issued pursuant to a stock award are forfeited back to or repurchased or reacquired by us (i) because of a failure to meet a contingency or condition required for the vesting of such shares; (ii) to satisfy the exercise, strike or purchase price of a stock award; or (iii) to satisfy a tax withholding obligation in connection with a stock award, the shares that are forfeited or repurchased or reacquired will revert to and again become available for issuance under our 2021 Plan.

**Plan Administration.** Our board of directors, or a duly authorized committee of our board of directors, administers our 2021 Plan. Our board of directors may delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards; and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, our board of directors has the authority to determine stock award recipients, the types of stock awards to be granted, grant dates, the number of shares subject to each stock award, the fair market value of our common stock, and the provisions of each stock award, including the period of exercisability and the vesting schedule applicable to a stock award.

Under our 2021 Plan, our board of directors also generally has the authority to effect, with the consent of any materially adversely affected participant, (i) the reduction of the exercise, purchase, or strike price of any outstanding option or stock appreciation right; (ii) the cancellation of any outstanding option or stock appreciation right and the grant in substitution therefore of other awards, cash, or other consideration; or (iii) any other action that is treated as a repricing under generally accepted accounting principles.

**Stock Options.** ISOs and NSOs are granted under stock option agreements adopted by the administrator. The administrator determines the exercise price for stock options, within the terms and conditions of our 2021 Plan, except the exercise price of a stock option generally will not be less than 100% of the fair market value of our common stock on the date of grant. Options granted under our 2021 Plan will vest at the rate specified in the stock option agreement as determined by the administrator.

The administrator determines the term of stock options granted under our 2021 Plan, up to a maximum of 10 years. Unless the terms of an optionholder's stock option agreement, or other written

agreement between us and the optionholder, provide otherwise, if an optionholder's service relationship with us or any of our affiliates ceases for any reason other than disability, death, or cause, the optionholder may generally exercise any vested options for a period of three months following the cessation of service. This period may be extended in the event that exercise of the option is prohibited by applicable securities laws. If an optionholder's service relationship with us or any of our affiliates ceases due to death, or an optionholder dies within a certain period following cessation of service, a beneficiary may generally exercise any vested options for a period of 18 months following the date of death. If an optionholder's service relationship with us or any of our affiliates ceases due to disability, the optionholder may generally exercise any vested options for a period of 12 months following the cessation of service. In the event of a termination for cause, options generally terminate upon the termination date. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the administrator and may include (i) cash, check, bank draft or money order; (ii) a broker-assisted cashless exercise; (iii) the tender of shares of our common stock previously owned by the optionholder; (iv) a net exercise of the option if it is an NSO; or (v) other legal consideration approved by the administrator.

Unless the administrator provides otherwise, options generally are not transferable except by will or the laws of descent and distribution. Subject to approval of the administrator or a duly authorized officer, an option may be transferred pursuant to a domestic relations order, official marital settlement agreement, or other divorce or separation instrument.

**Tax Limitations on ISOs.** The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an award holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our parent or subsidiary corporations unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the term of the ISO does not exceed five years from the date of grant.

**Restricted Stock Unit Awards.** Restricted stock unit awards are granted under restricted stock unit award agreements adopted by the administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, or other written agreement between us and the recipient, restricted stock unit awards that have not vested will be forfeited once the participant's continuous service ends for any reason.

**Restricted Stock Awards.** Restricted stock awards are granted under restricted stock award agreements adopted by the administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past or future services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

**Stock Appreciation Rights.** Stock appreciation rights are granted under stock appreciation right agreements adopted by the administrator. The administrator determines the purchase price or strike price for a stock appreciation right, which generally will not be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under our 2021 Plan will vest at the rate specified in the stock appreciation right agreement as determined by the administrator. Stock appreciation rights may be settled in cash or shares of our common stock or in any other form of payment as determined by our board of directors and specified in the stock appreciation right agreement.

The administrator determines the term of stock appreciation rights granted under our 2021 Plan, up to a maximum of 10 years. If a participant's service relationship with us or any of our affiliates ceases for any reason other than cause, disability, or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. This period may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant's service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate upon the termination date. In no event may a stock appreciation right be exercised beyond the expiration of its term.

**Performance Awards.** Our 2021 Plan permits the grant of performance awards that may be settled in stock, cash or other property. Performance awards may be structured so that the stock or cash will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. Performance awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, our common stock.

The performance goals may be based on any measure of performance selected by our board of directors. The performance goals may be based on company-wide performance or performance of one or more business units, divisions, affiliates, or business segments, and may be either absolute or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by our board of directors at the time the performance award is granted, our board will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (i) to exclude restructuring or other nonrecurring charges; (ii) to exclude exchange rate effects; (iii) to exclude the effects of changes to generally accepted accounting principles; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; (v) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (vi) to exclude the dilutive effects of acquisitions or joint ventures; (vii) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (viii) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (ix) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (x) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (xi) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles.



**Other Stock Awards.** The administrator may grant other awards based in whole or in part by reference to our common stock. The administrator will set the number of shares under the stock award (or cash equivalent) and all other terms and conditions of such awards.

**Non-Employee Director Compensation Limit.** The aggregate value of all compensation granted or paid to any non-employee director with respect to any fiscal year, including awards granted and cash fees paid by us to such non-employee director, will not exceed \$1,000,000 in total value.

**Changes to Capital Structure.** In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2021 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of ISOs and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

**Corporate Transactions.** In the event of a corporate transaction (as defined in the 2021 Plan), unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the administrator at the time of grant, any stock awards outstanding under our 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then (i) with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the corporate transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full (or, in the case of performance awards with multiple vesting levels depending on the level of performance, vesting will accelerate at 100% of the target level) to a date prior to the effective time of the corporate transaction (contingent upon the effectiveness of the corporate transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the corporate transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the corporate transaction); and (ii) any such stock awards that are held by persons other than current participants will terminate if not exercised (if applicable) prior to the effective time of the corporate transaction, except that any reacquisition or repurchase rights held by us with respect to such stock awards will not terminate and may continue to be exercised notwithstanding the corporate transaction.

In the event a stock award will terminate if not exercised prior to the effective time of a corporate transaction, the administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award, over (ii) any per share exercise price payable by such holder, if applicable. In addition, any escrow, holdback, earn out or similar provisions in the definitive agreement for the corporate transaction may apply to such payment to the same extent and in the same manner as such provisions apply to the holders of our common stock.

**Change in Control.** Stock awards granted under our 2021 Plan may be subject to acceleration of vesting and exercisability upon or after a change in control (as defined in the 2021 Plan) as may be provided in the applicable stock award agreement or in any other written agreement between us or any affiliate and the participant, but in the absence of such provision, no such acceleration will automatically occur.

**Plan Amendment or Termination.** Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan at any time, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

### **2021 Employee Stock Purchase Plan**

In June 2021, our board of directors adopted, and our stockholders approved, our ESPP. Our ESPP became effective immediately prior to the execution of the underwriting agreement related to this offering. The purpose of our ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. Our ESPP includes two components. One component is designed to allow eligible U.S. employees to purchase our common stock in a manner that may qualify for favorable tax treatment under Section 423 of the Code. The other component permits the grant of purchase rights that do not qualify for such favorable tax treatment in order to allow deviations necessary to permit participation by eligible employees who are foreign nationals or employed outside of the United States while complying with applicable foreign laws.

**Share Reserve.** Our ESPP authorizes the issuance of 2,470,000 shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our common stock reserved for issuance will automatically increase 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 (i) 1% of the total number of shares of our common stock outstanding on December 31 of the immediately preceding year; and (ii) 4,940,000 shares, except before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii).

**Administration.** Our board of directors, or a duly authorized committee of our board of directors, administers our ESPP. Our ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under our ESPP, our board of directors may specify offerings with durations of not more than 27 months and to specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. Our ESPP provides that an offering may be terminated under certain circumstances.

**Payroll Deductions.** Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in our ESPP and to contribute, normally through payroll deductions, up to 15% of their earnings (as defined in our ESPP) for the purchase of our common stock under our ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in our ESPP at a price per share that is not less than the lesser of (i) 85% of the fair market value of a share of our common stock on the first day of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

**Limitations.** Employees may have to satisfy one or more of the following service requirements before participating in our ESPP, as determined by our board of directors: (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not

to exceed two years). No employee may purchase shares under our ESPP at a rate in excess of \$25,000 worth of our common stock (based on the fair market value per share of our common stock at the beginning of an offering) for each calendar year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under our ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

**Changes to Capital Structure.** Our ESPP provides that in the event there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, our board of directors will make appropriate adjustments to: (i) the class(es) and maximum number of shares reserved under our ESPP; (ii) the class(es) and maximum number of shares by which the share reserve may increase automatically each year; (iii) the class(es) and number of shares subject to, and purchase price applicable to, outstanding offerings and purchase rights; and (iv) the class(es) and number of shares that are subject to purchase limits under ongoing offerings.

**Corporate Transactions.** Our ESPP provides that in the event of a corporate transaction (as defined in the ESPP), any then-outstanding rights to purchase our common stock under our ESPP may be assumed, continued, or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within 10 business days before such corporate transaction, and such purchase rights will terminate immediately after such purchase.

**Plan Amendment or Termination.** Our board of directors has the authority to amend or terminate our ESPP, except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our ESPP as required by applicable law or listing requirements.

### **2018 Equity Incentive Plan**

Our board of directors adopted, and our stockholders approved, the 2018 Plan in August 2018. The 2018 Plan was most recently amended in January 2021. The 2018 Plan will be terminated on the date the 2021 Plan becomes effective, and thereafter no further stock awards will be granted under the 2018 Plan. However, any outstanding stock awards granted under the 2018 Plan will remain outstanding, subject to the terms of our 2018 Plan and award agreements, until such outstanding options are exercised or until any stock awards terminate or expire by their terms.

**Awards.** Our 2018 Plan provides for the grant of ISOs, NSOs, restricted stock units, stock appreciation rights and restricted stock awards. ISOs may only be granted to our employees, including employees of any parent or subsidiary. All other stock awards may be granted to our employees, directors and consultants, including employees and consultants of any parent or subsidiary.

**Authorized Shares.** As of March 31, 2021, options to purchase 40,556,956 shares of our common stock were outstanding, and 3,723,796 shares of our common stock remained available for future issuance under our 2018 Plan. The options outstanding as of March 31, 2021 had a weighted-average exercise price of \$3.92 per share. Subject to capitalization adjustments, the maximum aggregate number of shares of our common stock that may be issued under the 2018 Plan is 47,044,980 shares, and the maximum number of shares issuable pursuant to ISOs is 94,089,960 shares.

**Plan Administration.** Our board or a duly authorized committee of our board administers our 2018 Plan and the awards granted under it. Under our 2018 Plan, the administrator has the authority to, among other things, determine who will be granted stock awards, to determine the terms and conditions of each stock award (including the number of shares subject to the stock award, when the stock award will vest and, as applicable, become exercisable), to accelerate the time(s) at which a stock award may vest or be exercised, and to construe and interpret the terms of our 2018 Plan and stock awards granted thereunder.

**Options.** Options granted under our 2018 Plan have terms substantially similar to options that may be granted under our 2021 Plan once it becomes effective.

**Changes to Capital Structure.** In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, proportionate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under our 2018 Plan, and (ii) the class and number of shares and exercise price or purchase price, if applicable, of all outstanding stock awards.

**Corporate Transactions.** Our 2018 Plan provides that in the event of an acquisition or other combination (such terms as defined under our 2018 Plan), stock awards outstanding under our 2018 Plan will be treated as provided in the agreement evidencing such acquisition or other combination, which may provide for one or more of the following: (i) continuation of outstanding stock awards, if we are the successor entity; (ii) assumption or substitution of outstanding stock awards by the successor or acquiring entity in accordance with the terms of the 2018 Plan; (iii) the full or partial exercisability or vesting and accelerated expiration of outstanding stock awards; (iv) the settlement of the fair market value of such stock awards (whether or not then vested or exercisable) in cash, cash equivalents, or securities of the successor entity (or its parent if any) (or the cancellation without consideration of any awards without value); or (v) the termination of outstanding stock awards, without the payment of any consideration that are not exercised upon or prior to the acquisition or other combination within such time specified by the administrator. Immediately following an acquisition or other combination, outstanding stock awards will terminate and cease to be outstanding, except to the extent such stock awards, have been continued, assumed or substituted, as described above.

**Plan Amendment or Termination.** Our board has the authority to terminate or amend our 2018 Plan at any time, except any amendment of our 2018 Plan will be subject to stockholder approval if required by applicable law. The termination or amendment of our 2018 Plan will not affect any share previously issued or any stock award previously granted under our 2018 Plan. As described above, our 2018 Plan will be terminated upon the effective date of the 2021 Plan and no future awards will be granted under the 2018 Plan following such termination.

#### **Limitations on Liability and Indemnification**

Our amended and restated certificate of incorporation, which will become effective immediately after the closing of this offering, will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions; or
- any transaction from which the director derived an improper personal benefit.

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Such limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation will authorize us to indemnify our directors, officers, employees and other agents to the fullest extent permitted by Delaware law. Our amended and restated bylaws will provide that we are required to indemnify our directors and officers to the fullest extent permitted by Delaware law and may indemnify our other employees and agents. Our amended and restated bylaws will also provide that, on satisfaction of certain conditions, we will advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee, or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. We have entered and expect to continue to enter into agreements to indemnify our directors, executive officers and other employees as determined by the board of directors. With certain exceptions, these agreements provide for indemnification for related expenses including attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding.

We believe that these amended and restated certificate of incorporation and amended and restated bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for directors, executive officers, or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **Rule 10b5-1 Plans**

Our directors, officers and key employees may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades under parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers may also buy or sell additional shares outside of a Rule 10b5-1 plan when they do not possess of material nonpublic information, subject to compliance with the terms of our insider trading policy. During the first 180 days from this offering, the sale of any shares under such plan would be subject to the lock-up agreement that the director or officer has entered into with the underwriters.

**CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS**

The following includes a summary of transactions since our inception and any currently proposed transactions to which we have been or are to be a party in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under the section titled "Executive Compensation." We also describe below certain other transactions with our directors, executive officers and stockholders.

**Convertible Note**

In August 2018, we issued and sold a convertible promissory note in the principal amount of \$500,000 to ARCH Venture Partners which converted into 274,751 shares of Series A convertible preferred stock in connection with the Series A convertible preferred stock financing described below. Mr. Nelsen, a member of our board of directors, is a Managing Director of Arch Venture Partners IX, LLC, an entity affiliated with ARCH Venture Partners. Messrs. Nelsen and Bishop, members of our board of directors, were designated to our board by ARCH Venture Partners.

**Series A Convertible Preferred Stock Financing**

In multiple closings held between September 2018 and February 2019, we issued and sold an aggregate of 97,933,475 shares of our Series A convertible preferred stock at a purchase price of \$1.8288 per share for an aggregate purchase price of \$179,100,739.08.

The following table summarizes the Series A convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<b>Participants<sup>(1)</sup></b>	<b>Shares of Series A Convertible Preferred Stock Purchased (#)</b>	<b>Aggregate Purchase Price (\$)</b>
<b>Entities affiliated with ARCH Venture Partners<sup>(2)</sup></b>	<b>35,542,432</b>	<b>64,999,999.66</b>
Foresite Capital Fund IV, L.P.	10,936,132	19,999,998.21
Gemini Investments, L.P.	410,104	749,998.20
Lyell Investors, LLC <sup>(3)</sup>	3,765,842	6,886,971.85

- (1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled "Principal Stockholders."
- (2) Consists of (i) 17,771,216 shares of Series A Convertible Preferred Stock issued to ARCH Venture Fund IX, L.P. and (ii) 17,771,216 shares of Series A Convertible Preferred Stock issued to ARCH Venture Fund IX Overage, L.P. Mr. Nelsen, a member of our board of directors, is a managing director of AVP IX LLC. Mr. Nelson may be deemed to share the power to direct the disposition and vote of the shares held by ARCH IX and ARCH IX Overage, but disclaims beneficial ownership except to any pecuniary interest therein. Messrs. Nelsen and Bishop, members of our board of directors, were designated to our board by ARCH Venture Partners.
- (3) Dr. Klausner and Ms. Friedman are members of our board of directors and a manager and member of Lyell Investors, LLC, respectively. Dr. Klausner and Ms. Friedman may be deemed to share the power to direct the disposition and vote of the shares held by Lyell Investors, but disclaim beneficial ownership of all shares held by Lyell Investors except to any pecuniary interest therein.

### Series B Convertible Preferred Stock Financing

In multiple closings held between March 2019 and May 2019, we issued and sold an aggregate of 23,929,531 shares of our Series B convertible preferred stock at a purchase price of \$6.776145 per share for an aggregate purchase price of \$162,149,971.88.

The following table summarizes the Series B convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<u>Participants<sup>(1)</sup></u>	<u>Shares of Series B Convertible Preferred Stock Purchased (#)</u>	<u>Aggregate Purchase Price (\$)</u>
Foresite Capital Fund IV, L.P.	1,475,765	9,999,997.63
Gemini Investments, L.P.	14,757,653	99,999,996.59

(1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled "Principal Stockholders."

### Series AA Convertible Preferred Stock Financing

In July 2019, we issued and sold an aggregate of 30,253,189 shares of our Series AA convertible preferred stock at a purchase price of \$6.776145 per share for an aggregate purchase price of \$204,999,995.38.

The following table summarizes the Series AA convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<u>Participants<sup>(1)</sup></u>	<u>Shares of Series AA Convertible Preferred Stock Purchased (#)</u>	<u>Aggregate Purchase Price (\$)</u>
Glaxo Group Limited	30,253,189	204,999,995.38

(1) Additional details regarding this stockholder and its equity holdings are included in this prospectus under the section titled "Principal Stockholders."

### Series C Convertible Preferred Stock Financing

In March 2020, we issued and sold an aggregate of 42,905,042 shares of our Series C convertible preferred stock at a purchase price of \$11.49049 per share for an aggregate purchase price of \$492,999,956.08.

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The following table summarizes the Series C convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of our board of directors.

<b>Participants<sup>(1)</sup></b>	<b>Shares of Series C Convertible Preferred Stock Purchased (#)</b>	<b>Aggregate Purchase Price (\$)</b>
<b>Entities affiliated with ARCH Venture Partners<sup>(2)</sup></b>	<b>870,284</b>	<b>9,999,989.60</b>
Foresite Capital Fund IV, L.P.	870,284	9,999,989.60
Milky Way Investments Group Limited	17,405,698	199,999,998.82

- (1) Additional details regarding these stockholders and their equity holdings are included in this prospectus under the section titled "Principal Stockholders."  
(2) Consists of (i) 435,142 shares of Series C Convertible Preferred Stock issued to ARCH Venture Fund IX, L.P. and (ii) 435,142 shares of Series C Convertible Preferred Stock issued to ARCH Venture Fund IX Overage, L.P. Mr. Nelsen, a member of our board of directors, is a managing director of AVP IX LLC. Mr. Nelson may be deemed to share the power to direct the disposition and vote of the shares held by ARCH IX and ARCH IX Overage, but disclaims beneficial ownership except to any pecuniary interest therein. Messrs. Nelsen and Bishop, members of our board of directors, were designated to our board by ARCH Venture Partners.

