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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

OR

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

For the transition period from to

Commission File Number: 001-40502

Lyell Immunopharma, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

Registrant's telephone number, including area code: **(650) 695-0677**

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

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

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

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

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

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

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

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

As of August 2, 2024, the registrant had 256,003,113 shares of common stock, $0.0001 par value per share, outstanding.

Lyell Immunopharma, Inc.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, 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.

PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements.

Lyell Immunopharma, Inc.

Condensed Consolidated Balance Sheets

(in thousands, except per share amounts)

(unaudited)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 133,424	$ 145,647
Marketable securities	357,695	400,576
Prepaid expenses and other current assets	8,705	8,463
Total current assets	499,824	554,686
Restricted cash	287	284
Marketable securities, non-current	—	16,506
Other investments	19,000	32,001
Property and equipment, net	93,096	102,654
Operating lease right-of-use assets	37,696	39,663
Other non-current assets	4,239	4,235
Total assets	$ 654,142	$ 750,029
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,199	$ 4,817
Accrued liabilities and other current liabilities	25,670	28,126
Success payment liabilities	1,010	1,576
Total current liabilities	30,879	34,519
Operating lease liabilities, non-current	53,323	56,894
Other non-current liabilities	3,439	3,664
Total liabilities	87,641	95,077
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $ 0.0001 par value; 10,000 shares authorized at June 30, 2024 and December 31, 2023; no shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Common stock, $ 0.0001 par value; 500,000 shares authorized at June 30, 2024 and December 31, 2023; 255,948 and 253,958 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	26	25
Additional paid-in capital	1,675,460	1,657,133
Accumulated other comprehensive loss	(397)	(94)
Accumulated deficit	(1,108,588)	(1,002,112)
Total stockholders' equity	566,501	654,952
Total liabilities and stockholders' equity	$ 654,142	$ 750,029

The accompanying notes are an integral part of these unaudited 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ 13	$ 27	$ 16	$ 92
Operating expenses:				
Research and development	40,261	47,471	83,435	92,101
General and administrative	12,256	19,030	25,750	38,309
Other operating income, net	(976)	(569)	(2,066)	(1,857)
Total operating expenses	51,541	65,932	107,119	128,553
Loss from operations	(51,528)	(65,905)	(107,103)	(128,461)
Interest income, net	6,364	5,264	13,183	9,761
Other (expense) income, net	(645)	(326)	445	774
Impairment of other investments	—	(2,923)	(13,001)	(12,923)
Total other income (loss), net	5,719	2,015	627	(2,388)
Net loss	(45,809)	(63,890)	(106,476)	(130,849)
Other comprehensive loss:				
Net unrealized gain (loss) on marketable securities	7	1,500	(303)	5,220
Comprehensive loss	$ (45,802)	$ (62,390)	$ (106,779)	$ (125,629)
Net loss per common share, basic and diluted	$ (0.18)	$ (0.26)	$ (0.42)	$ (0.52)
Weighted-average shares used to compute net loss per common share, basic and diluted	255,398	250,204	254,825	249,899

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

Lyell Immunopharma, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands)
(unaudited)

	Three Months Ended June 30, 2024					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2024	254,927	$ 25	$ 1,666,315	$ (404)	$ (1,062,779)	$ 603,157
Issuance of common stock upon exercise of stock options	377	1	51	—	—	52
Issuance of common stock under employee stock purchase plan	491	—	810	—	—	810
Issuance of common stock in connection with restricted stock units, net of tax	153	—	—	—	—	—
Stock-based compensation	—	—	8,284	—	—	8,284
Other comprehensive income	—	—	—	7	—	7
Net loss	—	—	—	—	(45,809)	(45,809)
Balance as of June 30, 2024	255,948	$ 26	$ 1,675,460	$ (397)	$ (1,108,588)	$ 566,501

	Six Months Ended June 30, 2024					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	253,958	$ 25	$ 1,657,133	$ (94)	$ (1,002,112)	$ 654,952
Issuance of common stock upon exercise of stock options	1,246	1	154	—	—	155
Issuance of common stock under employee stock purchase plan	491	—	810	—	—	810
Issuance of common stock in connection with restricted stock units, net of tax	253	—	(76)	—	—	(76)
Stock-based compensation	—	—	17,439	—	—	17,439
Other comprehensive loss	—	—	—	(303)	—	(303)
Net loss	—	—	—	—	(106,476)	(106,476)
Balance as of June 30, 2024	255,948	$ 26	$ 1,675,460	$ (397)	$ (1,108,588)	$ 566,501

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

Lyell Immunopharma, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands)
(unaudited)

	Three Months Ended June 30, 2023					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of March 31, 2023	249,609	$ 25	$ 1,622,119	$ (3,879)	$ (834,439)	$ 783,826
Issuance of common stock upon exercise of stock options	833	—	83	—	—	83
Issuance of common stock under employee stock purchase plan	543	—	1,163	—	—	1,163
Issuance of common stock in connection with restricted stock units, net of tax	42	—	(50)	—	—	(50)
Stock-based compensation	—	—	14,223	—	—	14,223
Other comprehensive income	—	—	—	1,500	—	1,500
Net loss	—	—	—	—	(63,890)	(63,890)
Balance as of June 30, 2023	251,027	$ 25	$ 1,637,538	$ (2,379)	$ (898,329)	$ 736,855

	Six Months Ended June 30, 2023					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	249,567	$ 25	$ 1,608,306	$ (7,599)	$ (767,480)	$ 833,252
Issuance of common stock upon exercise of stock options	833	—	83	—	—	83
Issuance of common stock under employee stock purchase plan	543	—	1,163	—	—	1,163
Issuance of common stock in connection with restricted stock units, net of tax	84	—	(119)	—	—	(119)
Stock-based compensation	—	—	28,105	—	—	28,105
Other comprehensive income	—	—	—	5,220	—	5,220
Net loss	—	—	—	—	(130,849)	(130,849)
Balance as of June 30, 2023	251,027	$ 25	$ 1,637,538	$ (2,379)	$ (898,329)	$ 736,855

The accompanying notes are an integral part of these unaudited Condensed Consolidated Financial Statements.