## **Stock Repurchases**

In March 2020, we repurchased 546,806 shares of its Series A convertible preferred stock from Richard D. Klausner and Rachel D. Klausner, Trustees of the Klausner Family Revocable Trust of May 8, 2014 at the then estimated fair value of \$7.76 per share for a purchase price of \$4.2 million.

In March 2020, we repurchased 2,032,166 shares of its common stock from Richard D. Klausner at the then estimated fair value of \$5.81 per share for a purchase price of \$11.8 million.

## **Collaboration and License Agreement with GSK**

In May 2019, we entered into a Collaboration and License Agreement with GSK for potential T cell therapies that apply our platform technologies and cell therapy innovations to TCRs or CARs under distinct collaboration programs. We received a non-refundable upfront payment of \$45.0 million under the GSK Agreement. We are entitled to certain payments upon the achievement of specified development and commercial milestones (for each selected target that is already within GSK's pipeline and meet certain criteria, we are eligible to receive up to an aggregate of approximately \$400.0 million, and for each selected target that is not already within GSK's pipeline and meet certain criteria we are eligible to receive up to an aggregate of approximately \$900.0 million). We are also entitled to potential technology validation milestone payments of up to an aggregate of approximately \$200.0 million.

In connection with the GSK Agreement, in May 2019, we also entered into a Stock Purchase Agreement with GSK (GSK Stock Purchase Agreement), pursuant to which we sold and issued 30,253,189 shares of Series AA convertible preferred stock at a price of \$6.776145 per share in July 2019.

## **Employment Agreements and Stock Option Grants to Directors and Executive Officers**

We have entered into employment agreements with certain of our named executive officers, and granted stock options to our named executive officers and certain of our directors, as more fully described in the sections titled "Executive Compensation" and "Management—Non-Employee Director Compensation."



## **Investors' Rights Agreement**

In March 2020, we entered into an Amended and Restated Investors' Rights Agreement (the Rights Agreement) with certain holders of more than 5% of our outstanding capital stock, including ARCH Venture Fund IX, L.P., ARCH Venture Fund IX Overage, L.P., Foresite Capital Fund IV, L.P., Gemini Investments, L.P., Glaxo Group Limited, Milky Way Investments Group Limited and certain affiliates of our directors.

The Rights Agreement grants to the holders of our outstanding convertible preferred stock certain rights, including certain registration rights with respect to the registrable securities held by them. See the section titled "Description of Capital Stock—Registration Rights" for additional information. In addition, the Rights Agreement imposes certain affirmative obligations on us, including our obligation to, among other things, (i) grant each holder who holds at least 7,736,917 shares of our convertible preferred stock (the Major Investors) a right of first offer with respect to future sales of our equity, excluding the shares to be offered and sold in this offering, and grant certain information and inspection rights to such Major Investors. Each of these obligations will terminate in connection with the closing of this offering.

## **Voting Agreement**

In April 2021, we entered into an Amended and Restated Voting Agreement (the Voting Agreement) with certain holders of more than 5% of our outstanding capital stock, including ARCH Venture Fund IX, L.P., ARCH Venture Fund IX Overage, L.P., Foresite Capital Fund IV, L.P., Gemini Investments, L.P., Glaxo Group Limited, Milky Way Investments Group Limited and certain affiliates of our directors.

Pursuant to the Voting Agreement, as amended, ARCH Venture Fund IX, L.P. and ARCH Venture Fund IX Overage, L.P., collectively, have the right to designate two members to be elected to our board of directors. See the section titled "Management—Composition of Our Board of Directors." The Voting Agreement will terminate by its terms in connection with the closing of this offering and none of our stockholders will have any continuing rights regarding the election or designation of members of our board of directors following this offering.

## **Right of First Refusal and Co-Sale Agreement**

In March 2020, we entered into an Amended and Restated Right of First Refusal and Co-Sale Agreement (the Co-Sale Agreement) with certain holders of more than 5% of our outstanding capital stock, including ARCH Venture Fund IX, L.P., ARCH Venture Fund IX Overage, L.P., Foresite Capital Fund IV, L.P., Gemini Investments, L.P., Glaxo Group Limited, Milky Way Investments Group Limited and certain affiliates of our directors.

Pursuant to the Co-Sale Agreement, we have a right of first refusal in respect of certain sales of securities by certain holders of our common stock and convertible preferred stock. To the extent we do not exercise such right in full, the Major Investors are granted certain rights of first refusal and co-sale in respect of such sale. The Co-Sale Agreement will terminate in connection with the closing of this offering.

## **Limitations on Liability and Indemnification Agreements**

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our

directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our employees and other agents when determined appropriate by the board. In addition, we have entered into or intend to enter into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. For more information regarding these agreements, see the section titled “Executive Compensation—Limitations on Liability and Indemnification.”

### **Directed Share Program**

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 1,250,000 of the shares offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale to certain of our directors and officers and certain other parties related to us.

### **Policies and Procedures for Transactions with Related Persons**

We have adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our board of directors or our audit committee. Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds \$120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our board of directors or our audit committee for review, consideration and approval. In approving or rejecting any such proposal, our board of directors or our audit committee is to consider the material facts of the transaction, including whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances and the extent of the related person’s interest in the transaction.

## PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock as of March 31, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each our of named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership before the offering is based on 217,829,956 shares of our common stock outstanding as of March 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 194,474,431 shares of our common stock in connection with the closing of this offering and including 5,525,002 shares of our unvested restricted common stock subject to repurchase as of such date.

Applicable percentage ownership after the offering is based on 242,829,956 shares of common stock outstanding immediately after the closing of this offering, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 194,474,431 shares of our common stock in connection with the closing of this offering and including 5,525,002 shares of our unvested restricted common stock subject to repurchase as of March 31, 2021. In computing the number of shares beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares subject to options held by the person that are currently exercisable, or exercisable within 60 days of March 31, 2021. However, except as described above, we did not deem such shares outstanding for the purpose of computing the percentage ownership of any other person. The percentage ownership information does not reflect any potential purchases pursuant to the directed share program or otherwise of any shares of common stock in this offering by the beneficial owners identified in the table below.

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Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Lyell Immunopharma, Inc., 400 East Jamie Court, Suite 301, South San Francisco, CA 94080.

Name of Beneficial Owner	Number of Shares Beneficially Owned (#)	Percentage of Shares Beneficially Owned	
		Before Offering (%)	After Offering (%)
<b>Greater than 5% Holders:</b>			
Entities affiliated with ARCH Venture Partners <sup>(1)</sup>	36,412,716	16.7	15.0
Celgene Corporation <sup>(2)</sup>	10,936,132	5.0	4.5
Foresite Capital Fund IV, L.P. <sup>(3)</sup>	13,282,181	6.1	5.5
Gemini Investments, L.P. <sup>(4)</sup>	15,167,757	7.0	6.2
Glaxo Group Limited <sup>(5)</sup>	30,253,189	13.9	12.5
Milky Way Investments Group Limited <sup>(6)</sup>	17,405,698	8.0	7.2
Parker Institute for Cancer Immunotherapy <sup>(7)</sup>	10,936,132	5.0	4.5
<b>Directors and Named Executive Officers:</b>			
Richard D. Klausner, M.D. <sup>(8)</sup>	16,325,949	7.2	6.5
Elizabeth Homans <sup>(9)</sup>	4,899,939	2.2	2.0
Stephen Hill <sup>(10)</sup>	342,186	*	*
Heather Turner <sup>(11)</sup>	369,269	*	*
Hans Bishop <sup>(12)</sup>	4,709,844	2.2	1.9
Otis Brawley, M.D. <sup>(13)</sup>	400,000	*	*
Catherine Friedman <sup>(14)</sup>	4,515,842	2.1	1.9
Elizabeth Nabel <sup>(15)</sup>	400,000	*	*
Robert Nelsen <sup>(16)</sup>	36,412,716	16.7	15.0
William Rieflin <sup>(17)</sup>	400,000	*	*
Lynn Seely, M.D. <sup>(18)</sup>	400,000	*	*
All directors and executive officers as a group (12 persons) <sup>(19)</sup>	69,175,745	31.4	28.2

\* Represents beneficial ownership of less than 1%.

- (1) Consists of (i) 17,771,216 shares of Series A convertible preferred stock and 435,142 shares of Series C convertible preferred stock held by ARCH Venture Fund IX, L.P. (ARCH IX) and (ii) 17,771,216 shares of Series A convertible preferred stock and 435,142 shares of Series C convertible preferred stock held by ARCH Venture Fund IX Overage, L.P., (ARCH IX Overage). ARCH Venture Partners IX, L.P. (AVP IX LP) is the sole general partner of ARCH IX. ARCH Venture Partners IX Overage, L.P. (AVP IX Overage LP) is the sole general partner of ARCH IX Overage. ARCH Venture Partners IX, LLC (AVP IX LLC) is the sole general partner of each of AVP IX LP and AVP IX Overage LP. Keith Crandell, Clinton Bybee, and Robert Nelsen are managing directors of AVP IX LLC (the AVP IX MDs). AVP IX LP and AVP IX Overage LP may be deemed to beneficially own the shares held by ARCH IX and ARCH IX Overage, respectively, AVP IX LLC may be deemed to beneficially own the shares held by ARCH IX and ARCH IX Overage, and each of the AVP IX MDs may be deemed to share the power to direct the disposition and vote of the shares held by ARCH IX and ARCH IX Overage. AVP IX LP, AVP IX Overage LP, AVP IX LLC, and the AVP IX MDs each disclaim beneficial ownership except to any pecuniary interest therein. The mailing address of ARCH IX and ARCH IX Overage is 8755 W. Higgins Road, Suite 1025, Chicago, IL 60631.
- (2) Consists of 10,936,132 shares of Series A convertible preferred stock. Celgene Corporation (Celgene) is wholly owned and controlled by Bristol-Myers Squibb Company. The mailing address of Celgene is 86 Morris Avenue, Summit, New Jersey 07901.
- (3) Consists of (i) 10,936,132 shares of Series A convertible preferred stock, (ii) 1,475,765 shares of Series B convertible preferred stock and (iii) 870,284 shares of Series C convertible preferred stock. Foresite Capital Management IV, LLC (FCM IV) is the general partner of Foresite Capital Fund IV, L.P. (Foresite). James Tananbaum is the managing member of FCM IV. FCM IV may be deemed to beneficially own the shares held by Foresite and James Tananbaum may be deemed to have the power to direct the disposition and vote of the shares held by Foresite. FCM IV and James Tananbaum each disclaim beneficial ownership of the shares held by Foresite except to any pecuniary interest therein. The mailing address of Foresite is 600 Montgomery Street, Suite 4500, San Francisco, CA 94111.
- (4) Consists of (i) 410,104 shares of Series A convertible preferred stock and (ii) 14,757,653 shares of Series B convertible preferred stock. Gemini GP Limited (GGPL) is the general partner of Gemini Investments, L.P. (Gemini). GGPL holds ultimate voting and investment power over the shares held by Gemini. The mailing address of Gemini is c/o Trident Trust Company (Cayman) Limited, One Capital Place, PO Box 847, Grand Cayman, KY1-1103, Cayman Islands.

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- (5) Consists of 30,253,189 shares of Series AA convertible preferred stock, of which GSK has sole voting and dispositive power through its indirect wholly-owned subsidiary, Glaxo Group Limited (GGL). The mailing address of each of GSK and GGL is 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.
- (6) Consists of 17,405,698 shares of Series C convertible preferred stock. Milky Way Investment Group Limited (Milky Way) is wholly owned and controlled by Milky Way Holdings Limited. The mailing address of Milky Way is c/o Trident Trust Company (Cayman) Limited, One Capital Place, PO Box 847, Grand Cayman, KY1-1103, Cayman Islands.
- (7) Consists of 10,936,132 shares of Series A convertible preferred stock. The mailing address of Parker Institute of Cancer Immunotherapy is 1 Letterman Drive, Suite D3500, San Francisco, CA 94129.
- (8) Consists of (i) 4,967,834 shares of common stock, (ii) 7,592,273 shares of common stock issuable upon exercise of stock options held by Dr. Klausner that are exercisable within 60 days of March 31, 2021 and (iii) 3,765,842 shares of Series A convertible preferred stock held by Lyell Investors, LLC. Dr. Klausner is a manager of Lyell Investors, LLC (Lyell Investors) and may be deemed to share the power to direct the disposition and vote of the shares held by Lyell Investors. Dr. Klausner disclaims beneficial ownership of all shares held by Lyell Investors except to any pecuniary interest therein.
- (9) Consists of 4,899,939 shares of common stock issuable upon exercise of stock options held by Ms. Homans that are exercisable within 60 days of March 31, 2021.
- (10) Consists of 342,186 shares of common stock issuable upon exercise of stock options held by Mr. Hill that are exercisable within 60 days of March 31, 2021.
- (11) Consists of 369,269 shares of common stock issuable upon exercise of stock options held by Ms. Turner that are exercisable within 60 days of March 31, 2021.
- (12) Consists of (i) 3,000,000 shares of common stock, (ii) 546,806 shares of Series A convertible preferred stock and (iii) 1,163,038 shares of common stock issuable upon exercise of stock options held by Mr. Bishop that are exercisable within 60 days of March 31, 2021.
- (13) Consists of 400,000 shares of common stock issuable upon exercise of stock options held by Dr. Brawley that are exercisable within 60 days of March 31, 2021.
- (14) Consists of (i) 650,000 shares of common stock issuable upon exercise of stock options held by Ms. Friedman that are exercisable within 60 days of March 31, 2021, (ii) 100,000 shares of common stock held by The Duane Irrevocable Trust 2020 (Duane Trust) and (iii) 3,765,842 shares of Series A convertible preferred stock held by Lyell Investors. Ms. Friedman is a trustee of the Duane Trust and a member of Lyell Investors, and therefore may be deemed to share the power to direct the disposition and vote of the shares held by each. Ms. Friedman disclaims beneficial ownership of all shares held by Duane Trust and Lyell Investors except to any pecuniary interest therein.
- (15) Consists of 400,000 shares of common stock issuable upon exercise of stock options held by Dr. Nabel that are exercisable within 60 days of March 31, 2021.
- (16) Mr. Nelsen is an AVP IX MD and may be deemed to beneficially own the shares held by ARCH IX and ARCH IX Overage as discussed in footnote (1). Mr. Nelsen disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.
- (17) Consists of 400,000 shares of common stock issuable upon exercise of stock options held by Mr. Rieflin that are exercisable within 60 days of March 31, 2021.
- (18) Consists of 400,000 shares of common stock issuable upon exercise of stock options held by Dr. Seely that are exercisable within 60 days of March 31, 2021.
- (19) Consists of (i) 8,067,834 shares of common stock held by our current directors and executive officers as a group, (ii) 43,620,922 shares of common stock issuable upon the conversion of Series A convertible preferred stock held by our current directors and executive officers as a group, (iii) 870,284 shares of common stock issuable upon the conversion of Series C convertible preferred stock held by our current directors and executive officers as a group, and (iv) 16,616,705 shares of common stock issuable upon the exercise of stock options held by our current directors and executive officers that are exercisable within 60 days of March 31, 2021.

## DESCRIPTION OF CAPITAL STOCK

### General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation, which will become effective immediately after the closing of this offering, and the amended and restated bylaws, which will become effective upon the closing of this offering. Copies of these documents have been filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect on the closing of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of 500,000,000 shares of common stock, par value \$0.0001 per share and 10,000,000 shares of preferred stock, par value \$0.0001 per share. All of our authorized shares of preferred stock will be undesignated.

As of March 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into 194,474,431 shares of our common stock upon the closing of this offering and including 5,525,002 shares of our unvested restricted common stock subject to repurchase as of such date, there were 217,829,956 shares of common stock outstanding and held of record by 103 stockholders.

### Common Stock

#### *Voting Rights*

The common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

#### *Economic Rights*

Except as otherwise expressly provided in our amended and restated certificate of incorporation or required by applicable law, all shares of common stock will have the same rights and privileges and rank equally, share ratably and be identical in all respects for all matters, including those described below.

*Dividends.* Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled "Dividend Policy" for further information.

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*Liquidation Rights.* On our liquidation, dissolution, or winding-up, the holders of common stock will be entitled to share equally, identically and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

### **No Preemptive or Similar Rights**

The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, redemption or sinking fund provisions.

### **Fully Paid and Non-Assessable**

In connection with this offering, our legal counsel will opine that the shares of our common stock to be issued under this offering will be fully paid and non-assessable.

### **Preferred Stock**

Upon the closing of this offering, all of our currently outstanding shares of convertible preferred stock will convert into common stock and we will not have any convertible preferred stock outstanding. Immediately after the closing of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

### **Stock Options**

As of March 31, 2021, 40,556,956 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of \$3.92 per share. Subsequent to March 31, 2021, we granted an additional 1,930,000 shares of common stock with a weighted-average exercise price of \$13.20 per share. Following completion of this offering, 24,700,000 additional shares of our common stock will be reserved for future issuance under the 2021 Plan, which became effective once the registration statement of which this prospectus forms a part was declared effective, as well as any future automatic annual increases in the number of shares of common stock reserved for issuance under the 2021 Plan.

## **Registration Rights**

Upon the closing of this offering and subject to the lock-up agreements entered into in connection with this offering and federal securities laws, certain holders of shares of our common stock, including those shares of our common stock that will be issued upon the conversion of our convertible preferred stock in connection with this offering, will initially be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are referred to as registrable securities. The holders of these registrable securities possess registration rights pursuant to the terms of our amended and restated investors' rights agreement and are described in additional detail below. The registration of shares of our common stock pursuant to the exercise of the registration rights described below would enable the holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective. We will pay the registration expenses, other than underwriting discounts, selling commissions and stock transfer taxes, of the shares registered pursuant to the demand, piggyback and Form S-3 registrations described below.

Generally, in an underwritten offering, the managing underwriter, if any, has the right, subject to specified conditions and limitations, to limit the number of shares the holders may include. The demand, piggyback and Form S-3 registration rights described below will expire no later than three years after the closing of this offering.

### ***Demand Registration Rights***

Upon the closing of this offering, holders of an aggregate of 194,474,431 shares of our common stock will be entitled to certain demand registration rights. At any time beginning 180 days after the closing of this offering, the holders of 40% of these shares may request that we register all or a portion of their shares. We are not required to effect more than two registration statements which are declared or ordered effective. Such request for registration must cover shares with an anticipated aggregate offering price of at least \$35 million. With certain exceptions, we are not required to effect the filing of a registration statement during the period starting with the date of the filing of, and ending on a date 180 days following the effective date of the registration statement for this offering.