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

	Six Months Ended June 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (106,476)	$ (130,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	17,439	28,105
Impairment of other investments	13,001	12,923
Depreciation and amortization expense	9,925	10,089
Net amortization and accretion on marketable securities	(8,129)	(3,925)
Non-cash lease income	(979)	(816)
Change in fair value of success payment liabilities	(566)	(603)
Gain on marketable equity security	(149)	—
Loss on property and equipment disposals, net	15	430
Changes in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	(246)	641
Accounts payable	(630)	2,449
Accrued liabilities and other current liabilities	(3,090)	(3,592)
Other non-current liabilities	(225)	(225)
Net cash used in operating activities	(80,110)	(85,373)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(361)	(2,466)
Purchases of marketable securities	(224,475)	(141,815)
Maturities of marketable securities	291,837	329,347
Net cash provided by investing activities	67,001	185,066
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of stock options	155	83
Proceeds from employee stock purchase plan	810	1,163
Taxes paid related to net share settlement of equity awards	(76)	(119)
Net cash provided by financing activities	889	1,127
Net (decrease) increase in cash, cash equivalents and restricted cash	(12,220)	100,820
Cash, cash equivalents and restricted cash at beginning of period	145,931	123,834
Cash, cash equivalents and restricted cash at end of period	$ 133,711	$ 224,654
Represented by:		
Cash and cash equivalents	$ 133,424	$ 224,372
Restricted cash	287	282
Total	$ 133,711	$ 224,654
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid for amounts included in the measurement of lease liabilities	$ 5,551	$ 5,215
Non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 50	$ 33

The accompanying notes are an integral part of these unaudited 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 clinical-stage cell therapy company advancing a pipeline of product candidates enhanced with proprietary anti-exhaustion T-cell reprogramming technologies for patients with solid tumors or hematologic malignancies. The Company's primary activities since incorporation have been to develop T-cell therapies, conduct research and development, acquire technology, enter into strategic collaboration and license arrangements, enable and execute manufacturing activities in support of its product candidate development efforts, organize and staff the Company, conduct business planning, establish its intellectual property portfolio, submit regulatory submissions, execute clinical trials, raise capital and provide general and administrative support for these activities.

2. Summary of Significant Accounting Policies

Basis of Presentation

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

The Condensed Consolidated Balance Sheet as of December 31, 2023 included herein was derived from the audited consolidated financial statements as of that date. Certain information and footnote disclosures typically included in the Company's audited consolidated financial statements have been condensed or omitted. The accompanying 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, results of operations and cash flows for the periods presented, but are not necessarily indicative of results to be expected for any future annual or interim period.

These unaudited Condensed Consolidated Financial Statements should be read in conjunction with the Company's audited financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

Liquidity and Management's Plan

The Company discovers and develops product candidates that involve experimental technologies. The product candidates may require several years and substantial expenditures to complete and ultimately may be unsuccessful. The Company plans to finance operations with available cash resources or from the issuance of equity or debt securities. The Company believes that its available cash, cash equivalents and marketable securities as of June 30, 2024 will be adequate to fund its operations at least through the next 12 months from the date these unaudited Condensed Consolidated Financial Statements are issued.

Use of Estimates

The preparation of the unaudited 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, valuation of other investments and accrued expenses. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Concentrations of Credit Risk and Off-balance Sheet Risk

The Company maintains its cash, cash equivalents and restricted cash with high quality, accredited financial institutions. Restricted cash is cash held in a bank account and is used as collateral associated with the Company's corporate credit card program. Cash, cash equivalents and restricted cash amounts, at times, may exceed federally insured limits. The Company also makes short-term investments in money market funds, U.S. Treasury securities, U.S. government agency securities and corporate debt securities, which can be subject to certain credit risk. 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.

Significant Accounting Policies

There have been no material changes to the significant accounting policies from the Annual Report on Form 10-K for the year ended December 31, 2023, except as set forth below regarding the Company's stock-based compensation policy for performance-based restricted stock units ("PSUs").

Stock-based Compensation

Under ASC 718, the Company measures and recognizes expense for PSUs that settle in stock. The Company granted PSUs that vest upon the achievement of certain performance conditions to certain key employees. For awards with performance conditions that do not vest unless a performance condition is met, the Company recognizes expense if, and to the extent that, the Company estimates that the achievement of the performance condition is probable. At each reporting date, the Company is required to evaluate whether achievement of a performance condition is probable. Compensation expense is recorded over the appropriate service period based upon the Company's assessment of accomplishing each performance condition.

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

The fair values of PSUs that do not have market-based metrics are based upon the grant date stock price. Compensation expense is recognized for the number of shares expected to be earned after assessing the probability that a certain performance condition will be met and the targeted payout level associated with the performance condition expected to be achieved. Cumulative adjustments are recorded each quarter to reflect the estimated outcome of the performance-related conditions until the date results are determined and settled. If performance conditions are not met or not expected to be met, any compensation expense previously recognized associated with the awards will be reversed.

Recent Accounting Pronouncements

Recently Adopted

None.

Not Yet Adopted

Segment Reporting

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures, which expands required disclosures about a public entity's reportable segments and requires more enhanced information about a reportable segment's expenses, interim segment profit or loss, and how a public entity's chief operating decision maker uses reported segment profit or loss information in assessing segment performance and allocating resources. Entities with a single reportable segment are required to provide all the updated and existing segment disclosures required by Topic 280. The amendments are effective for annual periods beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024 on a retrospective basis. The Company is assessing the effect of the new disclosure requirements and does not anticipate the adoption will have a material impact to the Company's financial statements.

Income Taxes

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

3. License, Collaboration and Success Payment Agreements

Fred Hutch

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

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

Collaboration - In 2018, the Company entered into a research and collaboration agreement with Fred Hutch ("Fred Hutch Collaboration Agreement") focused on research and development of cancer immunotherapy products. The Company funded aggregate research performed by Fred Hutch of $ 12.0 million under the Fred Hutch Collaboration Agreement, with the research conducted in accordance with a research plan and budget approved by the parties. The Fred Hutch Collaboration Agreement has a six-year term. The Company incurred $ 0.1 million in expense in connection with the Fred Hutch Collaboration Agreement for both the three months ended June 30, 2024 and 2023, and $ 0.2 million and $ 0.4 million for the six months ended June 30, 2024 and 2023, respectively.

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

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

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

The success payments will be owed if the per share fair value of the Company's common stock on the contractually specified valuation measurement dates during the term of the success payment agreement equals or exceeds the above outlined multiples. The valuation measurement dates are triggered by the following events: the one-year anniversary of the Company's IPO and each two-year anniversary of the Company's IPO thereafter, the closing of a change in control transaction and the last day of the term of the success payment agreement, unless the term has ended due to the closing of a change of control transaction. As of June 30, 2024, no success payments have been incurred as the per share fair value of the Company's common stock was below the price required for payment.

The success payment liability was $ 0.3 million and $ 0.7 million as of June 30, 2024 and December 31, 2023, respectively. With respect to the Fred Hutch Collaboration Agreement success payment obligations, the Company recognized a success payment expense reversal of $ 0.7 million and an expense of $ 0.5 million for the three months ended June 30, 2024 and 2023, respectively, and expense reversals of $ 0.3 million and $ 0.6 million for the six months ended June 30, 2024 and 2023, respectively, which are recognized in other (expense) income, net.

Stanford

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

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

Collaboration Agreement - In October 2020, the Company entered into a research and collaboration agreement with Stanford ("Stanford Collaboration Agreement"), focused on research and development of cellular immunotherapy products. The Stanford Collaboration Agreement has a four-year term. The Company is committed to fund aggregate research performed by Stanford of $ 12.0 million under the Stanford Collaboration Agreement, and the research will be conducted in accordance with a research plan and budget approved by the parties. The Company incurred $ 0.7 million in expense in connection with the Stanford Collaboration Agreement for both the three months ended June 30, 2024 and 2023, and $ 1.5 million for both the six months ended June 30, 2024 and 2023.

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

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

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

The success payments will be owed if the per share fair value of the Company's common stock on the contractually specified valuation measurement dates during the term of the success payment agreement equals or exceeds the above outlined multiples. The valuation measurement dates are triggered by the following events: the one-year anniversary of the Company's IPO and each two-year anniversary of the Company's IPO thereafter, the closing of a change in control transaction and the last day of the term of the success payment agreement, unless the term has ended due to the closing of a change of control transaction. As of June 30, 2024, no success payments have been incurred as the per share fair value of the Company's common stock was below the price required for payment.

The estimated fair values of the success payments to Stanford as of June 30, 2024 and December 31, 2023 were $ 0.7 million and $ 1.1 million, respectively. The success payment liability is estimated at the fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Stanford Collaboration Agreement as research and development expense. The success payment liability was $ 0.7 million and $ 0.9 million as of June 30, 2024 and December 31, 2023, respectively. With respect to the Stanford Collaboration Agreement success payment obligations, the Company recognized a success payment expense reversal of $ 0.8 million and an expense of $ 0.6 million for the three months ended June 30, 2024 and 2023, respectively, and an expense reversal of $ 0.3 million and an expense of approximately zero for the six months ended June 30, 2024 and 2023, respectively.

4. Cash Equivalents and Marketable Securities

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

	June 30, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 66,942	$ —	$ —	$ 66,942
U.S. Treasury securities	291,040	4	(251)	290,793
U.S. government agency securities	38,651	1	(77)	38,575
Corporate debt securities	81,010	—	(74)	80,936
Total cash equivalents and fixed income marketable securities	$ 477,643	$ 5	$ (402)	$ 477,246

Classified as:	Fair Value
Cash equivalents	$ 119,701
Marketable securities	357,545
Marketable securities, non-current	—
Total cash equivalents and fixed income marketable securities	$ 477,246

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

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

The fair values of money market and fixed income marketable securities held by the Company in an unrealized loss position for less than 12 months were $ 338.2 million and $ 117.8 million as of June 30, 2024 and December 31, 2023, respectively. The fair values of money market and fixed income marketable securities held by the Company in an unrealized loss position for greater than 12 months were $ 31.1 million and $ 43.6 million as of June 30, 2024 and December 31, 2023, respectively. As of June 30, 2024 and December 31, 2023, all of the Company's money market and fixed income marketable securities had a maturity date of two years or less, were available for use and were classified as available-for-sale. The Company does not intend to sell these securities nor does the Company believe that it will be required to sell these securities before recovery of their amortized cost basis. The Company determined that there was no material change in the credit risk of the above investments as of both June 30, 2024 and December 31, 2023. As such, an allowance for credit losses has not been recognized. Gross realized gains and losses were *de minimis* for the three and six months ended June 30, 2024 and 2023 and as a result, amounts reclassified out of accumulated other comprehensive loss for the three and six months ended June 30, 2024 and 2023 were also *de minimis*. See Note 6, *Fair Value Measurements,* for additional information regarding cash equivalents and fixed income marketable securities.

5. Other Investments

In prior years the Company made minority ownership strategic investments. As of June 30, 2024 and December 31, 2023, the aggregate carrying amount of the Company's strategic investments in non-publicly traded companies was $ 19.0 million and $ 32.0 million, respectively. These investments are measured at initial cost, minus impairment, if any, and plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Cumulative impairments of strategic investments in equity investments without readily determinable fair values still held as of June 30, 2024 and December 31, 2023 were $ 23.0 million and $ 15.0 million, respectively.

As a part of the acquisition of each of the Company's other investments, the Company determines whether an investment or other interest is considered a variable interest. As of both June 30, 2024 and December 31, 2023, the Company held an interest in one entity that was concluded to be a variable interest for which the Company was not the primary beneficiary as the Company did not have the power to direct the activities that most significantly impact the economic performance of the variable interest entity. As of June 30, 2024 and December 31, 2023, the carrying value and maximum exposure to loss of the Company's variable interests were zero and $ 13.0 million, respectively, which are recorded in other investments in the Company's Condensed Consolidated Balance Sheets.