### ***Piggyback Registration Rights***

In connection with this offering, the holders of an aggregate of 194,474,431 shares of our common stock were entitled to, and the necessary percentage of holders waived, their rights to notice of this offering and to include their shares of registrable securities in this offering. After this offering, in the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, the holders of these shares will be entitled to certain piggyback registration rights allowing the holder to include their shares in such registration, subject to certain marketing and other limitations.

### ***Form S-3 Registration Rights***

Upon the closing of this offering, holders of an aggregate of 120,501,972 shares of common stock will be entitled to certain Form S-3 registration rights. Holders of 20% of these shares can make a request that we register their shares on Form S-3 if we are qualified to file a registration statement on Form S-3 and if the reasonably anticipated aggregate net proceeds of the shares offered would equal or exceed \$20 million. We will not be required to effect more than two registrations on Form S-3 within any 12-month period.

## **Anti-Takeover Provisions**

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws, which are summarized below, may have the effect of delaying,



deferring or discouraging another person from acquiring control of our company. They are also designed, in part, to encourage persons seeking to acquire control of us to negotiate first with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

### ***Certificate of Incorporation and Bylaws to be in Effect in Connection with this Offering***

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all of our directors. Our amended and restated certificate of incorporation, to be effective immediately after the closing of this offering, and our amended and restated bylaws, to be effective on the closing of this offering, will provide for stockholder actions at a duly called meeting of stockholders or, before the date on which all shares of common stock convert into a single class, by written consent. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, or our chief executive officer or president. Our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

As described above in “Management—Composition of Our Board of Directors,” in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

### ***Section 203 of the Delaware General Corporation Law***

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the DGCL which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

### ***Choice of Forum***

Our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located

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within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom is the sole and exclusive forum for the following claims or causes of action under the Delaware statutory or common law: (i) any derivative claim or cause of action brought on our behalf; (ii) any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or our stockholders; (iii) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the DGCL, our amended and restated certificate of incorporation, or our bylaws (as each may be amended from time to time); (iv) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation, or remedy thereunder); (v) any claim or cause of action as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any claim or cause of action against us or any of our current or former directors, officers, or other employees governed by the internal-affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. Our amended and restated certificate of incorporation to be effective on the closing of this offering will further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against an defendant to such complaint. The choice of forum provisions would not apply to claims or causes of action brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction.

For the avoidance of doubt, these provisions are intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated certificate of incorporation to be effective immediately after the closing of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

### **Limitations on Liability and Indemnification**

See the section titled "Executive Compensation—Limitations on Liability and Indemnification."

### **Exchange Listing**

Our common stock is currently listed on The Nasdaq Global Select Market under the symbol "LYEL."

### **Transfer Agent and Registrar**

On the closing of this offering, the transfer agent and registrar for our common stock will be American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue | Brooklyn, NY 11219.

## SHARES ELIGIBLE FOR FUTURE SALE

Before the closing of this offering, there has been no public market for our common stock. Future sales of substantial amounts of our common stock, including shares issued on the exercise of outstanding options, in the public market after this offering, or the possibility of these sales or issuances occurring, could adversely affect the prevailing market price for our common stock or impair our ability to raise equity capital.

Based on our shares outstanding as of March 31, 2021, upon the closing of this offering, a total of 242,829,956 shares of common stock will be outstanding, assuming the automatic conversion of all outstanding shares of our convertible preferred stock into 194,474,431 shares of our common stock in connection with the closing of this offering and 5,525,002 shares of unvested restricted common stock subject to repurchase. Of these shares, all of the common stock sold in this offering by us, plus any shares sold by us on exercise of the underwriters' option to purchase additional common stock, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless these shares are held by "affiliates," as that term is defined in Rule 144 under the Securities Act (Rule 144).

The remaining shares of common stock will be, and shares of common stock subject to stock options will be on issuance, "restricted securities," as that term is defined in Rule 144. These restricted securities are eligible for public sale only if they are registered under the Securities Act or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which are summarized below. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market after the date of this prospectus.

### Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, an eligible stockholder is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. To be an eligible stockholder under Rule 144, such stockholder must not be deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and must have beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144, subject to the expiration of the lock-up agreements described below.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell shares on expiration of the lock-up agreements described below. Beginning 90 days after the date of this prospectus, within any three-month period, such stockholders may sell a number of shares that does not exceed the greater of:

- 1% of the number of shares of common stock then outstanding, which will equal approximately 2,428,300 shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares of common stock from us; or

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- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

### **Rule 701**

Rule 701 of the Securities Act (Rule 701) generally allows a stockholder who was issued shares under a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days, to sell these shares in reliance on Rule 144, but without being required to comply with the public information, holding period, volume limitation, or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares under Rule 701, subject to the expiration of the lock-up agreements described below.

### **Form S-8 Registration Statements**

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under our 2018 Plan, 2021 Plan and ESPP. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below, and Rule 144 limitations applicable to affiliates.

### **Lock-up Arrangements**

We, and all of our directors, executive officers and the holders of substantially all of our common stock and securities exercisable for or convertible into our common stock outstanding immediately on the closing of this offering, have agreed with the underwriters that, until 180 days after the date of the underwriting agreement related to this offering, we and they will not, without the prior written consent of the representatives of the underwriters, subject to certain exceptions, directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any of our shares of common stock, or any securities convertible into or exercisable or exchangeable for shares of our common stock, or enter into any hedging, swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the securities, whether any such swap or transaction is to be settled by delivery of our common stock or other securities, in cash or otherwise. These agreements are described in "Underwriting." The representatives of the underwriters may, in their sole discretion, release any of the securities subject to these lock-up agreements at any time.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain security holders, including the amended and restated investors' rights agreement, our standard form of option agreement and our standard form of restricted stock agreement, that contain market stand-off provisions or incorporate market stand-off provisions from our equity incentive plan imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

## **Registration Rights**

Upon the closing of this offering, pursuant to our amended and restated investors' rights agreement, the holders of 194,474,431 shares of our common stock, or their transferees, will be entitled to certain rights with respect to the registration of the offer and sale of their shares under the Securities Act, subject to the terms of the lock-up agreements described under the section titled "—Lock-Up Arrangements" above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately on the effectiveness of the registration. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See the section titled "Description of Capital Stock—Registration Rights" for additional information.

## CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the purchase, ownership and disposition of our common stock issued pursuant to this offering. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, and does not address any estate or gift tax consequences or any tax consequences arising under any state, local or foreign tax laws, or any other U.S. federal tax laws. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions and published rulings and administrative pronouncements of the Internal Revenue Service (the IRS), all as in effect on the date of this prospectus. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock pursuant to this offering and who hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to an individual non-U.S. holder in light of such non-U.S. holder's particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to non-U.S. holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other pass-through entities (and investors therein);
- "controlled foreign corporations";
- "passive foreign investment companies";
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers, dealers or traders in securities;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons who acquire our common stock through the exercise of an option or otherwise as compensation;
- qualified foreign pension funds as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds;
- persons subject to the alternative minimum tax;
- persons subject to special tax accounting rules under Section 451(b) of the Code;
- persons that own or have owned, actually or constructively, more than 5% of our common stock;
- persons who have elected to mark securities to market; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner, the activities of the partnership and certain determinations made at the partner level. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL OR FOREIGN TAX LAWS AND ANY OTHER U.S. FEDERAL TAX LAWS.**

#### **Definition of Non-U.S. Holder**

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (ii) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

#### **Distributions on Our Common Stock**

As described in the section titled “Dividend Policy,” we do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. However, if we distribute cash or other property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any excess will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under “—Gain on Disposition of Our Common Stock” below.

Subject to the discussion below regarding effectively connected income, backup withholding and FATCA (as defined below), dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or our withholding agent with a valid IRS Form W-8BEN (in the case of individuals) or IRS Form W-8BEN-E (in the case of entities), or other appropriate form, certifying such holder’s qualification for the reduced rate. This certification must be provided to us or our withholding agent before the payment of dividends and must be updated periodically. In the case of a

non-U.S. holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of the tax treaty, dividends will be treated as paid to the entity or to those holding an interest in the entity. If the non-U.S. holder holds our common stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or our withholding agent, either directly or through other intermediaries.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment or fixed base in the United States if required by an applicable tax treaty), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Gain on Disposition of Our Common Stock**

Subject to the discussion below regarding backup withholding and FATCA (as defined below), a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- we are or become a United States real property holding corporation (aUSRPHC) for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market during the calendar year in which the sale or other disposition occurs.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We believe that we are not currently and we do not anticipate becoming a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such



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holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. A non-U.S. holder described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), on gain realized upon the sale or other taxable disposition of our common stock which may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. If we are or become a United States real property holding corporation during the period described in the third bullet point above and our common stock is not regularly traded for purposes of the relevant rules, gain arising from the sale or other taxable disposition of our common stock by a non-U.S. holder will generally be subject to U.S. federal income tax in the same manner as gain that is effectively connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply.

Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E or IRS Form W-8ECI, or certain other requirements are met, and if the payor does not have actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

### **Withholding on Payment to Certain Foreign Accounts or Entities**

Sections 1471 through 1474 of the Code (commonly referred to as FATCA), impose a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might

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be eligible for refunds or credits of such taxes. FATCA currently applies to dividends paid on our common stock and would have applied also to payments of gross proceeds from the sale or other disposition of our common stock. The U.S. Treasury Department has released proposed regulations under FATCA providing for the elimination of the federal withholding tax of 30% applicable to gross proceeds of a sale or other disposition of our common stock. Under these proposed Treasury Regulations (which may be relied upon by taxpayers prior to finalization), FATCA will not apply to gross proceeds from sales or other dispositions of our common stock.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

## UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the number of shares indicated in the following table. Goldman Sachs & Co. LLC, BofA Securities, Inc., J.P. Morgan Securities, LLC and Morgan Stanley & Co. LLC are the representatives of the underwriters.

<b>Underwriters</b>	<b>Number of Shares</b>
Goldman Sachs & Co. LLC	6,250,000
BofA Securities, Inc.	6,250,000
J.P. Morgan Securities, LLC	6,250,000
Morgan Stanley & Co. LLC	6,250,000
<b>Total</b>	<b>25,000,000</b>

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until this option is exercised.

The underwriters have an option to buy up to an additional 3,750,000 shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise that option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above.

The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters by us. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase 3,750,000 additional shares.

	<b>No Exercise</b>	<b>Full Exercise</b>
Per Share	\$ 1.19	\$ 1.19
Total	\$ 29,750,000	\$ 34,212,500

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to \$0.714 per share from the initial public offering price. After the initial offering of the shares, the representatives may change the offering price and the other selling terms. The offering of the shares by the underwriters is subject to receipt and acceptance and subject to the underwriters' right to reject any order in whole or in part.

We and our officers, directors and holders of substantially all of our common stock and securities convertible into or exchangeable for our common stock have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their common stock or securities convertible into or exchangeable for shares of our common stock during the period from the date of this prospectus continuing through the date 180 days after the date of this prospectus, except with the prior written consent of the representatives. This agreement does not apply to any existing employee benefit plans. See "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for the shares. The initial public offering price has been negotiated among us and the representatives. Among the factors to be considered in

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determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of the business potential and our earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol "LYEL".

In connection with the offering, the underwriters may purchase and sell shares of common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our common stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on NYSE, Nasdaq NMS or relevant exchange, in the over-the-counter market or otherwise.

We estimate that our share of the total expenses of the offering, excluding underwriting discounts and commissions, will be approximately \$3,845,960. We will reimburse the underwriters for certain of their expenses incurred in connection with this offering in an amount up to \$50,000.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and

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their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

### ***Directed Share Program***

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 1,250,000 of the shares offered by this prospectus, excluding the additional shares that the underwriters have a 30-day option to purchase, for sale to certain of our directors and officers and certain other parties related to us. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. If purchased by any of our officers or directors, these shares will be subject to the terms of lock-up agreements described above. Other than the underwriting discount described on the front cover of this prospectus, the underwriters will not be entitled to any commission with respect to shares of our common stock sold pursuant to the directed share program.

### **Selling Restrictions**

#### *European Economic Area*

In relation to each EEA Member State (each a “**Relevant Member State**”), no common shares (the “Shares”) have been offered or will be offered pursuant to the Offering to the public in that Relevant Member State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Regulation, except that the Shares may be offered to the public in that Relevant Member State at any time:

- a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;
- b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation) subject to obtaining the prior consent of the Joint Global Coordinators for any such offer; or
- c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of the Shares shall require the Company and/or Selling Shareholders or any Bank to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

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For the purposes of this provision, the expression an 'offer to the public' in relation to the Shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase any Shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any Shares under, the Offering contemplated hereby will be deemed to have represented, warranted and agreed to and with each of the Underwriters and their affiliates and the Company that:

- a) it is a qualified investor within the meaning of the Prospectus Regulation; and
- b) in the case of any Shares acquired by it as a financial intermediary, as that term is used in Article 5 of the Prospectus Regulation, (i) the Shares acquired by it in the Offering have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Regulation, or have been acquired in other circumstances falling within the points (a) to (d) of Article 1(4) of the Prospectus Regulation and the prior consent of the Joint Global Coordinators has been given to the offer or resale; or (ii) where the Shares have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those Shares to it is not treated under the Prospectus Regulation as having been made to such persons.

The Company, the Underwriters and their affiliates, and others will rely upon the truth and accuracy of the foregoing representation, acknowledgement and agreement. Notwithstanding the above, a person who is not a qualified investor and who has notified the Joint Global Coordinators of such fact in writing may, with the prior consent of the Joint Global Coordinators, be permitted to acquire Shares in the Offering.

### *United Kingdom*

This Prospectus and any other material in relation to the common shares (the "Shares") described herein is only being distributed to, and is only directed at, and any investment or investment activity to which this Prospectus relates is available only to, and will be engaged in only with persons who are (i) persons having professional experience in matters relating to investments who fall within the definition of investment professionals in Article 19(5) of the FPO; or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the FPO; (iii) outside the UK; or (iv) persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) in connection with the issue or sale of any Shares may otherwise lawfully be communicated or caused to be communicated, (all such persons together being referred to as "**Relevant Persons**"). The Shares are only available in the UK to, and any invitation, offer or agreement to purchase or otherwise acquire the Shares will be engaged in only with, the Relevant Persons. This Prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the UK. Any person in the UK that is not a Relevant Person should not act or rely on this Prospectus or any of its contents.

No Shares have been offered or will be offered pursuant to the Offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the Shares may be offered to the public in the United Kingdom at any time:

- a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;

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- b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the Global Coordinators for any such offer; or
- c) in any other circumstances falling within Section 86 of the FSMA.

provided that no such offer of the Shares shall require the Company and/or any Underwriters or any of their affiliates to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the Shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any Shares to be offered so as to enable an investor to decide to purchase or subscribe for any Shares and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Each person in the UK who acquires any Shares in the Offer or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company, the Underwriters and their affiliates that it meets the criteria outlined in this section.

### *Canada*

The securities may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions, and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption form, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

### *Hong Kong*

The shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32 of the Laws of Hong Kong) (“Companies (Winding Up and Miscellaneous Provisions) Ordinance”) or which do not constitute an invitation to the public within the meaning of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong) (“Securities and Futures Ordinance”); or (ii) to “professional investors” as defined in the Securities and Futures Ordinance and any rules made thereunder; or (iii) in other circumstances which do not result in the document being a “prospectus” as defined in the Companies (Winding Up and Miscellaneous Provisions) Ordinance, and no advertisement, invitation or document relating to the shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be

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accessed or read by, the public in Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” in Hong Kong as defined in the Securities and Futures Ordinance and any rules made thereunder.

### *Singapore*

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares may not be circulated or distributed, nor may the shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”) under Section 274 of the SFA; (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for 6 months after that corporation has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA); (ii) where such transfer arises from an offer in that corporation’s securities pursuant to Section 275(1A) of the SFA; (iii) where no consideration is or will be given for the transfer; (iv) where the transfer is by operation of law; (v) as specified in Section 276(7) of the SFA; or (vi) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore (“Regulation 32”).

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries’ rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired the shares under Section 275 of the SFA except: (i) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA); (ii) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets); (iii) where no consideration is or will be given for the transfer; (iv) where the transfer is by operation of law; (v) as specified in Section 276(7) of the SFA; or (vi) as specified in Regulation 32.

Singapore Securities and Futures Act Product Classification—Solely for the purposes of its obligations pursuant to Sections 309B(1)(a) and 309B(1)(c) of the SFA, we have determined, and hereby notify all relevant persons (as defined in Section 309A of the SFA) that the common shares are “prescribed capital markets products” (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).



*Japan*

The securities have not been and will not be registered under the Financial Instruments and Exchange Act of Japan (Act No. 25 of 1948, as amended) (the FIEA). The securities may not be offered or sold, directly or indirectly, in Japan or to or for the benefit of any resident of Japan (including any person resident in Japan or any corporation or other entity organized under the laws of Japan) or to others for reoffering or resale, directly or indirectly, in Japan or to or for the benefit of any resident of Japan, except pursuant to an exemption from the registration requirements of the FIEA and otherwise in compliance with any relevant laws and regulations of Japan.

## LEGAL MATTERS

The validity of the shares of our common stock being offered in this prospectus will be passed upon for us by Cooley LLP. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited our consolidated financial statements at December 31, 2019 and 2020, and for the years then ended as set forth in their report. We've included our consolidated financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC also maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

On the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

We also maintain a website at [www.lyell.com](http://www.lyell.com). Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

LYELL IMMUNOPHARMA, INC.

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## 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, 2019 and 2020, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for the years then ended, 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, 2019 and 2020, and the results of its operations and its cash flows for the years then ended 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.

/s/ Ernst & Young LLP

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

Seattle, Washington  
April 12, 2021

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

	As of December 31,	
	2019	2020
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 96,674	\$ 140,406
Short-term marketable securities	339,375	472,213
Prepaid expenses and other current assets	4,210	4,928
Total current assets	440,259	617,547
Restricted cash	1,798	466
Long-term marketable securities	34,983	79,995
Other investments	34,000	83,448
Property and equipment, net	17,976	77,045
Right-of-use assets, net	25,729	47,010
Other non-current assets	886	2,769
Total assets	<u>\$ 555,631</u>	<u>\$ 908,280</u>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 2,844	\$ 9,396
Accrued liabilities and other current liabilities	14,254	28,021
Success payment liabilities	436	5,773
Deferred revenue	4,511	6,095
Total current liabilities	22,045	49,285
Operating lease liabilities, net of current portion	27,125	50,957
Deferred revenue, net of current portion	98,406	89,066
Other non-current liabilities	—	532
Total liabilities	147,576	189,840
<i>Commitments and contingencies (Note 16)</i>		
Convertible preferred stock, \$0.0001 par value; 152,537 and 195,021 shares authorized at December 31, 2019 and 2020, respectively; 152,116 and 194,474 shares issued and outstanding at December 31, 2019 and 2020, respectively	519,163	1,010,968
Stockholders' deficit:		
Common stock, \$0.0001 par value; 205,600 and 264,905 shares authorized at December 31, 2019 and 2020, respectively; 11,181 and 15,570 shares issued and outstanding at December 31, 2019 and 2020, respectively	1	2
Additional paid-in capital	18,108	41,357
Accumulated other comprehensive income	454	256
Accumulated deficit	(129,671)	(334,143)
Total stockholders' deficit	(111,108)	(292,528)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 555,631</u>	<u>\$ 908,280</u>

*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,	
	2019	2020
Revenue	\$ 657	\$ 7,756
Operating expenses (income):		
Research and development	63,595	182,243
General and administrative	39,151	46,881
Other operating income, net	—	(9,431)
Total operating expenses	<u>102,746</u>	<u>219,693</u>
Loss from operations	(102,089)	(211,937)
Interest income, net	8,121	5,939
Other (expense) income, net	(35,409)	1,526
Net loss	(129,377)	(204,472)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on marketable securities	454	(198)
Net comprehensive loss	<u>\$ (128,923)</u>	<u>\$ (204,670)</u>
Net loss attributed to common stockholders:		
Net loss	\$ (129,377)	\$ (204,472)
Deemed dividends upon issuance or repurchase of convertible preferred stock	(1,144)	(3,582)
Net loss attributed to common stockholders	<u>\$ (130,521)</u>	<u>\$ (208,054)</u>
Net loss per common share, basic and diluted	<u>\$ (24.04)</u>	<u>\$ (15.69)</u>
Weighted-average shares used to compute net loss per common share, basic and diluted	<u>5,429</u>	<u>13,258</u>

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Retained Earnings (Accumulated Deficit)	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2018	74,406	\$ 120,296	1,092	\$ —	\$ 826	\$ —	\$ 24	\$ 850
Issuance of Series A convertible preferred stock, net of \$29 in issuance costs	23,527	89,380	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of \$133 in issuance costs	23,930	162,018	—	—	—	—	—	—
Issuance of Series AA convertible preferred stock, net of \$101 in issuance costs	30,253	146,325	—	—	—	—	—	—
Deemed dividends on issuance of Series A convertible preferred stock	—	1,144	—	—	(826)	—	(318)	(1,144)
Issuance of common stock to strategic partners	—	—	910	—	2,562	—	—	2,562
Repurchase of common stock	—	—	—	—	(185)	—	—	(185)
Stock-based compensation	—	—	9,179	1	15,731	—	—	15,732
Other comprehensive income	—	—	—	—	—	454	—	454
Net loss	—	—	—	—	—	—	(129,377)	(129,377)
Balance as of December 31, 2019	<u>152,116</u>	<u>\$ 519,163</u>	<u>11,181</u>	<u>\$ 1</u>	<u>\$ 18,108</u>	<u>\$ 454</u>	<u>\$ (129,671)</u>	<u>\$ (111,108)</u>
Issuance of Series C convertible preferred stock, net of \$533 in issuance costs	42,905	492,467	—	—	—	—	—	—
Issuance of common stock to strategic partners	—	—	275	—	1,004	—	—	1,004
Issuance of common stock for asset acquisition	—	—	688	—	4,000	—	—	4,000
Issuance of common stock upon exercise of stock options	—	—	113	—	373	—	—	373
Stock-based compensation	—	—	5,345	1	33,260	—	—	33,261
Repurchase of convertible preferred stock	(547)	(662)	—	—	(3,582)	—	—	(3,582)
Repurchase of common stock	—	—	(2,032)	—	(11,806)	—	—	(11,806)
Other comprehensive loss	—	—	—	—	—	(198)	—	(198)
Net loss	—	—	—	—	—	—	(204,472)	(204,472)
Balance as of December 31, 2020	<u>194,474</u>	<u>\$1,010,968</u>	<u>15,570</u>	<u>\$ 2</u>	<u>\$ 41,357</u>	<u>\$ 256</u>	<u>\$ (334,143)</u>	<u>\$ (292,528)</u>

*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,	
	2019	2020
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (129,377)	\$ (204,472)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,256	4,294
Accretion of marketable securities	(1,511)	595
Stock-based compensation expense	15,732	33,261
Change in fair value of success payment liabilities	436	5,337
Change in fair value of warrants	—	(1,323)
Loss on remeasurement of convertible preferred stock tranche liabilities	35,444	—
Gain on sale of assets	—	(4,884)
Expense in connection with equity issuances	3,566	—
Lease expense, net of gain on lease remeasurement	3,127	3,181
Non-cash expense in connection with asset acquisition	—	3,529
Other	(7)	(56)
Changes in operating assets and liabilities:		
Prepaid expense and other assets	(5,767)	(1,388)
Accounts payable	1,709	(278)
Accrued liabilities and other liabilities	11,949	9,086
Deferred revenue	102,917	(7,756)
Net cash provided by (used in) operating activities	<u>39,474</u>	<u>(160,874)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(16,047)	(51,481)
Purchases of marketable securities	(610,842)	(864,909)
Sales and maturities of marketable securities	238,456	686,322
Purchases of other investments	(34,000)	(43,448)
Net cash used in investing activities	<u>(422,433)</u>	<u>(273,516)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	351,341	492,467
Proceeds from exercise of stock options	—	373
Payments for the repurchase of common stock	(185)	(11,806)
Payments for the repurchase of preferred stock	—	(4,244)
Net cash provided by financing activities	<u>351,156</u>	<u>476,790</u>
Net (decrease) increase in cash, cash equivalents, and restricted cash	(31,803)	42,400
Cash, cash equivalents and restricted cash at beginning of period	130,275	98,472
Cash, cash equivalents and restricted cash at end of period	<u>\$ 98,472</u>	<u>\$ 140,872</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Purchases of property and equipment included in accounts payable and accrued liabilities	<u>\$ 3,185</u>	<u>\$ 12,740</u>
Operating lease right-of-use assets obtained in exchange for lease obligations	<u>\$ 23,656</u>	<u>\$ 30,475</u>
Remeasurement of operating lease right of use asset for lease modification	<u>\$ —</u>	<u>\$ (8,958)</u>
Cash received for amounts related to tenant improvement allowances	<u>\$ 2,194</u>	<u>\$ 2,966</u>
Cash paid for amounts included in the measurement of lease liabilities	<u>\$ 1,464</u>	<u>\$ 5,147</u>
Other investments received for sale of assets	<u>\$ —</u>	<u>\$ 6,000</u>
Non-cash deemed dividends on convertible preferred stock	<u>\$ 1,144</u>	<u>\$ —</u>

*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 T cell reprogramming company dedicated to the mastery of T cells to eradicate solid tumors. The Company is building a multi-modality product pipeline. The Company's primary activities since incorporation have been to develop T cell therapies, perform research and development, acquire technology, enter into strategic collaboration and license arrangements, enable manufacturing activities in support of its product candidate development efforts, organize and staff the Company, business plan, establish its intellectual property portfolio, 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 Lyell Immunopharma, Inc. and its wholly-owned subsidiaries. All significant intercompany transactions and balances are eliminated in consolidation.

***Use of Estimates***

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect reported amounts and related disclosures. Specific accounts that require management estimates include, but are not limited to, stock-based compensation, valuation of success payments, revenue recognition, the fair value of convertible preferred and common stock 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.

***Comprehensive Loss***

Comprehensive loss includes net loss and certain changes in stockholders' deficit that are excluded from net loss. For the years ended December 31, 2019 and 2020 this was comprised of unrealized gains and losses on the Company's marketable securities.

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

**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 money market accounts. The following table provides a reconciliation of cash and cash equivalents and restricted cash reported within the consolidated balance sheets that sum to the total of the same such amounts shown in the consolidated statements of cash flows (in thousands):

	December 31,	
	2019	2020
Cash and cash equivalents	\$96,674	\$140,406
Restricted cash	1,798	466
Total cash, cash equivalents and restricted cash shown in the statements of cash flows	<u>\$98,472</u>	<u>\$140,872</u>

Restricted cash is cash held in bank accounts and is used as collateral for letters of credits issued in conjunction with the Company's lease agreements and collateral associated with the Company's corporate credit card program.

**Marketable Securities**

The Company generally invests its excess cash in investment grade short-to intermediate-term fixed income securities. Such investments are included in cash and cash equivalents, short-term marketable securities or long-term marketable securities, classified as available-for-sale and are carried at fair value. Unrealized gains and losses are excluded from net loss and are reported as a component of comprehensive loss. Realized gains and losses on available-for-sale securities are included in other (expense) income, net. The cost of investments sold is based on the specific-identification method. Investments in securities with maturities of less than one year, or those which the Company intends to use to fund current operations, are included in current assets.

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 are recorded as an allowance through other (expense) income, net.

**Other Investments**

The Company determines at the inception of each arrangement whether an investment or other interest is considered a variable interest entity ("VIE"). If the investment or other interest is determined to be a VIE, the Company evaluates whether it is considered the primary beneficiary. The primary beneficiary of a VIE is the party that meets both of the following criteria: (i) has the power to direct the activities that most significantly impact the VIE's economic performance; and (ii) has the obligation to absorb losses or the right to receive benefits from the VIE. For investments in VIEs in which the Company is considered the primary beneficiary, the assets, liabilities and results of operations of the VIE are consolidated in its consolidated financial statements. As of December 31, 2019 and 2020, there were no VIEs for which the Company was the primary beneficiary.

The Company accounts for its strategic equity interests in non-publicly traded companies for which it does not have the ability to exercise significant influence in accordance with Accounting

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

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. 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.

Additionally, the Company holds an investment in equity warrants giving it the right to acquire stock of a non-publicly traded company. Equity warrant investments are recorded within other assets at the estimated fair value, with gains and losses recognized in other (expense) income, net.

***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. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets. 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 (expense) income, net in the period realized. Maintenance and repairs are expensed as incurred.

The Company has determined the estimated life of the assets to be as follows:

Laboratory equipment	5 years
Computer equipment and software	3 years
Furniture and fixtures	5 years
Leasehold improvements	Shorter of asset’s useful life or remaining lease term

***Impairment of Long-Lived Assets***

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

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

**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. Transaction costs are expensed as incurred. 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.

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.

**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, 2019 and 2020, all of the Company’s leases were classified as operating leases.

The Company will recognize 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.

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**Notes to Consolidated Financial Statements—(Continued)**

***Fair Value of Financial Instruments***

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. The fair value hierarchy prioritizes valuation inputs based on the observable nature of those inputs. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The hierarchy defines three levels of valuation inputs:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.
- Level 3 – Unobservable inputs that reflect the Company's own assumptions about the assumptions market participants would use in pricing the asset or liability.

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

***Convertible Preferred Stock Option***

Pursuant to the Series A convertible preferred stock purchase agreement ("Series A SPA") entered into in September 2018, the Company had the right to sell, or "put," additional shares of its Series A convertible preferred stock in subsequent closings, contingent upon the approval of the Company's board of directors, as well as potential obligations to issue additional convertible preferred shares upon the occurrence of certain events. As of December 31, 2018, certain holders of Series A convertible preferred stock were obligated to purchase an additional aggregate of 23,272,720 shares at \$1.83 per share in a subsequent closing. Such closing was contingent upon the approval by the Company's board of directors, and the Company was obligated to sell the same number of shares upon the occurrence of certain events.

The Company assessed its rights and obligations to sell additional shares and determined that these rights and obligations were a single unit of accounting that created an obligation for the Company to issue additional shares of its Series A convertible preferred stock and represented a freestanding financial instrument that was recorded as a convertible preferred stock tranche liability in 2018 ("Series A Tranche Liability"). The Series A Tranche Liability was recorded at fair value on issuance with subsequent changes in fair value being recorded in other (expense) income, net.

In February 2019, pursuant to the Series A SPA, the Company exercised its right to sell and certain holders of Series A convertible preferred stock were obligated to purchase an additional 22,961,250 shares of its Series A convertible preferred stock at \$1.83 per share, resulting in aggregate gross proceeds to the Company of \$42.0 million. Prior to the exercise, the Series A convertible preferred stock option was revalued to fair value of \$46.4 million, which equated to intrinsic value, resulting in other expense of \$35.4 million for the year ended December 31, 2019.

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**Notes to Consolidated Financial Statements—(Continued)**

***Deemed Dividends Upon Issuance or Repurchase of Convertible Preferred Stock***

In addition to the sale of Series A convertible preferred shares sold pursuant to the tranche right discussed above, the Company sold 566,490 shares of Series A convertible preferred stock in January 2019, at which time the estimated fair value of the Series A convertible preferred stock was \$3.85 per share, compared with the purchase price per share of \$1.83. The differences between the estimated fair value as of the closing dates and the purchase prices were deemed to be equivalent to a preferred stock dividend. As a result, the Company recorded deemed dividends of \$1.1 million for the year ended December 31, 2019. The deemed dividends increased convertible preferred stock by \$1.1 million, reduced additional paid-in capital by \$0.8 million, and increased accumulated deficit by \$0.3 million. The deemed dividends increased the net loss attributed to common stockholders by \$1.1 million.

In March 2020, 546,806 shares of the Company's Series A convertible preferred stock were repurchased by the Company at the then estimated fair value of \$7.76 per share, which was higher than the carrying value of those shares. See Note 10, *Convertible Preferred Stock*. As a result, the Company recorded deemed dividends of \$3.6 million for the year ended December 31, 2020. The transaction decreased convertible preferred stock by \$0.7 million and reduced additional paid-in capital by \$3.6 million. The deemed dividends increased the net loss attributed to common stockholders by \$3.6 million.

***Revenue***

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which 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 to be not probable until such milestones are actually achieved. 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.

***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

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**Notes to Consolidated Financial Statements—(Continued)**

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 which have not reached technological feasibility and do not have an alternative future use are expensed as incurred.

**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 and patent matters.

**Success Payments**

The Company granted rights to success payments to Fred Hutchinson Cancer Research Center ("Fred Hutch") and The Board of Trustees of the Leland Stanford Junior University ("Stanford") pursuant to the terms of its research and collaboration agreements with each of those entities. Pursuant to the terms of these agreements, on each contractually prescribed measurement date, the Company may be required to make success payments based on increases in the estimated per share fair value of the Company's Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, payable in cash or cash equivalents or, at the Company's discretion, publicly-tradeable shares of the Company's common stock. The Company's common stock is not currently publicly-tradeable. See Note 3, *Collaboration, License and Success Payment Agreements*. The success payments are accounted for under ASC 718, *Compensation – Stock Compensation*, with the expense being recorded in research and development expenses. Once the service period is complete, the instrument will be accounted for under ASC 815, *Derivatives and Hedging*, and continue to be remeasured each reporting period with all changes in value recognized immediately in other (expense) income, net.

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

The potential payments for both the Fred Hutch and Stanford success payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the estimated per share fair value of the Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, relative to its original \$1.83 issuance price. The aggregate success payments to Fred Hutch and Stanford are not to exceed \$200.0 million for

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each entity, which would only occur upon a 50 times increase in value. For each entity, each threshold is associated with a success payment, ascending from \$10.0 million at \$18.29 per share to \$200.0 million at \$91.44 per share, payable if such threshold is reached during the measurement period. Any previous success payments made are credited against the success payment owed as of any valuation date, so that each entity does not receive multiple success payments in connection with the same threshold. The term of each success payment agreement ends on the earlier to occur of (i) the nine year anniversary of the date of the agreement and (ii) a change in control transaction.

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

<b>Fred Hutch</b>					
Multiple of initial equity value at issuance	10x	20x	30x	40x	50x
Per share Series A convertible preferred 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

<b>Stanford</b>					
Multiple of initial equity value at issuance	10x	20x	30x	40x	50x
Per share Series A convertible preferred 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 estimated per share fair value of the Series A convertible preferred 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 an initial public offering ("IPO") of the Company's common stock and each two-year anniversary of the 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.

#### **Concentrations of Credit Risk and Off-Balance Sheet Risk**

The Company maintains its cash and cash equivalents and restricted cash with high quality, accredited financial institutions. These 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, corporate bonds and commercial paper, 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.

#### **Risks and Uncertainties**

The Company is subject to a number of risks similar to other biopharmaceutical companies in the early stage, including, but not limited to, the need to obtain adequate additional funding, the need to



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manage cash burn, the inability to hire key employees, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new superior technological innovations, the need to successfully commercialize and gain market acceptance of the Company's products and access to, maintenance of and protection of its proprietary technology and ensuring freedom to operate. If the Company does not successfully commercialize or partner any of its product candidates, it will be unable to generate product revenue or achieve profitability.

***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") and stock options granted to employees, directors and consultants based on the fair value of the awards on the date of grant. The fair value of stock options is estimated at the date of grant using the Black-Scholes option pricing model, which requires the use of subjective assumptions and for management to apply judgment and make estimates, including:

- Expected term – The expected term represents the period that the stock-based awards are expected to be outstanding. The Company use 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 options.
- Expected volatility – Since the Company is not yet a public company and does not have any trading history for its common stock, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a time period equal to the expected term of the stock option grants. The comparable companies are chosen based on their size, stage in the product development cycle and area of specialty. The Company will continue to apply this process until sufficient historical information regarding the volatility of its own stock price becomes available.
- Risk-free interest rate – The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- Expected dividend – The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.
- Fair value of the Company's common stock.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock for financial reporting purposes. The Company recorded expense for RSAs and stock options at prices not less than the fair market value of its common stock as determined by the board of directors, taking into consideration input from management and an independent third-party valuation

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**Notes to Consolidated Financial Statements—(Continued)**

analysis, and in accordance with the American Institute of Certified Public Accountants (“AICPA”) Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*.

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

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

**Convertible Preferred Stock**

The carrying value of the Company’s Series A, Series B, Series AA and Series C convertible preferred stock is adjusted to reflect dividends when and if declared by the Company’s board of directors. No dividends have been declared by the board of directors since inception. The Company classifies its convertible preferred stock outside of permanent equity as the redemption of such stock is not solely under the control of the Company.

**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.

**Recent Accounting Pronouncements**

Accounting Standards Update (“ASU”) No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements*, (“ASU 2016-13”), ASU No. 2019-5 *Financial Instruments – Credit Losses (Topic 326): Targeted Transition Relief*, ASU No. 2019-11, *Codification Improvements to Topic 326, Financial Instruments – Credit Losses* – In June 2016, the Financial Accounting Standards Board (“FASB”) issued ASU 2016-13, which implements an impairment model known as the current expected credit loss model that is based on expected losses rather than incurred losses. Under the new guidance, an entity will recognize as an allowance its

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estimate of expected credit losses. The Company adopted this standard on January 1, 2020 on a modified-retrospective approach and the adoption did not have a material impact on its consolidated financial statements.