In connection with the preparation of the financial statements for the three and six months ended June 30, 2024 and 2023, the Company performed a qualitative assessment of potential indicators of impairment and determined that indicators existed for certain of its other investments with carrying amounts of zero and $ 2.9 million for the three months ended June 30, 2024 and 2023, respectively, and $ 13.0 million and $ 12.9 million for the six months ended June 30, 2024 and 2023, respectively. During the six months ended June 30, 2024, the anticipated funding for one of its other investments was not secured within the expected timeframe. The Company considered all of the underlying companies' operating cash flow requirements over the next year, liquid asset balances to fund those requirements and the underlying companies' inability to raise funds as indicators of impairment. Due to these indicators, the Company assessed the valuation of these investments and determined the fair values to be negligible and the impairments to be other-than-temporary in nature. As a result, the Company recorded impairment expenses of zero and $ 2.9 million for one investment for the three months ended June 30, 2024 and 2023, respectively. Additionally, the Company recorded impairment expenses of $ 13.0 million for one investment and $ 12.9 million for two investments for the six months ended June 30, 2024 and 2023, respectively. The impairment expenses were recorded within impairment of other investments on the Condensed Consolidated Statements of Operations and Comprehensive Loss and as a reduction to the investment balances within other investments on the Condensed Consolidated Balance Sheets.

6. Fair Value Measurements

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

	June 30, 2024			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 66,942	$ —	$ —	$ 66,942
U.S. Treasury securities	—	290,793	—	290,793
U.S. government agency securities	—	38,575	—	38,575
Corporate debt securities	—	80,936	—	80,936
Marketable equity security	149	—	—	149
Total financial assets	$ 67,091	$ 410,304	$ —	$ 477,395
Financial liabilities:				
Success payment liabilities	$ —	$ —	$ 1,010	$ 1,010
Total financial liabilities	$ —	$ —	$ 1,010	$ 1,010

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

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

The Company's marketable equity security relates to a company that began being publicly traded on the Nasdaq Global Market in February 2024 and had a fair value of $ 0.1 million as of June 30, 2024. The Company recorded unrealized losses of $ 1.4 million and zero for the three months ended June 30, 2024 and 2023, respectively, and unrealized gains of $ 0.1 million and zero for the six months ended June 30, 2024 and 2023, respectively, within other (expense) income, net in the Company's Condensed Consolidated Statement of Operations and Comprehensive Loss. Prior to being publicly traded, as of December 31, 2023, the investment was fully impaired and classified in the Company's Condensed Consolidated Balance Sheet as other investments.

The Company's success payment liabilities are Level 3 financial instruments, which were estimated using Monte Carlo simulations through December 31, 2023. Monte Carlo simulations model the future movement of stock prices based on several key variables combined with empirical knowledge of the process governing the behavior of the stock price. The following variables were incorporated in the Monte Carlo simulation to determine the estimated fair value of the success payment liabilities: fair value of the Company's common stock, expected volatility, the risk-free interest rate and the estimated number and timing of valuation measurement dates on the basis of which payments may be triggered. The computation of expected volatility was estimated based on available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption. As of June 30, 2024, success payment liabilities were estimated by management using its historical experience of the correlation of success payment fair values relative to the Company's stock price.

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

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

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

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

	Success Payment Liabilities
Balance at December 31, 2023	$ 1,576
Change in fair value [1]	(566)
Balance at June 30, 2024	$ 1,010

(1) The change in the fair value associated with the Fred Hutch success payment liabilities is recorded in other (expense) income, net. The change in the fair value associated with the Stanford success payment liabilities is recorded as research and development expenses. (See Note 3, *License, Collaboration and Success Payment Agreements).*

7. Leases

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

The following table summarizes the Company's future minimum operating lease commitments as of June 30, 2024 (in thousands):

Year Ending December 31:	
2024 (remaining six months)	$ 5,796
2025	11,859
2026	12,209
2027	12,569
2028	12,940
Thereafter	22,585
Total undiscounted lease payments	77,958
Less: imputed interest	(17,737)
Total operating lease liabilities	$ 60,221

Reported as of June 30, 2024:	
Short-term portion of lease liabilities (included in accrued liabilities and other current liabilities)	$ 6,898
Operating lease liabilities, non-current	53,323
Total	$ 60,221

The operating lease costs for all operating leases were $ 2.3 million for both the three months ended June 30, 2024 and 2023, and $ 4.6 million and $ 4.4 million for the six months ended June 30, 2024 and 2023, respectively. The operating lease costs and total commitments for short-term leases were *de minimis* for the three and six months ended June 30, 2024 and 2023. Variable lease costs for operating leases were $ 1.6 million and $ 1.4 million for the three months ended June 30, 2024 and 2023, respectively, and $ 3.9 million and $ 2.8 million for the six months ended June 30, 2024 and 2023, respectively. The weighted-average remaining lease terms for operating leases were 6.3 and 6.8 years as of June 30, 2024 and December 31, 2023, respectively. The weighted-average discount rate for operating leases was 8.5 % as of both June 30, 2024 and December 31, 2023.

In May 2021, the Company entered into a sublease, whereby the Company agreed to sublease approximately 11,000 square feet of its space in South San Francisco, California currently leased by the Company. The sublease is classified as an operating lease and will expire in March 2031. The Company recognized sublease income for this sublease of $ 0.2 million for both the three months ended June 30, 2024 and 2023, and $ 0.4 million for both the six months ended June 30, 2024 and 2023.

In September 2021, the Company entered into a sublease with Sonoma Biotherapeutics, Inc. ("Sonoma"), a related party, whereby the Company agreed to sublease approximately 18,000 square feet of space in South San Francisco,

California currently leased by the Company. See Note 12, *Related-Party Transactions.* As a part of the sublease, in September 2021, the Company received a $ 4.6 million tenant improvement contribution payment, which is recognized over the term of the sublease. The sublease is classified as an operating lease and will expire in March 2031. The Company recognized Sonoma sublease income of $ 0.5 million for both the three months ended June 30, 2024 and 2023, and $ 0.9 million for both the six months ended June 30, 2024 and 2023.