ASU No. 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606* (“ASU 2018-18”) – In November 2018, the FASB issued ASU 2018-18, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, ASU 2018-18 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The Company adopted this standard on January 1, 2020, on a retrospective basis to the date of initial application of ASC 606. The adoption did not have a material impact on its consolidated financial statements.

ASU No. 2018-15, *Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* (“ASU 2018-15”) – In 2018, the FASB issued ASU 2018-15, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. The Company adopted this guidance on a prospective basis on January 1, 2020 and the adoption did not have a material impact on its consolidated financial statements.

### **3. Collaboration, License and Success Payment Agreements**

#### ***Fred Hutch***

**License Agreement** – In 2018, the Company entered into a license agreement with Fred Hutch that grants the Company an exclusive, worldwide, sublicensable license under certain patent rights, and a non-exclusive, worldwide, sublicensable license for certain technology, to research, develop, manufacture, improve and commercialize products and processes covered by such patent rights or incorporating such technology for all therapeutic uses for the treatment of human cancer.

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

**Collaboration Agreement** – In 2018, the Company entered into a research and collaboration agreement with Fred Hutch (“Fred Hutch Collaboration Agreement”), focused on research and development of cancer immunotherapy products. The Company is committed to fund aggregate research performed by Fred Hutch of \$12.0 million under the Fred Hutch Collaboration Agreement and the research will be conducted in accordance with a research plan and budget approved by the parties. The Fred Hutch Collaboration Agreement has a six-year term, which would be extended for three additional one-year extensions if the \$12.0 million funding commitment has not yet been met. The Company incurred \$3.7 million and \$4.1 million in expense in connection with the Fred Hutch Collaboration Agreement for the years ended December 31, 2019 and 2020, respectively.

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**Success Payments** – In 2018, the Company granted Fred Hutch rights to certain success payments, pursuant to the terms of the Fred Hutch Collaboration Agreement. Pursuant to the terms of the success payment agreement, the Company may be required to make success payments payable in cash or cash equivalents or, at the Company's discretion, publicly-tradeable shares of the Company's common stock when available, based on increases in the estimated per share fair value of the Company's Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged.

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

	December 31,	
	2019	2020
Fair value of the Series A convertible preferred stock	\$ 5.08	\$ 9.07
Risk-free interest rate	1.56% - 2.23%	0.10% - 1.52%
Expected volatility	75%	80%
Expected term (in years)	1.00 - 7.97	1.00 - 6.97

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

The estimated fair value of the success payments to Fred Hutch as of December 31, 2019 and 2020 was \$3.8 million and \$8.0 million, respectively. The success payment liability is estimated at fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Fred Hutch Collaboration Agreement. With respect to Fred Hutch success payment obligations, the Company recognized expense of \$0.4 million and \$4.8 million for the years ended December 31, 2019 and 2020, respectively.

#### **Stanford**

**License Agreement** – In 2019, the Company entered into a license agreement with Stanford to license specified patent rights. The Company paid an upfront license fee of \$0.4 million upon the execution of the agreement which was recorded as research and development expense for the year ended December 31, 2019. The Company also issued Stanford 910,000 shares of its common stock in consideration for the license agreement and recognized \$2.6 million in research and development expense for the year ended December 31, 2019 based on the estimated fair value of the common stock on the issuance date. The Company granted a right for Stanford to purchase an additional \$5.0 million of the Company's Series B convertible preferred stock at fair value. In March 2019, Stanford exercised this right and purchased 737,882 shares of the Company's Series B convertible preferred stock.

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

Milestone payments to Stanford of up to a maximum of \$3.7 million per target are payable upon achievement of certain specified clinical and regulatory milestones. The Company is also obligated to

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pay Stanford \$2.5 million collectively for all licensed products upon the achievement of a certain commercial milestone. Additionally, low single-digit tiered royalties based on annual net sales of the licensed products are payable to Stanford.

**Collaboration Agreement** – In October 2020, the Company entered into a research and collaboration agreement with Stanford (“Stanford Collaboration Agreement”), focused on research and development of cellular immunotherapy products. The Stanford Collaboration Agreement has a four-year term. The Company is committed to fund aggregate research performed by Stanford of \$12.0 million under the Stanford Collaboration Agreement, and the research will be conducted in accordance with a research plan and budget approved by the parties. The Company incurred \$0.8 million in expense in connection with the Stanford Collaboration Agreement for the year ended December 31, 2020.

**Success Payments** – In October 2020, the Company granted Stanford rights to certain success payments, pursuant to the terms of the Stanford Collaboration Agreement. Pursuant to the terms of the success payment agreement, the Company may be required to make success payments payable in cash or cash equivalents or, at the Company’s discretion, publicly-tradeable shares of the Company’s common stock when available, based on increases in the estimated per share fair value of the Company’s Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged.

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

	<b>December 31, 2020</b>
Fair value of the Series A convertible preferred stock	\$ 9.07
Risk-free interest rate	0.10% - 1.53%
Expected volatility	80%
Expected term (in years)	1.00 - 8.75

The Company utilizes estimates and assumptions in determining the estimated success payment liabilities and associated expense. A small change in the valuation of the Company’s Series A convertible preferred stock may have a relatively large change in the estimated fair value of the success payment liability and associated expense.

The estimated fair value of the success payments to Stanford as of December 31, 2020 was \$8.9 million. The success payment liability is estimated at fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Stanford Collaboration Agreement. With respect to Stanford success payment obligations, the Company recognized expense of \$0.6 million for the year ended December 31, 2020.

### **GSK**

In 2019, the Company entered into a Collaboration and License Agreement, amended in June 2020 (“GSK Agreement”) with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, “GSK”) for potential T cell therapies that apply the Company’s platform technologies and cell therapy innovations with T cell receptors (“TCRs”) or chimeric antigen receptors (“CARs”) under distinct collaboration programs. The GSK Agreement has defined two initial collaboration targets and allows GSK to nominate seven additional targets through July 2024. The Company is expected to

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**Notes to Consolidated Financial Statements—(Continued)**

perform research and development services for each selected target up until a defined point (the “GSK Option Point”), at which time GSK will 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. For each selected target, both parties will determine whether it will be developed under a Proof of Concept (“PoC”) Development Program or Component Development Program. For a PoC Development Program, the Company is expected to conduct both preclinical and clinical development for the target and present clinical trial data to GSK in connection with their evaluation of whether to exercise the License Option. For a Component Development Program, the Company is obligated to perform preclinical studies only. Along with the research activities, the Company will also appoint three representatives to the joint steering committee (“JSC”) and be responsible for the manufacture of all compounds and products necessary for its research and development activities.

The Company received a non-refundable upfront payment of \$45.0 million under the GSK Agreement. The Company is entitled to certain payments upon the achievement of specified development and sales milestones (for each selected target that is already within GSK’s pipeline and meet certain criteria, the Company is eligible to receive up to an aggregate of approximately \$400.0 million, and for each selected target that is not already within GSK’s pipeline and meet certain criteria the Company is eligible to receive up to an aggregate of approximately \$900.0 million) and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK’s pipeline and meet certain criteria, or from high single digit to low teens for all other targets. The Company is also entitled to potential milestone payments based on validating the Company’s technology in a clinical setting up to an aggregate of approximately \$200.0 million. Royalties and milestones are paid once per target, even if there is more than one Lyell innovation applied to a T cell therapy directed to that target. Any amounts received from GSK are generally non-refundable unless the Company terminates a collaboration target for safety or feasibility reasons and the funding received from GSK exceeds the costs incurred for the terminated target.

In connection with the GSK Agreement, in May 2019, the Company also entered into a Stock Purchase Agreement with GSK (the “GSK Stock Purchase Agreement”), 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. As of the issuance date, the estimated fair value of the Series AA convertible preferred stock was \$4.84 per share, compared with the purchase price per share of \$6.78. The difference of \$58.6 million between the estimated fair value of the stock as of the issuance date and the purchase price was deemed to be additional consideration for the GSK Agreement. As a result, the total upfront payment for accounting purposes allocated to the GSK Agreement was \$103.6 million.

The GSK Agreement was deemed to be within the scope of ASC 606 because GSK engaged the Company to provide research and development services, which are outputs of its ongoing activities, in exchange for consideration.

The Company identified the following two distinct performance obligations: (i) research and development services related to the two initial collaboration targets, inclusive of the JSC participation and the manufacture of compounds necessary for providing the research and development services and (ii) a material right for GSK to nominate seven additional collaboration targets for which the Company will perform research and development services until the GSK Option Point.

To allocate revenue among the performance obligations, the Company determined standalone selling prices (“SSP”) of each obligation. For the research and development services, the SSP was calculated using a cost-plus margin approach. For the material right, the Company allocated the

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

transaction price to the material right by reference to the underlying research and development services expected to be provided and the corresponding expected consideration. All amounts included in the transaction price are allocated to performance obligations proportionate to their SSPs.

As of December 31, 2020, the transaction price was deemed to be \$103.6 million, consisting of the upfront payment of \$45.0 million under the GSK Agreement and the \$58.6 million allocated from the GSK Stock Purchase Agreement. Other than the upfront payment and the amounts allocated from the GSK Stock Purchase Agreement, all other contingent consideration that may be earned under the GSK Agreement is subject to uncertainties including but not limited to target addition, research and investigational new drug enabling studies, initiation of clinical trials, and other related achievements. Consequently, the transaction price currently does not include any such contingent consideration that, if included, could result in a probable significant reversal of cumulative revenue when related uncertainties become resolved. The Company will re-evaluate the transaction price at each reporting period. If and when contingent consideration is included in the transaction price, it will be allocated to the two performance obligations proportionate to their SSPs and a cumulative catchup in revenue will be recorded for the portion of the services already completed. The remaining amounts will be deferred and recognized as the services are rendered.

The research and development services are transferred as the services are performed, with cost used as the measure of progress compared to total estimated cost to complete. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. The determination of the percentage of completion requires the Company to estimate the costs to complete the project. The Company makes a detailed estimate of the costs to complete, which is reassessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate will be adjusted, and the revenue will be recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate would be recognized as an adjustment to revenue in the period in which the change in estimate occurs. The Company recognized revenue related to the research and development services related to the two initial targets of \$0.7 million and \$7.8 million for the years ended December 31, 2019 and 2020, respectively. Revenue recognized for the year ended December 31, 2020 previously was included in deferred revenue as of December 31, 2019.

**PACT**

In June 2020, the Company entered into an agreement (the "PACT Agreement") with PACT Pharma, Inc. ("PACT") to jointly develop and test a next generation personalized anti-cancer T cell therapy against solid tumors. The Company paid PACT an upfront non-refundable payment of \$50.0 million upon execution of the PACT Agreement, which was recorded in research and development expense for the year ended December 31, 2020. In November 2020, the parties agreed to suspend research and development activity under the PACT Agreement, and neither party would be required to conduct any further work under the development plan (including manufacturing development) nor incur any financial obligations (including milestone payments) that might otherwise arise, for as long as the parties continued to negotiate in good faith to resolve the issues that have arisen between them relating to the PACT Agreement.

In June 2020 in connection with the entry into the PACT Agreement, the Company also entered into a stock purchase agreement with PACT ("PACT SPA"), pursuant to which the Company purchased 17,806,901 shares of Series C-1 convertible preferred stock at a purchase price of \$2.81

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

per share. As of the purchase date, the estimated fair value of the Series C-1 convertible preferred stock was \$2.05 per share, and the difference between the estimated fair value of the preferred stock as of the purchase date and the purchase price of \$13.6 million was deemed to be additional consideration for the PACT Agreement and recognized as research and development expense. As a result, the total upfront payment paid in connection with the PACT Agreement was \$63.6 million and included in R&D expense.

Subsequently, in February 2021, the Company filed a demand for arbitration seeking, among other things, rescission of the PACT Agreement and the PACT SPA and recovery of the consideration paid thereunder.

**National Cancer Institute**

In December 2020, the Company entered into a license agreement with the National Cancer Institute (“NCI”) to license specified patents and know-how rights. The Company recorded an upfront license fee of \$0.1 million upon the execution of the agreement which was recorded as research and development expense for the year ended December 31, 2020. The Company is required to pay NCI a minimum annual maintenance fee of \$75,000, which payments may be credited against earned royalties.

Milestone payments to NCI up to a maximum of \$3.1 million are payable upon achievement of certain specified clinical and regulatory milestones and up to a maximum of \$12.0 million collectively for all licensed products upon achievement of certain commercial milestones. The Company is also obligated to pay low single-digit royalties based on annual net sales of the licensed products.

**4. Cash Equivalents and Marketable Securities**

The fair value and amortized cost of cash equivalents and marketable securities by major security type as of December 31, 2019 and 2020 are presented in the following table (in thousands):

	December 31, 2019			Fair Value
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	
Money market funds	\$ 34,223	\$ —	\$ —	\$ 34,223
U.S. Treasury securities	187,996	297	(1)	188,292
U.S. government agency securities	118,828	79	(4)	118,903
Corporate debt securities	118,245	96	(13)	118,328
Total cash equivalents and marketable securities	<u>\$459,292</u>	<u>\$ 472</u>	<u>\$ (18)</u>	<u>\$459,746</u>
Classified as:				<b>Fair Value</b>
Cash equivalents				\$ 85,388
Short-term marketable securities				339,375
Long-term marketable securities				34,983
Total cash equivalents and marketable securities				<u>\$ 459,746</u>



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**Notes to Consolidated Financial Statements—(Continued)**

	December 31, 2020			Fair Value
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	
Money market funds	\$ 50,513	\$ —	\$ —	\$ 50,513
U.S. Treasury securities	202,674	27	—	202,701
U.S. government agency securities	205,558	207	(1)	205,764
Corporate debt securities	211,086	34	(11)	211,109
<b>Total cash equivalents and marketable securities</b>	<b><u>\$669,831</u></b>	<b><u>\$ 268</u></b>	<b><u>\$ (12)</u></b>	<b><u>\$670,087</u></b>

Classified as:	Fair Value
Cash equivalents	\$ 117,879
Short-term marketable securities	472,213
Long-term marketable securities	79,995
<b>Total cash equivalents and marketable securities</b>	<b><u>\$ 670,087</u></b>

As of December 31, 2019 and 2020, the fair value of securities held by the Company in an unrealized loss position was \$54.7 million and \$132.6 million, respectively, and as of December 31, 2019 and 2020, securities held by the Company in an unrealized loss position have been in the continuous loss position for less than 12 months. The Company evaluated its securities for other-than-temporary impairment and considers the decline in market value for the securities to be primarily attributable to current economic and market conditions. 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. Gross realized gains and losses were *de minimis* for the years ended December 31, 2019 and 2020 and as a result, amounts reclassified out of accumulated other comprehensive loss for the years ended December 31, 2019 and 2020 were also *de minimis*.

As of December 31, 2019 and 2020, all of the Company's marketable securities had a maturity date of two years or less, were available for use, and were classified as available-for-sale.

**5. Other Investments**

In 2020, the Company made a strategic equity investment of \$13.0 million in Outpace Bio, Inc. ("Outpace"), a privately-held company, which represented a minority ownership interest at the time of the strategic investment. Outpace is engaged in the research and development of protein and cell technology platforms and has financed its activities via issuances of preferred stock. The Company determined that Outpace is a VIE as the at-risk equity holders, as a group, lack the characteristics of a controlling financial interest. The Company does not have majority voting rights, representation on Outpace's board of directors, or the power to direct the activities of this entity, and therefore it is not the primary beneficiary. As of December 31, 2020, the carrying value of the Company's investment in Outpace is \$13.0 million, which is recorded in other investments.

From time to time, the Company makes minority ownership strategic investments. As of December 31, 2019 and 2020, the aggregate carrying amounts of the Company's strategic investments in non-publicly traded companies were \$34.0 million and \$83.4 million, respectively. These investments are measured at initial cost, minus impairment and changes, plus or minus, resulting from observable price changes in orderly transactions for the identical or a similar investment of the same

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

issuer. There were no adjustments recorded to the carrying amount for other investments for the years ended December 31, 2019 and 2020.

**6. Fair Value Measurements**

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

	December 31, 2019			Total
	Level 1	Level 2	Level 3	
<b>Financial assets:</b>				
Money market funds	\$34,223	\$ —	\$ —	\$ 34,223
U.S. Treasury securities	—	188,292	—	188,292
U.S. government agency securities	—	118,903	—	118,903
Corporate debt securities	—	118,328	—	118,328
Total financial assets	<u>\$34,223</u>	<u>\$425,523</u>	<u>\$ —</u>	<u>\$459,746</u>
<b>Financial liabilities:</b>				
Success payment liabilities	\$ —	\$ —	\$ 436	\$ 436
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 436</u>	<u>\$ 436</u>

	December 31, 2020			Total
	Level 1	Level 2	Level 3	
<b>Financial assets:</b>				
Money market funds	\$50,513	\$ —	\$ —	\$ 50,513
U.S. Treasury securities	—	202,701	—	202,701
U.S. government agency securities	—	205,764	—	205,764
Corporate debt securities	—	211,109	—	211,109
Equity warrant investment	—	—	1,323	1,323
Total financial assets	<u>\$50,513</u>	<u>\$619,574</u>	<u>\$ 1,323</u>	<u>\$671,410</u>
<b>Financial liabilities:</b>				
Success payment liabilities	\$ —	\$ —	\$ 5,773	\$ 5,773
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 5,773</u>	<u>\$ 5,773</u>

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Level 2 marketable securities include U.S. Treasury and government agency securities, and corporate debt securities. The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize 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 Level 3 financial instruments include an equity warrant investment and success payment liabilities. The Company's Level 3 financial instruments are valued using valuation models which include the Black Scholes model for valuing the equity warrant investment and a Monte Carlo simulation for the success payment liabilities. See Note 2, *Significant Accounting Policies* and Note 3, *Collaboration, License and Success Payment Agreements*, for additional discussion on the valuation methodology and the related significant inputs.

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

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

	Equity Warrant Investment	Success Payment Liabilities	Convertible Preferred Tranche Liabilities
Balance at December 31, 2018	\$ —	\$ —	\$ 10,938
Change in fair value (1)	—	436	35,444
Settlement	—	—	(46,382)
Balance at December 31, 2019	—	436	—
Additions	1,380	—	—
Change in fair value (1)	(57)	5,337	—
Balance at December 31, 2020	<u>\$ 1,323</u>	<u>\$ 5,773</u>	<u>\$ —</u>

(1) The change in fair value associated with the equity warrant investment and convertible preferred tranche liabilities is recorded in other (expense) income, net and the change in fair value associated with success payments liabilities is recorded in research and development expense.