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

8. Stockholders' Equity

Preferred Stock

The Company is authorized to issue 10.0 million shares of preferred stock with a par value of $ 0.0001 per share. As of June 30, 2024 and December 31, 2023, no shares of preferred stock were outstanding.

Common Stock

The Company is authorized to issue 500.0 million shares of common stock with a par value of $ 0.0001 per share. As of June 30, 2024 and December 31, 2023, there were 255,948,333 shares and 253,957,709 shares of the Company's common stock outstanding, respectively.

On February 28, 2024, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen") acting as the Company's sales agent (the "Sales Agreement"), pursuant to which the Company may offer and sell shares of common stock having an aggregate offering price of up to $ 150.0 million from time to time in a series of one or more at-the-market equity offerings. The Company will pay Cowen commissions of up to 3.0 % of the gross proceeds of the sale, and reimbursement of certain expenses, under this agreement. Neither the Company nor Cowen is obligated to sell any shares and, to date, the Company has not made any sales under the Sales Agreement.

9. Stock-based Compensation

2021 Equity Incentive Plan

In June 2021, the Company adopted the 2021 Equity Incentive Plan ("2021 Plan"), which on the date of the underwriting agreement related to the Company's IPO became effective with an initial reserve of 26,662,087 shares, plus any shares subject to outstanding awards granted under the 2018 Equity Incentive Plan ("2018 Plan") that, on or after the effectiveness of the 2021 Plan, terminate or expire before exercise or settlement, are not issued because the award is settled in cash, are forfeited because of the failure to vest, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price. In addition, the number of shares reserved for issuance under the 2021 Plan automatically increases on January 1 of each year for a period of ten years , beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to (1) 5 % of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, or (2) a lesser number of shares determined by the Company's board of directors no later than December 31 of the immediately preceding year. On January 1, 2024, the Company reserved an additional 12,697,885 shares of common stock for issuance under the 2021 Plan representing 5 % of the total common shares outstanding as of December 31, 2023. Under the 2021 Plan, the Company may grant incentive stock options, non-statutory stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), PSUs, stock appreciation rights, performance awards and other stock-based awards. Terms of stock awards, including vesting requirements, are determined by the Company's board of directors or by a committee authorized by the Company's board of directors, subject to provisions of the 2021 Plan. The term of any stock option granted under the 2021 Plan cannot exceed ten years . Generally, option and RSU awards granted by the Company vest over four years but may be granted with different vesting terms. PSUs generally vest over three years , subject to the achievement of the associated performance conditions. In conjunction with adopting the 2021 Plan, the Company discontinued the 2018 Plan with respect to new equity awards.

As of June 30, 2024, 41,668,968 shares were available for future issuance pursuant to the 2021 Plan.

2021 Employee Stock Purchase Plan

In June 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("2021 ESPP"), which became effective immediately prior to the execution of the underwriting agreement related to the Company's IPO with an initial reserve of 2,470,000 shares. The 2021 ESPP allows eligible employees to purchase shares of the Company's common stock at a discount through payroll deductions of up to 15 % of their earnings, subject to plan limitations. Unless otherwise determined by the Company's board of directors, employees are able to purchase shares at 85 % of the lower of the fair

market value of the Company's common stock on the first date of an offering or on the purchase date. The number of shares of the Company's common stock reserved for issuance under the 2021 ESPP automatically increases on January 1 of each year for a period of ten years , beginning on January 1, 2022 and continuing through January 1, 2031, by the lesser of (1) 1 % of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, and (2) 4,940,000 shares; provided, however, that the Company's board of directors may act to provide a lesser increase in number of shares. On January 1, 2024, the Company reserved an additional 2,539,577 shares of common stock for issuance under the 2021 ESPP representing 1 % of the total common shares outstanding as of December 31, 2023. The Company may specify offerings with durations not more than 27 months and may specify shorter purchase periods within each offering. Under the 2021 ESPP, 491,303 shares were issued for the three and six months ended June 30, 2024 and 542,921 shares for the three and six months ended June 30, 2023.

As of June 30, 2024, 5,509,903 shares were available for future issuance pursuant to the 2021 ESPP.

2018 Equity Incentive Plan

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

Stock-based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	$ 3,865	$ 5,279	$ 7,657	$ 9,891
General and administrative	4,419	8,944	9,782	18,214
Total stock-based compensation expense	$ 8,284	$ 14,223	$ 17,439	$ 28,105

At June 30, 2024, total stock-based compensation cost related to unvested awards not yet recognized was $ 59.0 million, which is expected to be recognized over a remaining weighted-average period of 2.6 years.

Stock Options Repricing

In November 2023, the Board of Directors of the Company approved, effective November 16, 2023, a one-time repricing of certain stock option awards that had been granted to date under the 2021 Plan and 2018 Plan. The repricing impacted stock options with exercise prices greater than $ 2.37 held by employees who remained employed as of November 16, 2023 and were not impacted by the Company's November 2023 reduction in workforce. The original exercise prices of the repriced stock options ranged from $ 2.61 to $ 17.95 per share for 200 total grantees with 23,416,860 shares repriced. Each stock option was repriced to have a per share exercise price of $ 1.87 , which was the closing price of the Company's common stock on November 16, 2023. To receive the new exercise price, option holders must remain employed with the Company through November 15, 2024. Additionally, the vesting schedule for the unvested shares underlying repriced stock options held by executives at the level of senior vice president and above was extended for an additional year. There were no changes to the vesting schedules for employees below the level of senior vice president. No changes were made to the expiration dates of, or the number of shares underlying, the repriced stock options. Incremental stock-based compensation expense resulting from the repricing was $ 8.9 million in the aggregate. Expense for vested awards will be recognized through November 15, 2024 and expense for unvested awards will be recognized over the remaining service life of the option.

Performance-Based Restricted Stock Units

During the six months ended June 30, 2024, the Company granted PSU awards to certain key employees. PSUs awarded to employees have a three-year performance period and vest based upon the Company's performance against a two and three-year relative total shareholder return ("rTSR") metric, as well as upon the achievement of certain clinical development milestones. None of the clinical development milestones were probable of achievement as of June 30, 2024.

For the portion of PSUs subject to certain clinical development milestones (other than the bonus clinical development milestone), 50 % vest upon the achievement of the applicable milestone, and the remaining 50 % vest upon the earlier of (a) one year of service from the date of such achievement and (b) the end of the three-year performance period. The vesting of all PSU awards granted is also subject to the respective employee's continued employment. The Company valued the portion of PSUs subject to the rTSR metric using a Monte Carlo simulation. The number of PSUs granted subject to the rTSR metrics represents the target number of units that are eligible to be earned based on the achievement of the metrics established at the beginning of the performance period, which ends on December 31st of the three year performance period. For the portion of PSUs subject to the rTSR metrics, employees may ultimately earn between zero and 200 % of the target number of PSUs granted based on the degree of achievement of the applicable rTSR metric. Accordingly, additional PSUs may be issued or currently outstanding PSUs may be cancelled upon final determination of the number of units earned.

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

	Performance-Based Restricted Stock Units Outstanding		Weighted-Average Value at Grant Date Per Share
Unvested PSUs as of December 31, 2023	—	$	—
PSUs granted[(1)]	2,703,400	$	1.88
PSUs vested	—	$	—
PSUs forfeited or canceled	—	$	—
Unvested PSUs as of June 30, 2024	2,703,400	$	1.88

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

Restricted Stock Units

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

	Restricted Stock Units Outstanding		Weighted-Average Value at Grant Date Per Share
Unvested RSUs as of December 31, 2023	2,072,855	$	2.96
RSUs granted	3,622,426	$	1.84
RSUs vested	(295,570)	$	3.41
RSUs forfeited or canceled	(225,914)	$	2.07
Unvested RSUs as of June 30, 2024	5,173,797	$	2.19

Stock Options

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

	Number of Stock Options		Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)		Aggregate Intrinsic Value (in thousands)
Options outstanding as of December 31, 2023	55,596,831	$	4.75	6.89	$	7,368
Granted	3,405,500	$	1.97			
Exercised	(1,245,836)	$	0.12			
Canceled or forfeited	(12,044,059)	$	6.74			
Options outstanding as of June 30, 2024	45,712,436	$	4.14	7.33	$	3,696
Options exercisable as of June 30, 2024	26,720,167	$	4.71	6.42	$	3,696

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

	Six Months Ended June 30,	
	2024	2023
Risk-free interest rate	4.17 %	4.09 %
Expected volatility	76.0 %	92.4 %
Expected term (in years)	5.90	5.99
Expected dividend yield	0 %	0 %

The weighted-average grant date fair value of options granted for the six months ended June 30, 2024 and 2023 were $ 1.35 per share and $ 1.72 per share, respectively.

10. Net Loss Per Share

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

11. Commitments and Contingencies

License and Collaboration Agreements

The Company has entered into certain license and collaboration agreements, including those identified in Note 3, *License, Collaboration and Success Payment Agreements* above, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial milestones. The Company's obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events that could cause the discontinuance of the programs, including termination of such agreements. Due to the nature of these agreements, the future potential payments are inherently uncertain, and accordingly no amounts had been recorded for the potential future achievement of these targets as of both June 30, 2024 and December 31, 2023.

12. Related-party Transactions

In September 2021, the Company entered into a sublease with Sonoma ("Sonoma Sublease"), with whom the Company has common stockholders with board seats, whereby the Company agreed to sublease approximately 18,000 square feet of space in South San Francisco, California currently leased by the Company. Dr. Klausner, the Chair of the Company's board of directors, also serves as Board Chair of Sonoma's board of directors. As a part of the Sonoma Sublease, a $ 4.6 million tenant improvement contribution payment was made by Sonoma, which is recognized over the term of the Sonoma Sublease. As of both June 30, 2024 and December 31, 2023, there were accrued liabilities and other current liabilities of $ 0.5 million and as of June 30, 2024 and December 31, 2023, other non-current liabilities of $ 2.8 million and $ 3.0 million, respectively, in connection with the Sonoma Sublease. Total operating income from Sonoma and income solely attributable to the Sonoma Sublease are shown in the table below (in thousands). Total operating income includes income attributable to the sublease, as well as additional operating fees recognized in "other operating income, net" such as common area maintenance charges. See Note 7, *Leases* , for more detail on the Sonoma Sublease.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Sonoma other operating income, net	$ 677	$ 648	$ 1,484	$ 1,317
Sonoma sublease income	$ 465	$ 464	$ 930	$ 930

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited Condensed Consolidated Financial Statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

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

Our growing pipeline of promising cell product candidates target indications with large unmet needs that are collectively responsible for approximately 224,000 deaths in the United States annually. Our programs provide opportunities to expand into additional indications beyond the patient populations we are targeting. Our lead product candidates are summarized in Table 1 below:

Product	Target	Reprogramming				Target Indications	Preclinical	Phase 1	Phase 2/ Pivotal	Next Milestone
		Genetic		Epigenetic						
		c-Jun	NR4A3	Epi-R™	Stim-R™					
LYL797 CAR T cell	ROR1	✓		✓		ROR1+ TNBC, NSCLC, Ovarian, Endometrial				• Initiate dose expansion and provide data update in late 24 - early 25 • Updated Ph 1 data - 1H25
LYL797 CAR T cell	ROR1	✓		✓		ROR1+ Multiple Myeloma, CLL				• Submit IND - 2H24
LYL119 CAR T cell	ROR1	✓	✓	✓	✓	ROR1+ Ovarian, Endometrial TNBC, NSCLC, CRC				• Initial data - 2H25
LYL845 TIL	Multiple antigens			✓		Melanoma (Orphan Drug Designation), NSCLC, CRC				• Initial data - 2H24
Next Gen TIL	Multiple antigens	Genetic and Epigenetic Reprogramming				Solid tumors				