**7. Property and Equipment, Net**

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

	December 31,	
	2019	2020
Laboratory equipment	\$ 11,182	\$ 17,083
Leasehold improvements	3,693	8,452
Computer equipment and software	591	724
Furniture and fixtures	178	178
Construction in progress	3,588	55,712
Property and equipment, at cost	19,232	82,149
Less: Accumulated depreciation	(1,256)	(5,104)
Total property and equipment, net	<u>\$ 17,976</u>	<u>\$ 77,045</u>

Depreciation expense was \$1.3 million and \$4.2 million for the years ended December 31, 2019 and 2020, respectively.

**8. Accrued Liabilities and Other Current Liabilities**

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

	December 31,	
	2019	2020
Accrued compensation and related benefits	\$ 8,911	\$ 14,850
Accrued property and equipment	2,426	5,910
Current lease liabilities	344	3,617
Accrued research and development expenses	1,338	2,575
Other	1,235	1,069
Total accrued liabilities and other current liabilities	<u>\$ 14,254</u>	<u>\$ 28,021</u>

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

**9. Leases**

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 an operating lease for approximately 34,000 square feet of office and laboratory space in South San Francisco, California. The initial lease term expires in August 2029 with no option to extend the lease. In August 2019, the Company amended the lease to add an additional approximately 6,000 square feet of office and laboratory space for a total of approximately 40,000 square feet. In August 2019, the Company also amended the lease to add an early termination right, which allows the Company to terminate the lease by the delivery of 12 months advance written notice to the landlord delivered no later than December 2020. In December 2020, the Company exercised the early termination right and the lease term will end in December 2021. The Company remeasured the remaining consideration in the contract, which resulted in a gain of \$2.9 million, which was recognized in other operating income, net.

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.

The following table summarizes the Company's future minimum operating lease commitments, including expected lease incentives to be received, as of December 31, 2020 (in thousands):

Year Ending December 31:	
2021	\$ 10,096
2022	10,734
2023	11,054
2024	11,385
2025	11,898
Thereafter	58,962
Total undiscounted lease payments	114,129
Less: imputed interest	(41,497)
Less: tenant improvement allowances	(18,057)
Total operating lease liabilities(1)	\$ 54,575

(1) Total operating lease liabilities consisted of \$3.6 million included in accrued liabilities and other current liabilities and \$51.0 million in long-term lease liabilities.

The operating lease costs for all operating leases were \$4.6 million and \$11.2 million for the years ended December 31, 2019 and 2020, respectively. The operating lease costs and total commitments for short-term leases was *de minimis* for the years ended December 31, 2019 and 2020. Variable lease costs for operating leases were \$1.0 million and \$2.1 million for the years ended

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

December 31, 2019 and 2020, respectively. The weighted average remaining lease term and discount rate for operating leases as of December 31, 2020 was 9.0 years and 9.6%, respectively.

**10. Convertible Preferred Stock**

During 2019, the Company sold shares of its Series A, Series B and Series AA convertible preferred stock. The Company sold 23,527,740 shares of Series A convertible preferred stock at a price of \$1.83 per share for proceeds of \$43.0 million. The Company sold 23,929,531 shares of its Series B convertible preferred stock at a price of \$6.78 per share for proceeds of \$162.0 million, net of issuance costs of \$0.1 million. The Company sold 30,253,189 shares of its Series AA convertible preferred stock at an estimated fair value of \$4.84 per share for proceeds of \$146.3 million, net of issuance costs of \$0.1 million.

In March 2020, the Company sold 42,905,042 shares of its Series C convertible preferred stock at a price of \$11.49 per share for proceeds of \$492.5 million, net of issuance costs of \$0.5 million. In connection with this financing, the Company amended and restated its certificate of incorporation to increase its authorized capital stock to 264,905,000 shares designated as common stock and 195,021,237 shares designated as preferred stock, of which 97,933,475 shares are designated as Series A convertible preferred stock, 23,929,531 shares are designated as Series B convertible preferred stock, 30,253,189 shares are designated as Series AA convertible preferred stock and 42,905,042 shares are designated as Series C convertible preferred stock.

In March 2020, the Company repurchased 546,806 shares of its Series A convertible preferred stock from a related party for a purchase price of \$4.2 million.

**Conversion**

Shares of the Company's Series A, Series B, Series AA and Series C preferred stock are convertible into common stock based on a defined conversion ratio, which was initially set at one-for-one, adjustable for certain events. No such adjustment had occurred as of December 31, 2019 and 2020.

The preferred stock is convertible into common stock at the option of the holder at any time without any additional consideration, and all shares convert automatically upon the closing of the sale of shares of common stock in an underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "Securities Act"), provided that such offering results in at least \$50.0 million of gross proceeds to the Company. The Company's Series A, Series B, Series AA and Series C convertible preferred stock will automatically convert into shares of common stock upon the vote or written consent of the holders of at least a majority of the outstanding Series A, Series B, Series AA and Series C convertible preferred stock voting together as a single class on an as-converted to common stock basis.

**Dividends**

Each holder of the Company's Series A, Series B, Series AA and Series C convertible preferred stock is entitled to receive non-cumulative dividends, when and if declared by the Company's board of directors, at an annual rate of 8% of the original issue price prior to and in preference to the payment of a dividend on common stock. No dividends have been declared to date.

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

***Liquidation Preference***

In the event that the Company is liquidated either voluntarily or involuntarily, or if any event occurs that is deemed a liquidation under the Company's certificate of incorporation, each holder of the Company's Series A, Series B, Series AA and Series C convertible preferred stock will be entitled to receive a liquidation preference out of any proceeds from the liquidation before any distributions are made to the holders of common stock. The liquidation preference for each share of the Series A, Series B and Series C convertible preferred stock is equal to the original issue price for such series (plus any declared but unpaid dividends), which is \$1.83 for each of the Series A convertible preferred stock, \$6.78 for each of the Series B convertible preferred stock and \$11.49 for each of the Series C convertible preferred stock or the amount per share as would have been payable had all shares of Series A, Series B and Series C convertible preferred been converted into common stock, respectively. The liquidation preference for each share of the Series AA convertible preferred stock is equal to fifty percent (50%) of the original issue price of Series AA preferred stock of \$6.78 per share (plus any declared but unpaid dividends), which is \$3.39 for each of the Series AA convertible preferred stock, or the amount per share as would have been payable had all shares of Series AA convertible preferred been converted into common stock.

***Voting Rights***

Each holder of convertible preferred stock votes (on an as-converted to common stock basis) with the other voting stock of the Company. Certain actions specified in the certificate of incorporation require the consent of at least a majority of the Company's Series A convertible preferred stock, Series B convertible preferred stock, Series AA convertible preferred stock and Series C convertible preferred stock, together as a single class on an as-converted to common stock basis. Certain actions specified in the certificate of incorporation may also require the consent of at least a majority of the Series A convertible preferred stock, voting as a single class, and/or at least a majority of the Series B convertible preferred stock, voting as a single class, and/or at least a majority of the Series AA convertible preferred stock, voting as a single class and/or at least a majority of the Series C convertible preferred stock, voting as a single class. Certain actions specified in the certificate of incorporation require the consent of at least a majority of the Series A convertible preferred stock, Series B and Series C convertible preferred stock voting together, separately as a single class.

In addition, the stockholders of the Company have entered into a voting agreement pursuant to which one of the holders of Series A convertible preferred stock is permitted to designate two members of the Company's board of directors, which right expires upon an IPO.

***Redemption Rights***

The stockholders holding the majority of the Series A convertible preferred stock had the right to request redemption of their shares at the original issue price for each share plus all declared, but unpaid dividends, commencing on the 121<sup>st</sup> day after the original issue date of September 20, 2018 if certain events had not occurred. In January 2019, the redemption right pursuant to the Series A SPA was waived based on the Company's board of directors' determination regarding the status of certain events, as permitted by the Series A SPA.

***Convertible Preferred Stock Option***

In February 2019, pursuant to the Series A SPA, the Company exercised its right to sell and certain holders of Series A convertible preferred stock were obligated to purchase an additional

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

22,961,250 shares of its Series A preferred stock at \$1.83 per share in exchange for \$42.0 million. See Note 2, *Significant Accounting Policies*.

**11. Common Stock**

As of December 31, 2019 and 2020, there were 11,180,711 shares and 15,569,788 shares of the Company's common stock outstanding, respectively, excluding 13,663,338 shares and 7,562,503 shares, respectively, of RSAs outstanding that are subject to vesting requirements.

The Company is required to reserve sufficient shares of common stock for future issuance upon the conversion of convertible preferred stock. As of December 31, 2020, the Company had reserved 195,021,237 shares of common stock for future conversion of its Series A, Series B, Series AA and Series C convertible preferred stock.

Each share of the Company's common stock is entitled to one vote, subject to certain voting rights of its Series A, Series B, Series AA and Series C convertible preferred stock.

In March 2020, the Company repurchased 2,032,166 shares of its common stock from a related party for a purchase price of \$11.8 million.

**12. Stock-Based Compensation**

***Equity Incentive Plan***

In 2018, the Company established the 2018 Equity Incentive Plan (the "2018 Plan") under which it may grant incentive stock options, non-statutory stock options, RSAs, restricted stock units, stock appreciation rights, and other stock-based awards. Terms of stock awards, including vesting requirements, are 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 may be granted with different vesting terms.

Initially, the Company's board of directors approved a plan that provided for a reserve of 100,000 shares of its common stock for issuance pursuant to awards granted under the 2018 Plan to eligible employees, directors and consultants. The board of directors have approved amendments to the plan to increase the reserve to 42,744,980 shares as of December 31, 2020.

As of December 31, 2020, 5,808,847 shares were available for future issuance pursuant to the 2018 Plan.

Prior to the adoption of the 2018 Plan, the Company issued 20,450,000 of founder's RSAs to certain employees, directors and consultants.

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

**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):

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2020</u>
Research and development	\$ 4,926	\$ 14,977
General and administrative	10,806	18,284
Total stock-based compensation expense	<u>\$ 15,732</u>	<u>\$ 33,261</u>

Stock-based compensation expense for the year ended December 31, 2020 includes the impact of stock options modifications. Stock option modifications in 2020 were due to the reduction in the service levels for certain employees, changes in the vesting schedules and an increase to certain awards' post termination exercise window. The total amount of incremental stock-based compensation expense associated with these modifications was \$19.8 million, of which \$5.7 million was recognized for the year ended December 31, 2020. Amounts relating to options that were already vested were recorded on the date of the modification and amounts relating to options that were unvested are expensed over the remaining service life of the options. Stock-based compensation expense also includes the impact of RSA modifications due to reduction in the service levels for certain employees and accelerated vesting, resulting in an incremental expense of \$29.8 million, of which \$11.8 million was recognized for the year ended December 31, 2020.

Stock-based compensation expense for the year ended December 31, 2019 includes the impact of the Company repricing certain stock options in December 2019 by canceling all existing outstanding option grants with a per share exercise price at, and higher than, \$4.78 in exchange for new option grants at an exercise price of \$3.65 per share. Except for the change in exercise price, the new options had the same terms and conditions as the original options, including the contractual term, vesting schedule and the vesting start date. The total amount of incremental stock-based compensation expense associated with the repricing was \$3.3 million, of which, \$0.6 million and \$0.7 million was recognized for the years ended December 31, 2019 and 2020, respectively. Amounts relating to options that were already vested were recorded on the date of the modification and amounts relating to options that were unvested are expensed over the remaining vesting term of the new options. Stock-based compensation expense also includes the impact of the accelerated vesting of certain RSAs in 2019, resulting in an incremental expense of \$8.6 million, which was recorded for the year ended December 31, 2019.

Total stock-based compensation cost related to unvested awards not yet recognized and the weighted- average periods over which the awards are expected to be recognized as of December 31, 2020 were as follows:

Unrecognized stock-based compensation cost (in thousands)	\$ 87,075
Expected weighted-average period compensation cost to be recognized (in years)	2.54



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

**Restricted Stock Awards**

A summary of the Company's RSAs activity were as follows:

	Number of Shares	Weighted-Average Value at Grant Date Per Share
Unvested shares as of December 31, 2018	24,696,373	\$ 0.02
Vested	(9,179,046)	0.03
Forfeited	(1,853,989)	0.10
Unvested shares as of December 31, 2019	13,663,338	0.0001
Vested	(5,344,585)	0.0001
Forfeited	(756,250)	0.0001
Unvested shares as of December 31, 2020	<u>7,562,503</u>	<u>\$ 0.0001</u>

The fair value of RSAs vested during the years ended December 31, 2019 and 2020 was \$33.5 million and \$29.4 million, respectively.

**Stock Options**

A summary of the Company's stock option activity were 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, 2018	8,460,548	\$ 0.10		
Granted	18,742,669	4.85		
Canceled or forfeited	(175,000)	4.84		
Options outstanding as of December 31, 2019	27,028,217	\$ 2.54		
Granted	12,989,880	5.11		
Exercised	(113,195)	3.29		
Canceled or forfeited	(5,491,013)	3.67		
Options outstanding as of December 31, 2020	<u>34,413,889</u>	<u>\$ 3.33</u>	<u>8.67</u>	<u>\$ 100,223</u>
Options exercisable as of December 31, 2020	<u>19,379,578</u>	<u>\$ 2.25</u>	<u>8.32</u>	<u>\$ 77,244</u>

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 assumptions:

	Year Ended December 31,	
	2019	2020
Risk-free interest rate	1.91%	0.79%
Expected volatility	75%	75%
Expected term (in years)	6.08	6.11
Expected dividend yield	0%	0%

The weighted-average grant date fair value of options granted for the years ended December 31, 2019 and 2020 was \$2.24 per share and \$3.36 per share, respectively. The intrinsic value of options

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

exercised during the year ended December 31, 2020 was \$0.3 million. No options were exercised for the year ended December 31, 2019.

### 13. Income Taxes

As of December 31, 2019 and 2020, the Company had U.S. federal net operating loss ("NOL") carryforwards of approximately \$64.4 million and \$116.1 million, respectively, which were available to reduce future taxable income. The Company also had U.S. federal and state tax credits of \$2.3 million and \$5.0 million as of December 31, 2019 and 2020, 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 aforementioned 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.

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

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2020</u>
Federal statutory tax	21.00%	21.00%
State tax, net of federal benefit	0.52	4.71
Valuation allowance	(15.27)	(24.60)
Convertible preferred stock tranche liabilities	(5.75)	—
Stock-based compensation	(1.69)	(1.77)
Tax credits	1.24	0.95
Other	(0.05)	(0.29)
Effective income tax rate	<u>0.00%</u>	<u>0.00%</u>

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

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

	Year Ended December 31,	
	2019	2020
Deferred tax assets:		
Net operating loss carryforwards	\$ 13,524	\$ 28,692
Tax credit carryforwards	2,318	4,980
Accrued liabilities & allowances	1,797	3,518
Deferred revenue	—	8,997
Amortization	2,095	14,375
Investment basis difference	—	3,334
Lease liability	5,768	13,421
Stock-based compensation	1,038	5,175
Other	95	1,454
Gross deferred tax assets	26,635	83,946
Valuation allowance	(20,734)	(71,093)
Deferred tax assets, net of valuation allowance	5,901	12,853
Deferred tax liabilities:		
Right-of-use asset	(5,201)	(11,221)
Property and equipment	(700)	(1,632)
Deferred tax liabilities	(5,901)	(12,853)
Net deferred tax assets	\$ —	\$ —

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

The Company will continue to assess the realizability of its deferred tax assets and adjust the valuation allowance as required by ASC 740. The increase in the valuation allowance was \$50.4 million for the year ended December 31, 2020.

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, 2019 and 2020, the Company had no uncertain tax positions.

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

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.

#### 14. Net Loss Per Share

Basic and diluted net loss per share attributed to common stockholders is calculated by dividing net loss attributed to common stockholders 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 preferred stock, unvested RSAs 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.

The amounts in the table below were excluded from the calculation of diluted net loss per share attributed to common stockholders for the periods indicated due to their anti-dilutive effect:

	<u>Year Ended December 31,</u>	
	<u>2019</u>	<u>2020</u>
Series A convertible preferred stock	97,933,475	97,386,669
Series B convertible preferred stock	23,929,531	23,929,531
Series AA convertible preferred stock	30,253,189	30,253,189
Series C convertible preferred stock	—	42,905,042
Unvested RSAs	13,663,338	7,562,503
Options to purchase common stock	27,028,217	34,413,889
Total	<u>192,807,750</u>	<u>236,450,823</u>

#### 15. Employee Benefit Plan

In January 2019, the Company adopted a 401(k) retirement and savings plan (the "401(k) Plan") covering all of its employees. The 401(k) Plan allows employees to make pre- and post-tax contributions up to the maximum allowable amount set by the IRS. As of December 31, 2020, the Company had not made any matching contributions to the 401(k) Plan on behalf of participants.

#### 16. Commitments and Contingencies

##### ***Collaboration and License Agreements***

We have entered into certain collaboration and license agreements, including those identified in Note 3, *Collaboration, License 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 which could cause the discontinuance of the programs. 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, 2019 and 2020.

#### 17. Related-Party Transactions

The Company is party to the GSK Agreement, who is a holder of more than 10% of the Company's equity. See Note 3, *Collaboration, License and Success Payment Agreements*. All revenue

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

recognized for the years ended December 31, 2019 and 2020 as well as deferred revenue and deferred revenue, net of current portion, as of December 31, 2019 and 2020 was in connection with the GSK Agreement.

In March 2020, the Company repurchased 546,806 shares of its Series A convertible preferred stock and 2,032,166 shares of its common stock from a related party. See Note 10, *Convertible Preferred Stock* and Note 11, *Common Stock*.

## **18. Asset Acquisition and Asset Sale**

### **Asset Acquisition**

In May 2020, the Company completed the acquisition of 100% of the outstanding equity of Immulus, Inc. ("Immulus"), a company focused on developing technology platforms that enable the development and production of cell therapeutics. As consideration for the acquisition, the Company paid \$3.5 million in cash and issued an aggregate of 688,463 shares of its common stock, with an estimated fair value of \$4.0 million. The Company also incurred \$0.5 million of direct expenses, for total consideration of \$8.0 million.

The Company concluded the acquisition did not meet the accounting definition of a business as inputs were acquired, but no processes or outputs were acquired. Consequently, the Company accounted for the transaction as an asset acquisition with the value concentrated in IPR&D. The following table summarizes the fair value of assets acquired (in thousands):

Other assets	\$ 487
In-process research and development (IPR&D)	7,528
<b>Total assets acquired</b>	<b>\$ 8,015</b>

The amount allocated to the IPR&D asset was charged to research and development expenses for the year ended December 31, 2020 as this asset had no alternative future use at the time of the acquisition transaction.

In addition, the Company is also required to make milestone payments of up to \$37.0 million to the former stockholders of Immulus upon successful completion of specified development milestones. Triggering of these milestones payments was not considered probable as of the date of the acquisition, and no expense has been recorded for these milestones for the year ended December 31, 2020.

### **Asset Sale**

In November 2020, the Company entered into a contribution agreement with Outpace, wherein the Company contributed tangible and intangible assets consisting of equipment and intellectual property to Outpace. As consideration for the contributed tangible and intangible assets, Outpace issued the Company 3,033,382 shares of its Series A convertible preferred stock with an estimated fair value of \$6.0 million. The carrying amount of the contributed assets was \$1.1 million, which resulted in the Company recognizing a gain in other operating (expense) income, net of \$4.9 million for the year ended December 31, 2020. The Company also acquired 3,539,319 shares of Outpace's Series A convertible preferred stock for a cash investment of \$7.0 million. See Note 5, *Other Investments*.

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

**19. Subsequent Events**

From January 1, 2021 to April 12, 2021, the Company granted stock options to purchase 9,371,532 shares of common stock with a weighted-average exercise price of \$6.86 per share to certain employees pursuant to the 2018 Plan. In January 2021, Company's board of directors amended the 2018 Plan to increase the number of shares reserved for issuance thereunder to 47,044,980 shares.

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

	<u>December 31,</u> <u>2020</u>	<u>March 31,</u> <u>2021</u> <u>(unaudited)</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 140,406	\$ 244,370
Short-term marketable securities	472,213	360,563
Prepaid expenses and other current assets	<u>4,928</u>	<u>4,802</u>
Total current assets	617,547	609,735
Restricted cash	466	466
Long-term marketable securities	79,995	35,204
Other investments	83,448	83,448
Property and equipment, net	77,045	95,478
Right-of-use assets, net	47,010	49,396
Other non-current assets	<u>2,769</u>	<u>3,462</u>
Total assets	<u>\$ 908,280</u>	<u>\$ 877,189</u>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 9,396	\$ 7,121
Accrued liabilities and other current liabilities	28,021	26,035
Success payment liabilities	5,773	15,740
Deferred revenue	<u>6,095</u>	<u>7,916</u>
Total current liabilities	49,285	56,812
Operating lease liabilities, net of current portion	50,957	57,756
Deferred revenue, net of current portion	89,066	84,808
Other non-current liabilities	<u>532</u>	<u>893</u>
Total liabilities	<u>189,840</u>	<u>200,269</u>
<i>Commitments and contingencies (Note 12)</i>		
Convertible preferred stock, \$0.0001 par value; 195,021 shares authorized at December 31, 2020 and March 31, 2021; 194,474 shares issued and outstanding at December 31, 2020 and March 31, 2021	1,010,968	1,010,968
Stockholders' deficit:		
Common stock, \$0.0001 par value; 264,905 shares authorized at December 31, 2020 and March 31, 2021; 15,570 and 17,831 shares issued and outstanding at December 31, 2020 and March 31, 2021, respectively	2	2
Additional paid-in capital	41,357	54,973
Accumulated other comprehensive income	256	163
Accumulated deficit	<u>(334,143)</u>	<u>(389,186)</u>
Total stockholders' deficit	<u>(292,528)</u>	<u>(334,048)</u>
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 908,280</u>	<u>\$ 877,189</u>

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

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

	Three Months Ended March 31,	
	2020	2021
Revenue	\$ 1,256	\$ 2,445
Operating expenses (income):		
Research and development	25,500	41,529
General and administrative	8,880	16,831
Other operating income, net	(120)	(545)
Total operating expenses	34,260	57,815
Loss from operations	(33,004)	(55,370)
Interest income, net	2,341	354
Other income (expense), net	1,423	(27)
Net loss	(29,240)	(55,043)
Other comprehensive gain (loss):		
Net unrealized gain (loss) on marketable securities	632	(93)
Net comprehensive loss	\$ (28,608)	\$ (55,136)
Net loss attributed to common stockholders:		
Net loss	\$ (29,240)	\$ (55,043)
Deemed dividends upon repurchase of convertible preferred stock	(3,582)	—
Net loss attributed to common stockholders	\$ (32,822)	\$ (55,043)
Net loss per common share, basic and diluted	\$ (2.82)	\$ (3.19)
Weighted-average shares used to compute net loss per common share, basic and diluted	11,656	17,272

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



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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2019	152,116	\$ 519,163	11,181	\$ 1	\$ 18,108	\$ 454	\$ (129,671)	\$ (111,108)
Issuance of Series C convertible preferred stock, net of \$531 in issuance costs	42,905	492,469	—	—	—	—	—	—
Issuance of common stock to strategic partners	—	—	275	—	1,004	—	—	1,004
Repurchase of convertible preferred stock	(547)	(662)	—	—	(3,582)	—	—	(3,582)
Repurchase of common stock	—	—	(2,032)	—	(11,806)	—	—	(11,806)
Stock-based compensation	—	—	1,289	—	3,274	—	—	3,274
Other comprehensive income	—	—	—	—	—	632	—	632
Net loss	—	—	—	—	—	—	(29,240)	(29,240)
Balance as of March 31, 2020	<u>194,474</u>	<u>\$1,010,970</u>	<u>10,713</u>	<u>\$ 1</u>	<u>\$ 6,998</u>	<u>\$ 1,086</u>	<u>\$ (158,911)</u>	<u>\$ (150,826)</u>

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	194,474	\$1,010,968	15,570	\$ 2	\$ 41,357	\$ 256	\$ (334,143)	\$ (292,528)
Issuance of common stock upon exercise of stock options	—	—	242	—	884	—	—	884
Stock-based compensation	—	—	2,019	—	12,732	—	—	12,732
Other comprehensive loss	—	—	—	—	—	(93)	—	(93)
Net loss	—	—	—	—	—	—	(55,043)	(55,043)
Balance as of March 31, 2021	<u>194,474</u>	<u>\$1,010,968</u>	<u>17,831</u>	<u>\$ 2</u>	<u>\$ 54,973</u>	<u>\$ 163</u>	<u>\$ (389,186)</u>	<u>\$ (334,048)</u>

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

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

	Three Months Ended March 31,	
	2020	2021
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (29,240)	\$ (55,043)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	776	1,958
Stock-based compensation expense	3,274	12,732
Change in fair value of success payment liabilities	2,070	9,967
Change in fair value of warrants	(1,380)	43
Non-cash lease expense	1,575	1,040
Other	(121)	483
Changes in operating assets and liabilities:		
Prepaid expense and other assets	(1,333)	(342)
Accounts payable	921	634
Accrued liabilities and other liabilities	1,121	(2,632)
Deferred revenue	(1,255)	(2,437)
Net cash used in operating activities	<u>(23,592)</u>	<u>(33,597)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(6,881)	(19,190)
Purchases of marketable securities	(239,032)	(48,291)
Sales and maturities of marketable securities	129,834	204,158
Net cash (used in) provided by investing activities	<u>(116,079)</u>	<u>136,677</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	492,469	—
Proceeds from exercise of stock options	—	884
Payments for the repurchase of common stock	(11,806)	—
Payments for the repurchase of preferred stock	(4,244)	—
Net cash provided by financing activities	<u>476,419</u>	<u>884</u>
Net increase in cash, cash equivalents and restricted cash	336,748	103,964
Cash, cash equivalents and restricted cash at beginning of period	98,472	140,872
Cash, cash equivalents and restricted cash at end of period	<u>\$ 435,220</u>	<u>\$ 244,836</u>
Represented by:		
Cash and cash equivalents	\$ 434,754	\$ 244,370
Restricted cash	466	466
Total	<u>\$ 435,220</u>	<u>\$ 244,836</u>
<b>SUPPLEMENTAL CASH FLOW INFORMATION</b>		
Purchases of property and equipment included in accounts payable and accrued liabilities	<u>\$ 2,201</u>	<u>\$ 13,543</u>
Operating lease right-of-use assets obtained in exchange for lease obligations	<u>\$ 30,476</u>	<u>\$ —</u>
Remeasurement of operating lease right of use asset for lease modification	<u>\$ 2,774</u>	<u>\$ 4,208</u>
Cash received for amounts related to tenant improvement allowances	<u>\$ 998</u>	<u>\$ 2,063</u>
Cash paid for amounts included in the measurement of lease liabilities	<u>\$ 897</u>	<u>\$ 1,362</u>
Deferred offering costs included in accounts payable and accrued liabilities	<u>\$ —</u>	<u>\$ 398</u>

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

**Lyell Immunopharma, Inc.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**

**1. Organization**

Lyell Immunopharma, Inc. (the "Company") was incorporated in Delaware in June 2018. The Company is a T cell reprogramming company dedicated to the mastery of T cells to eradicate solid tumors. The Company is building a multi-modality product pipeline. The Company's primary activities since incorporation have been to develop T cell therapies, perform research and development, acquire technology, enter into strategic collaboration and license arrangements, enable manufacturing activities in support of its product candidate development efforts, organize and staff the Company, business plan, establish its intellectual property portfolio, raise capital and provide general and administrative support for these activities.

**2. Basis of Presentation and Significant Accounting Policies**

***Basis of Presentation***

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

***Use of Estimates***

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect reported amounts and related disclosures. Specific accounts that require management estimates include, but are not limited to, stock-based compensation, valuation of success payments, revenue recognition, the fair value of convertible preferred and common stock 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.

***Unaudited Condensed Consolidated Financial Statements***

The condensed consolidated balance sheet as of March 31, 2021, and the condensed consolidated statements of operations and comprehensive loss, cash flows and convertible preferred stock and stockholders' deficit for the three months ended March 31, 2020 and 2021 are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's financial position as of March 31, 2021, results of operations and cash flows for the three months ended March 31, 2020 and 2021. The financial data and the other financial information disclosed in these notes to the condensed consolidated financial statements related to the three months ended March 31, 2020 and 2021 are also unaudited. The condensed consolidated results of operations for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The consolidated balance sheet as of December 31, 2020 included herein was derived from the audited consolidated financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the related notes thereto included elsewhere in this registration statement.

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

***Concentrations of Credit Risk and Off-Balance Sheet Risk***

The Company maintains its cash and cash equivalents and restricted cash with high quality, accredited financial institutions. These 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, corporate bonds and commercial paper, 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.

***Deferred Offering Costs***

The Company capitalizes incremental legal, accounting, filing and other third-party fees that are directly associated with the planned initial public offering ("IPO") as other non-current assets until the IPO is consummated. After consummation of the IPO, these costs will be recorded in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. In the event the offering is terminated, or delayed, deferred offering costs will be expensed. As of March 31, 2021, the Company had incurred \$0.4 million in deferred offering costs related to the planned IPO, which was recorded in other non-current assets.

**3. Collaboration, License and Success Payment Agreements**

***Fred Hutch***

In 2018, the Company entered into a license agreement with Fred Hutchinson Cancer Research Center ("Fred Hutch") pertaining to certain patent rights. In 2018, the Company also entered into a research and collaboration agreement ("Fred Hutch Collaboration Agreement"), focused on research and development of cancer immunotherapy products and the Company recognized \$1.0 million of research and development expenses in connection with the Fred Hutch Collaboration Agreement for both the three months ended March 31, 2020 and 2021.

In 2018, the Company also 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 10x to 50x based on a comparison of the estimated per share fair value of the Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, relative to its original \$1.83 issuance price. 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. Each threshold is associated with a success payment, ascending from \$10.0 million at \$18.29 per share to \$200.0 million at \$91.44 per share, payable if such threshold is reached during the measurement period. Any previous success payments made are credited against the success payment owed as of any valuation date, such that Fred Hutch does not receive multiple success payments in connection with the same threshold. The term of the success payment agreement ends on the earlier to occur of (i) the nine year anniversary of the date of the agreement and (ii) a change in control transaction.

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

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 Series A convertible preferred 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 estimated per share fair value of the Series A convertible preferred 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 an IPO of the Company's common stock and each two-year anniversary of the 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.

The estimated fair value of the success payments to Fred Hutch as of December 31, 2020 and March 31, 2021 was \$8.0 million and \$18.2 million, respectively. The success payment liability is estimated at fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Fred Hutch Collaboration Agreement. With respect to Fred Hutch success payment obligations, the Company recognized expense of \$2.1 million and \$8.1 million, which was recorded in research and development expense for the three months ended March 31, 2020 and 2021, respectively.

### **Stanford**

In 2019, the Company entered into a license agreement with The Board of Trustees of the Leland Stanford Junior University ("Stanford") pertaining to certain patent rights. 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 and the Company recognized \$0.8 million of research and development expenses in connection with the Stanford Collaboration Agreement for the three months ended March 31, 2021. As the Stanford Collaboration Agreement was entered into in October 2020, no expense was recognized for the three months ended March 31, 2020.

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

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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

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 Series A convertible preferred 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 estimated per share fair value of the Series A convertible preferred 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 an IPO of the Company's common stock and each two-year anniversary of the 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.

The estimated fair value of the success payments to Stanford as of December 31, 2020 and March 31, 2021 was \$8.9 million and \$19.6 million, respectively. The success payment liability is estimated at fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Stanford Collaboration Agreement. With respect to Stanford success payment obligations, the Company recognized expense of \$1.9 million, which was recorded in research and development expense for the three months ended March 31, 2021. As the rights to success payments were granted to Stanford in October 2020, no expense was recognized for the three months ended March 31, 2020.

### **GSK**

In 2019, the Company entered into a Collaboration and License Agreement, amended in June 2020 ("GSK Agreement") with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, "GSK") for potential T cell therapies that apply the Company's platform technologies and cell therapy innovations with T cell receptors ("TCRs") or chimeric antigen receptors ("CARs") under distinct collaboration programs. The GSK Agreement has defined two initial collaboration targets and allows GSK to nominate seven additional targets through July 2024. The Company is expected to perform research and development services for each selected target up until a defined point (the "GSK Option Point"), at which time GSK will 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. For each selected target, both parties will determine whether it will be developed under a Proof of Concept ("PoC") Development Program or Component Development Program. For a PoC Development Program, the Company is expected to conduct both preclinical and clinical development for the target and present clinical trial data to GSK in connection with their evaluation of whether to exercise the License Option. For a Component Development Program, the Company is obligated to perform preclinical studies only. Along with the research activities, the Company will also appoint three representatives to the joint steering committee ("JSC") and be responsible for the manufacture of all compounds and products necessary for its research and development activities.

The Company received a non-refundable upfront payment of \$45.0 million under the GSK Agreement. The Company is entitled to certain payments upon the achievement of specified development and sales milestones (for each selected target that is already within GSK's pipeline and

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meet certain criteria, the Company is eligible to receive up to an aggregate of approximately \$400.0 million, and for each selected target that is not already within GSK's pipeline and meet certain criteria the Company is eligible to receive up to an aggregate of approximately \$900.0 million) and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK's pipeline and meet certain criteria, or from high single digit to low teens for all other targets. The Company is also entitled to potential milestone payments based on validating the Company's technology in a clinical setting up to an aggregate of approximately \$200.0 million. Royalties and milestones are paid once per target, even if there is more than one Lyell innovation applied to a T cell therapy directed to that target. Any amounts received from GSK are generally non-refundable unless the Company terminates a collaboration target for safety or feasibility reasons and the funding received from GSK exceeds the costs incurred for the terminated target.

In connection with the GSK Agreement, in May 2019, the Company also entered into a Stock Purchase Agreement with GSK (the "GSK Stock Purchase Agreement"), 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. As of the issuance date, the estimated fair value of the Series AA convertible preferred stock was \$4.84 per share, compared with the purchase price per share of \$6.78. The difference of \$58.6 million between the estimated fair value of the stock as of the issuance date and the purchase price was deemed to be additional consideration for the GSK Agreement. As a result, the total upfront payment for accounting purposes allocated to the GSK Agreement was \$103.6 million.

The GSK Agreement was deemed to be within the scope of ASC 606 because GSK engaged the Company to provide research and development services, which are outputs of its ongoing activities, in exchange for consideration.

The Company identified the following two distinct performance obligations: (i) research and development services related to the two initial collaboration targets, inclusive of the JSC participation and the manufacture of compounds necessary for providing the research and development services and (ii) a material right for GSK to nominate seven additional collaboration targets for which the Company will perform research and development services until the GSK Option Point.

To allocate revenue among the performance obligations, the Company determined standalone selling prices ("SSP") of each obligation. For the research and development services, the SSP was calculated using a cost-plus margin approach. For the material right, the Company allocated the transaction price to the material right by reference to the underlying research and development services expected to be provided and the corresponding expected consideration. All amounts included in the transaction price are allocated to performance obligations proportionate to their SSPs.

As of March 31, 2021, the transaction price was deemed to be \$103.6 million, consisting of the upfront payment of \$45.0 million under the GSK Agreement and the \$58.6 million allocated from the GSK Stock Purchase Agreement. Other than the upfront payment and the amounts allocated from the GSK Stock Purchase Agreement, all other contingent consideration that may be earned under the GSK Agreement is subject to uncertainties including but not limited to target addition, research and investigational new drug enabling studies, initiation of clinical trials, and other related achievements. Consequently, the transaction price currently does not include any such contingent consideration that, if included, could result in a probable significant reversal of cumulative revenue when related uncertainties become resolved. The Company will re-evaluate the transaction price at each reporting period. If and when contingent consideration is included in the transaction price, it will be allocated to the two performance obligations proportionate to their SSPs and a cumulative catchup in revenue will

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be recorded for the portion of the services already completed. The remaining amounts will be deferred and recognized as the services are rendered.

The research and development services are transferred as the services are performed, with cost used as the measure of progress compared to total estimated cost to complete. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. The determination of the percentage of completion requires the Company to estimate the costs to complete the project. The Company makes a detailed estimate of the costs to complete, which is reassessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate will be adjusted, and the revenue will be recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate would be recognized as an adjustment to revenue in the period in which the change in estimate occurs.

The Company recognized revenue related to the research and development services related to the two initial targets of \$1.3 million and \$2.4 million for the three months ended March 31, 2020 and 2021, respectively. Changes in deferred revenue during the three months ended March 31, 2021 were as follows (in thousands):

Deferred revenue balance at December 31, 2020	\$95,161
Revenue recognized during the period	<u>(2,437)</u>
Deferred revenue balance at March 31, 2021	<u>\$92,724</u>

**PACT**

In June 2020, the Company entered into an agreement (the "PACT Agreement") with PACT Pharma, Inc. ("PACT") to jointly develop and test a next generation personalized anti-cancer T cell therapy against solid tumors. The Company paid PACT an upfront non-refundable payment of \$50.0 million upon execution of the PACT Agreement. In November 2020, the parties agreed to suspend research and development activity under the PACT Agreement, and neither party would be required to conduct any further work under the development plan (including manufacturing development) nor incur any financial obligations (including milestone payments) that might otherwise arise, for as long as the parties continued to negotiate in good faith to resolve the issues that have arisen between them relating to the PACT Agreement.