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

We were incorporated in June 2018. Our primary activities to date have included clinical development of T-cell therapies, conducting research and development, acquiring technology, entering into strategic collaboration and license agreements, enabling and executing manufacturing activities in support of our product candidate development efforts, organizing and staffing our company, business planning, establishing our intellectual property portfolio, making regulatory submissions, executing clinical trials, raising capital and providing general and administrative support for these activities. We are early in our research and development efforts. LYL797, our ROR1-targeted CAR T-cell product candidate, is in Phase 1 clinical development for multiple solid tumor indications, and we expect to initiate a second Phase 1 clinical trial of LYL797 for hematologic indications in the second half of 2024. LYL119, our next generation ROR1-targeted CAR T-cell product candidate, is entering Phase 1 clinical trial in patients with solid tumors in the second half of 2024; and LYL845, our TIL product candidate, is in Phase 1 clinical development. A second generation TIL product candidate enhanced with novel genetic and epigenetic reprogramming technologies is in preclinical development. We do not have any products approved for sale.

Pipeline Programs

We are advancing four wholly-owned product candidates. Two product candidates, LYL797 and LYL845, are in Phase 1 clinical development, and an additional product candidate, LYL119, is entering Phase 1 clinical development. A second-generation TIL product candidate is in preclinical development. Research stage programs include our proprietary T-cell rejuvenation technology and other undisclosed T-cell enhancing technologies.

LYL797 - A ROR1 CAR T-cell product candidate enhanced with anti-exhaustion technology designed for improved tumor infiltration and tumor cell killing

We are applying our c-Jun and Epi-R technologies to our lead CAR T-cell product candidate, LYL797, which is an intravenously-administered autologous CAR T-cell investigational product targeting the receptor tyrosine kinase-like orphan receptor 1 (ROR1) protein. ROR1 is a fetal protein expressed during embryogenesis and is believed to be important in cell migration, polarity and survival. It is expressed in several cancer types, including triple-negative breast cancer (TNBC), non-small cell lung cancer (NSCLC), ovarian cancer, endometrial cancer, multiple myeloma and chronic lymphocytic leukemia (CLL), and is generally associated with a poor prognosis. LYL797 contains a CAR with a 4-1BB/CD3ζ intracellular domain, a transmembrane domain, an optimized spacer domain and a single-chain variable fragment (scFv) derived from an R12 rabbit monoclonal antibody that recognizes and binds with high specificity to human ROR1. LYL797 also incorporates c-Jun and a proprietary optimized truncated version of human EGFR ($EGFR_{opt}$) used for tracking the CAR T cells in the peripheral blood post treatment and can also be used as a safety measure with the administration of cetuximab, if needed. LYL797 is manufactured utilizing Epi-R, our proprietary ex vivo manufacturing protocol that is designed to generate populations of T cells with stem-like qualities, reduced exhaustion and improved proliferation and antitumor activity.

Significant subsets of patients with common cancers express ROR1. We initiated development of LYL797 for the treatment of ROR1-positive TNBC and NSCLC, two of the highest ROR1-expressing solid tumor indications. Results from our own ROR1 screening program are consistent with what is reported in the literature. Using our immunohistochemistry assay in the screening for our Phase 1 trial, as of June 2024, we have found that approximately 50% of patients with TNBC and approximately 35% of patients with NSCLC have tumors that express ROR1.

Our hypothesis that T-cell exhaustion is a key barrier in the treatment of solid tumors is informed by a clinical study previously conducted at the Fred Hutchinson Cancer Center. In this study, autologous ROR1-targeted CAR T cells infused into patients with CLL underwent rapid expansion and retained T-cell effector function, leading to tumor cell clearance and clinical responses. However, when CAR T cells generated with the same method were infused into patients with solid tumors such as TNBC or NSCLC, these T cells often failed to expand adequately, rapidly upregulated cell surface markers of T-cell exhaustion and adopted a dysfunctional state.

We recently reported initial clinical and translational data from our ongoing Phase 1 trial, detailed below. We believe these initial clinical and translational data (1) demonstrated that T-cell exhaustion is a key barrier to cell therapy in solid tumors as elucidated by the Fred Hutch Cancer Center study, and (2) provided early validation of our in vivo preclinical models demonstrating that LYL797 ROR-1 CAR T cells reprogrammed with our c-Jun overexpression and Epi-R anti-exhaustion technology enhanced tumor control resulting in prolonged survival as compared to control ROR1 CAR T cells without our technologies.

Based on initial clinical data that demonstrated dose-dependent anti-tumor activity, we expanded the Phase 1 trial to include patients with platinum-resistant ovarian and endometrial cancers, where it is estimated in the literature that approximately 50% of patients have tumors in both indications that express ROR1. Ovarian cancer is one of the leading causes of cancer deaths among women. In the United States, approximately 20,000 women will be newly diagnosed with ovarian cancer in 2024. Only about 20% of ovarian cancers are diagnosed at an early stage. 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. Only 30% of advanced stage ovarian cancer patients survive for five years after initial diagnosis. Endometrial cancer (cancer of the lining of the uterus) is the most prevalent gynecological cancer and the sixth most common malignancy worldwide. Its incidence has been increasing over the last decade and it is one of the few cancers with increasing mortality. In 2024 in the United States, approximately 68,000 women will be newly diagnosed with uterine cancer, which includes patients with endometrial cancers and uterine sarcomas that together account for approximately 10% of uterine cancers. Only 19% of advanced stage endometrial cancer patients survive for five years after initial diagnosis.