In June 2020 in connection with the entry into the PACT Agreement, the Company also entered into a stock purchase agreement with PACT ("PACT SPA"), pursuant to which the Company purchased 17,806,901 shares of Series C-1 convertible preferred stock at a purchase price of \$2.81 per share. As of the purchase date, the estimated fair value of the Series C-1 convertible preferred stock was \$2.05 per share, and the difference between the estimated fair value of the preferred stock as of the purchase date and the purchase price of \$13.6 million was deemed to be additional consideration for the PACT Agreement and recognized as research and development expense. As a result, the total upfront payment paid in connection with the PACT Agreement was \$63.6 million and included in research and development expense. The remaining \$36.4 million associated with the PACT Series C-1 convertible preferred stock was recorded in other investments.



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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

In February 2021, the Company filed a demand for arbitration seeking, among other things, rescission of the PACT Agreement and the PACT SPA and recovery of the consideration paid thereunder.

**4. Cash Equivalents and Marketable Securities**

The fair value and amortized cost of cash equivalents and marketable securities by major security type as of December 31, 2020 and March 31, 2021 are presented in the following table (in thousands):

	December 31, 2020			Fair Value
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	
Money market funds	\$ 50,513	\$ —	\$ —	\$ 50,513
U.S. Treasury securities	202,674	27	—	202,701
U.S. government agency securities	205,558	207	(1)	205,764
Corporate debt securities	211,086	34	(11)	211,109
<b>Total cash equivalents and marketable securities</b>	<b>\$669,831</b>	<b>\$ 268</b>	<b>\$ (12)</b>	<b>\$670,087</b>

Classified as:	Fair Value
Cash equivalents	\$ 117,879
Short-term marketable securities	472,213
Long-term marketable securities	79,995
<b>Total cash equivalents and marketable securities</b>	<b>\$ 670,087</b>

	March 31, 2021			Fair Value
	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	
Money market funds	\$178,644	\$ —	\$ —	\$178,644
U.S. Treasury securities	137,460	42	—	137,502
U.S. government agency securities	158,934	130	—	159,064
Corporate debt securities	145,539	4	(13)	145,530
<b>Total cash equivalents and marketable securities</b>	<b>\$620,577</b>	<b>\$ 176</b>	<b>\$ (13)</b>	<b>\$620,740</b>

Classified as:	Fair Value
Cash equivalents	\$ 224,973
Short-term marketable securities	360,563
Long-term marketable securities	35,204
<b>Total cash equivalents and marketable securities</b>	<b>\$ 620,740</b>

As of December 31, 2020 and March 31, 2021, the fair value of securities held by the Company in an unrealized loss position was \$132.6 million and \$93.3 million, respectively, and as of December 31, 2020 and March 31, 2021, securities held by the Company in an unrealized loss position have been in

**Lyell Immunopharma, Inc.**  
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the continuous loss position for less than 12 months. The Company evaluated its securities for other-than-temporary impairment and considers the decline in market value for the securities to be primarily attributable to current economic and market conditions. 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. Gross realized gains and losses were *de minimis* for the three months ended March 31, 2020 and 2021 and as a result, amounts reclassified out of accumulated other comprehensive loss for the three months ended March 31, 2020 and 2021 were also *de minimis*.

As of December 31, 2020 and March 31, 2021, all of the Company's marketable securities had a maturity date of two years or less, were available for use and were classified as available-for-sale.

#### 5. Other Investments

From time to time, the Company makes minority ownership strategic investments. As of December 31, 2020 and March 31, 2021, the aggregate carrying amounts of the Company's strategic investments in non-publicly traded companies were \$83.4 million. These investments are measured at initial cost, minus impairment and changes, plus or minus, resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. There were no adjustments recorded to the carrying amount for other investments for the three months ended March 31, 2020 and 2021.

In November 2020, the Company made a strategic equity investment of \$13.0 million in Outpace Bio, Inc. ("Outpace"), a privately-held company, which represented a minority ownership interest at the time of the strategic investment. Outpace is engaged in the research and development of protein and cell technology platforms and has financed its activities via issuances of preferred stock. The Company determined that Outpace is a variable interest entity ("VIE") as the at-risk equity holders, as a group, lack the characteristics of a controlling financial interest. The Company does not have majority voting rights, representation on Outpace's board of directors, or the power to direct the activities of this entity and therefore it is not the primary beneficiary. As of December 31, 2020 and March 31, 2021, the carrying value of the Company's investment in Outpace is \$13.0 million, which is recorded in other investments.

#### 6. Fair Value Measurements

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

	December 31, 2020			Total
	Level 1	Level 2	Level 3	
<b>Financial assets:</b>				
Money market funds	\$50,513	\$ —	\$ —	\$ 50,513
U.S. Treasury securities	—	202,701	—	202,701
U.S. government agency securities	—	205,764	—	205,764
Corporate debt securities	—	211,109	—	211,109
Equity warrant investment	—	—	1,323	1,323
Total financial assets	<u>\$50,513</u>	<u>\$619,574</u>	<u>\$1,323</u>	<u>\$671,410</u>
<b>Financial liabilities:</b>				
Success payment liabilities	\$ —	\$ —	\$5,773	\$ 5,773
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$5,773</u>	<u>\$ 5,773</u>

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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

	March 31, 2021			Total
	Level 1	Level 2	Level 3	
<b>Financial assets:</b>				
Money market funds	\$ 178,644	\$ —	\$ —	\$ 178,644
U.S. Treasury securities	—	137,502	—	137,502
U.S. government agency securities	—	159,064	—	159,064
Corporate debt securities	—	145,530	—	145,530
Equity warrant investment	—	—	1,281	1,281
Total financial assets	<u>\$ 178,644</u>	<u>\$ 442,096</u>	<u>\$ 1,281</u>	<u>\$ 622,021</u>
<b>Financial liabilities:</b>				
Success payment liabilities	\$ —	\$ —	\$ 15,740	\$ 15,740
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 15,740</u>	<u>\$ 15,740</u>

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Level 2 marketable securities include U.S. Treasury and government agency securities and corporate debt securities. The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize 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 Level 3 financial instruments include an equity warrant investment and success payment liabilities. The Company's Level 3 financial instruments are valued using valuation models which include the Black Scholes model for valuing the equity warrant investment and a Monte Carlo simulation for the success payment liabilities. To determine the estimated fair value of the success payments, the Company uses a Monte Carlo simulation methodology which models the future movement of stock prices based on several key variables combined with empirical knowledge of the process governing the behavior of the stock price. The following variables were incorporated in the estimated fair value of the success payment liabilities: estimated fair value of the Series A convertible preferred stock, expected volatility, risk-free interest rate and the estimated number and timing of valuation measurement dates on the basis of which payments may be triggered. The computation of expected volatility was estimated based on available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption.

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

	December 31, 2020	March 31, 2021
Fair value of the Series A convertible preferred stock	\$ 9.07	\$ 14.99
Risk-free interest rate	0.10% - 1.52%	0.06% - 2.71%
Expected volatility	80%	75%
Expected term (in years)	1.00 - 6.97	0.75 - 6.72

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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

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

	December 31, 2020	March 31, 2021
Fair value of the Series A convertible preferred stock	\$ 9.07	\$ 14.99
Risk-free interest rate	0.10% - 1.53%	0.06% - 2.71%
Expected volatility	80%	75%
Expected term (in years)	1.00 - 8.75	0.75 - 8.50

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

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

	Equity Warrant Investment	Success Payment Liabilities
Balance at December 31, 2020	\$ 1,323	\$ 5,773
Change in fair value <sup>(1)</sup>	(42)	9,967
Balance at March 31, 2021	<u>\$ 1,281</u>	<u>\$ 15,740</u>

(1) The change in fair value associated with the equity warrant investment is recorded in other income (expense), net and the change in fair value associated with success payments liabilities is recorded in research and development expense.

## 7. Leases

The Company's lease portfolio is comprised of operating leases for laboratory, office and manufacturing facilities located in South San Francisco, California, Seattle, Washington and Bothell, Washington with contractual periods expiring between December 2021 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.

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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

The following table summarizes the Company's future minimum operating lease commitments, including expected lease incentives to be received, as of March 31, 2021 (in thousands):

<b>Year ending December 31:</b>	
2021 (remaining nine months)	\$ 7,031
2022	10,733
2023	11,054
2024	11,385
2025	11,898
Thereafter	60,564
Total undiscounted lease payments	112,665
Less: imputed interest	(36,414)
Less: tenant improvement allowances	(15,902)
Total operating lease liabilities(1)	<u>\$ 60,349</u>

(1) Total operating lease liabilities consisted of \$2.5 million included in accrued liabilities and other current liabilities and \$57.8 million in long-term lease liabilities.

The operating lease costs for all operating leases were \$2.5 million and \$2.4 million for the three months ended March 31, 2020 and 2021, respectively. The operating lease costs and total commitments for short-term leases was *de minimis* for the three months ended March 31, 2020 and 2021. Variable lease costs for operating leases were \$0.4 million and \$1.1 million for the three months ended March 31, 2020 and 2021, respectively.

## **8. Convertible Preferred Stock**

In March 2020, the Company sold 42,905,042 shares of its Series C convertible preferred stock at a price of \$11.49 per share for proceeds of \$492.5 million, net of issuance costs of \$0.5 million. In connection with this financing, the Company amended and restated its certificate of incorporation to increase its authorized capital stock to 264,905,000 shares designated as common stock and 195,021,237 shares designated as preferred stock, of which 97,933,475 shares are designated as Series A convertible preferred stock, 23,929,531 shares are designated as Series B convertible preferred stock, 30,253,189 shares are designated as Series AA convertible preferred stock and 42,905,042 shares are designated as Series C convertible preferred stock.

In March 2020, the Company repurchased 546,806 shares of its Series A convertible preferred stock from a related party for a purchase price of \$4.2 million.

### **Conversion**

Shares of the Company's Series A, Series B, Series AA and Series C preferred stock are convertible into common stock based on a defined conversion ratio, which was initially set at one-for-one, adjustable for certain events. No such adjustment had occurred as of December 31, 2020 and March 31, 2021.

The preferred stock is convertible into common stock at the option of the holder at any time without any additional consideration, and all shares convert automatically upon the closing of the sale of shares of common stock in an underwritten public offering pursuant to an effective registration

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statement under the Securities Act of 1933, as amended (the "Securities Act"), provided that such offering results in at least \$50.0 million of gross proceeds to the Company. The Company's Series A, Series B, Series AA and Series C convertible preferred stock will automatically convert into shares of common stock upon the vote or written consent of the holders of at least a majority of the outstanding Series A, Series B, Series AA and Series C convertible preferred stock voting together as a single class on an as-converted to common stock basis.

***Dividends***

Each holder of the Company's Series A, Series B, Series AA and Series C convertible preferred stock is entitled to receive non-cumulative dividends, when and if declared by the Company's board of directors, at an annual rate of 8% of the original issue price prior to and in preference to the payment of a dividend on common stock. No dividends have been declared to date.

***Liquidation Preference***

In the event that the Company is liquidated either voluntarily or involuntarily, or if any event occurs that is deemed a liquidation under the Company's certificate of incorporation, each holder of the Company's Series A, Series B, Series AA and Series C convertible preferred stock will be entitled to receive a liquidation preference out of any proceeds from the liquidation before any distributions are made to the holders of common stock. The liquidation preference for each share of the Series A, Series B and Series C convertible preferred stock is equal to the original issue price for such series (plus any declared but unpaid dividends), which is \$1.83 for each of the Series A convertible preferred stock, \$6.78 for each of the Series B convertible preferred stock and \$11.49 for each of the Series C convertible preferred stock or the amount per share as would have been payable had all shares of Series A, Series B and Series C convertible preferred been converted into common stock, respectively. The liquidation preference for each share of the Series AA convertible preferred stock is equal to fifty percent (50%) of the original issue price of Series AA preferred stock of \$6.78 per share (plus any declared but unpaid dividends), which is \$3.39 for each of the Series AA convertible preferred stock, or the amount per share as would have been payable had all shares of Series AA convertible preferred been converted into common stock.

***Voting Rights***

Each holder of convertible preferred stock votes (on an as-converted to common stock basis) with the other voting stock of the Company. Certain actions specified in the certificate of incorporation require the consent of at least a majority of the Company's Series A convertible preferred stock, Series B convertible preferred stock, Series AA convertible preferred stock and Series C convertible preferred stock, together as a single class on an as-converted to common stock basis. Certain actions specified in the certificate of incorporation may also require the consent of at least a majority of the Series A convertible preferred stock, voting as a single class, and/or at least a majority of the Series B convertible preferred stock, voting as a single class, and/or at least a majority of the Series AA convertible preferred stock, voting as a single class and/or at least a majority of the Series C convertible preferred stock, voting as a single class. Certain actions specified in the certificate of incorporation require the consent of at least a majority of the Series A convertible preferred stock, Series B and Series C convertible preferred stock voting together, separately as a single class.

In addition, the stockholders of the Company have entered into a voting agreement pursuant to which one of the holders of Series A convertible preferred stock is permitted to designate two members of the Company's board of directors, which right expires upon an IPO.

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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

**9. Common Stock**

As of December 31, 2020 and March 31, 2021, there were 15,569,788 shares and 17,830,523 shares of the Company's common stock outstanding, respectively, excluding 7,562,503 shares and 5,525,002 shares, respectively, of restricted stock awards ("RSAs") outstanding that are subject to vesting requirements.

The Company is required to reserve sufficient shares of common stock for future issuance upon the conversion of convertible preferred stock. As of March 31, 2021, the Company had reserved 195,021,237 shares of common stock for future conversion of its Series A, Series B, Series AA and Series C convertible preferred stock.

Each share of the Company's common stock is entitled to one vote, subject to certain voting rights of its Series A, Series B, Series AA and Series C convertible preferred stock.

In March 2020, the Company repurchased 2,032,166 shares of its common stock from a related party for a purchase price of \$11.8 million.

**10. Stock-Based Compensation*****Equity Incentive Plan***

In 2018, the Company established the 2018 Equity Incentive Plan (the "2018 Plan") under which it may grant incentive stock options, non-statutory stock options, RSAs, restricted stock units, stock appreciation rights and other stock-based awards. Terms of stock awards, including vesting requirements, are 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 may be granted with different vesting terms.

As of March 31, 2021, 3,723,796 shares were available for future issuance pursuant to the 2018 Plan.

***Stock-Based Compensation Expense***

Stock-based compensation expense by classification included within the condensed consolidated statements of operations and comprehensive loss was as follows (in thousands):

	Three Months Ended March 31,	
	2020	2021
Research and development	\$2,047	\$ 4,851
General and administrative	1,227	7,881
Total stock-based compensation expense	<u>\$3,274</u>	<u>\$12,732</u>

Total stock-based compensation cost related to unvested awards not yet recognized and the weighted-average periods over which the awards are expected to be recognized as of March 31, 2021 were as follows:

Unrecognized stock-based compensation cost (in thousands)	\$ 104,397
Expected weighted-average period compensation cost to be recognized (in years)	2.85

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**Notes to Unaudited Condensed Consolidated Financial Statements—(Continued)**

**Restricted Stock Awards**

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

	Number of Shares	Weighted-Average Value at Grant Date Per Share
Unvested shares as of December 31, 2020	7,562,503	\$ 0.0001
Vested	(2,018,751)	0.0001
Forfeited	(18,750)	0.0001
Unvested shares as of March 31, 2021	<u>5,525,002</u>	<u>\$ 0.0001</u>

**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, 2020	34,413,889	\$ 3.33		
Granted	8,522,032	6.29		
Exercised	(241,984)	3.65		
Canceled or forfeited	(2,136,981)	3.76		
Options outstanding as of March 31, 2021	<u>40,556,956</u>	<u>\$ 3.92</u>	<u>8.74</u>	<u>\$ 354,688</u>
Options exercisable as of March 31, 2021	<u>20,152,899</u>	<u>\$ 2.36</u>	<u>8.11</u>	<u>\$ 207,874</u>

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:

	Three Months Ended March 31,	
	2020	2021
Risk-free interest rate	1.65%	0.68%
Expected volatility	75%	80%
Expected term (in years)	6.04	6.06
Expected dividend yield	0%	0%

The weighted average grant date fair value of options granted for the three months ended March 31, 2020 and 2021 was \$2.46 per share and \$4.29 per share, respectively.

**11. Net Loss Per Share**

Basic and diluted net loss per share attributed to common stockholders is calculated by dividing net loss attributed to common stockholders 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 preferred stock, unvested RSAs 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.



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

The amounts in the table below were excluded from the calculation of diluted net loss per share attributed to common stockholders for the periods indicated due to their anti-dilutive effect:

	Three Months Ended March 31,	
	2020	2021
Series A convertible preferred stock	97,386,669	97,386,669
Series B convertible preferred stock	23,929,531	23,929,531
Series AA convertible preferred stock	30,253,189	30,253,189
Series C convertible preferred stock	42,905,042	42,905,042
Unvested RSAs	12,373,963	5,525,002
Options to purchase common stock	31,153,551	40,556,956
<b>Total</b>	<b>238,001,945</b>	<b>240,556,389</b>

## 12. Commitments and Contingencies

### *Collaboration and License Agreements*

We have entered into certain collaboration and license agreements, including those identified in Note 3, *Collaboration, License 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 which could cause the discontinuance of the programs. 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, 2020 and March 31, 2021.

## 13. Related-Party Transactions

The Company is party to the GSK Agreement, who is a holder of more than 10% of the Company's equity. See Note 3, *Collaboration, License and Success Payment Agreements*. Deferred revenue of \$6.1 million and \$7.9 million as of December 31, 2020 and March 31, 2021, respectively, and deferred revenue, net of current portion of \$89.1 million and \$84.8 million as of December 31, 2020 and March 31, 2021, respectively, was in connection with the GSK Agreement. Revenue recognized in connection with the GSK agreement was \$1.3 million and \$2.4 million for the three months ended March 31, 2020 and 2021, respectively.

In March 2020, the Company repurchased 546,806 shares of its Series A convertible preferred stock and 2,032,166 shares of its common stock from a related party. See Note 8, *Convertible Preferred Stock* and Note 9, *Common Stock*.

## 14. Subsequent Events

From April 1, 2021 to June 9, 2021, the Company granted stock options to purchase 1,930,000 shares of common stock with a weighted-average exercise price of \$13.20 per share pursuant to the 2018 Plan. The Company expects to recognize stock compensation expense of approximately \$5 million for these stock option grants based on an initial public offering price of \$17.00 per share.

25,000,000 Shares

# Lyell Immunopharma, Inc.

Common Stock



**Goldman Sachs & Co. LLC**

**BofA Securities**

**J.P. Morgan**

**Morgan Stanley**

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Through and including July 11, 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

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