We also plan to submit an investigational new drug (IND) application to initiate a second Phase 1 clinical trial of LYL797 in relapsed/refractory multiple myeloma and CLL, where it is estimated in the literature that 60% and 95% of patients' malignancies, respectively, express ROR1. While recent advances in the treatment of multiple myeloma, including CAR T-cell therapy, have improved the survival outcomes in patients, the disease is not curable, and the vast majority of patients with multiple myeloma eventually relapse or become resistant to treatment. Thus, new treatments with different targets and modalities are needed. In the United States, it is estimated that approximately 36,000 people will be newly diagnosed with multiple myeloma in 2024. CLL is a less common hematologic malignancy, with approximately 21,000 new cases in the United States annually. Although current treatments are effective in achieving remission, CLL remains incurable and similar to multiple myeloma, CLL is likely to relapse and require further line(s) of therapy.

We recently reported initial clinical and translational data from our ongoing Phase 1 trial:

- Enrollment in the Phase 1 clinical trial of LYL797 is ongoing. The study was initiated in patients with relapsed/refractory TNBC or NSCLC and expanded to include patients with platinum-resistant ovarian or endometrial cancers.
- The Phase 1 clinical trial is designed as an open-label, dose-escalation and -expansion trial in patients with relapsed/refractory TNBC or NSCLC and has been expanded to include patients with platinum-resistant ovarian or endometrial cancer. All patients enrolled have tumor specimens positive for ROR1 protein expression by immunohistochemistry. The expansion phase of the trial will enroll at least 15 patients with at least two tumor types.
- Initial data from the Phase 1 clinical trial of LYL797 were reported in June 2024:
    - The initial dataset of 20 treated patients included 16 patients with TNBC and four patients with NSCLC. All patients enrolled had relapsed/refractory metastatic disease with an average of six lines of prior therapies. Four dose levels, including two interim dose levels, have been explored to date: 50 x 10^6 cells, 100 x 10^6 cells, 150 x 10^6 cells and 300 x 10^6 cells. The efficacy evaluable subset included 16 patients, and the safety evaluable subset included 18 patients. The manufacturing success rate was 100%.
    - Of the five patients with TNBC treated with LYL797 at the 150 x 10^6 cell dose level, the highest dose level cleared when the data were reported, two patients had confirmed partial responses to Day 90, resulting in an objective response rate (ORR) of 40% (Figure 1). The clinical benefit rate (CBR), defined as a best response of stable disease, partial response or complete response, was dose-dependent with a 60% CBR at the 150 x 10^6 cell dose level and a 38% CBR across all four dose levels evaluated (Figure 2).

Figure 1: Best response of the target lesions for the 16 efficacy evaluable patients. The dark purple bars represent the target lesion tumor size reduction from baseline observed in patients treated at the 150 million cell dose level. Of the five patients with TNBC treated with LYL797 at this dose level, two patients had confirmed partial responses to Day 90, resulting in an ORR of 40%.

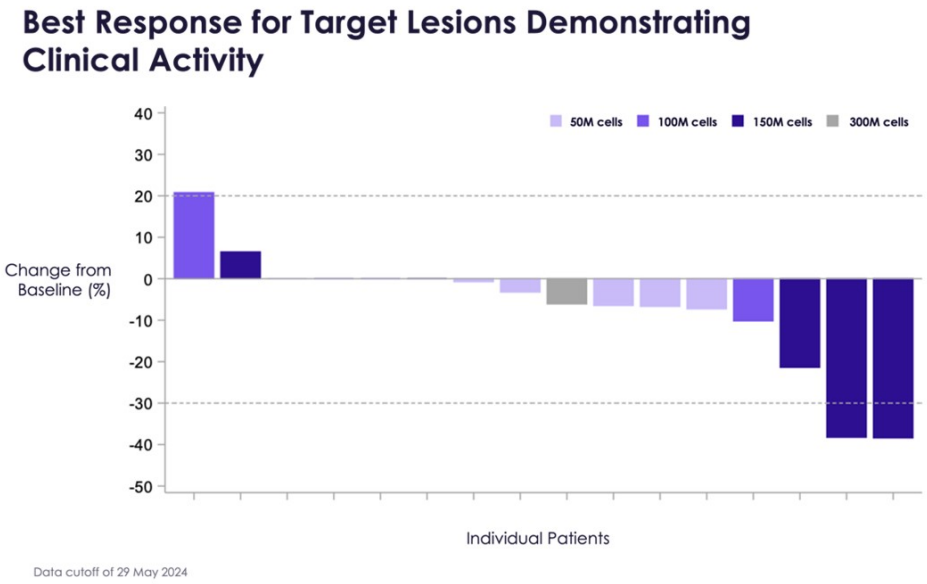
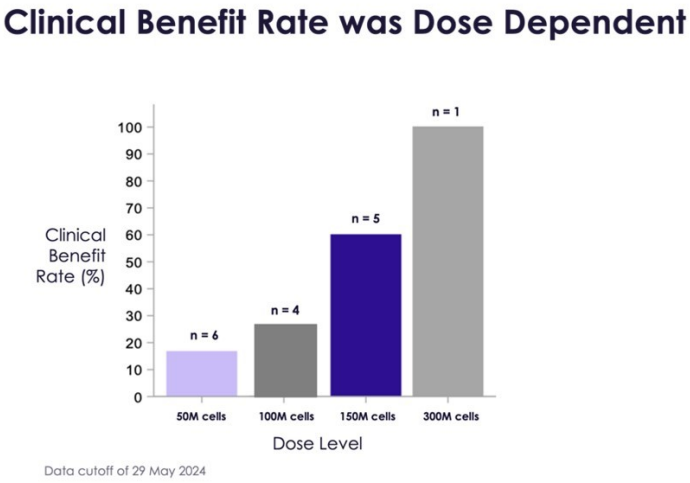


Figure 2: A pattern of dose-dependent clinical activity emerged when the data were plotted by dose and clinical benefit rate, defined as stable disease, partial response or complete response. In addition to having stable disease by imaging, several patients had additional observations of clinical benefit including weight gain, decreased pain and improved liver function tests.



- The most frequently reported related adverse events of any grade were cytokine release syndrome (CRS) (61%), pneumonitis (22%) and headache (17%), as well as the expected cytopenia from lymphodepletion in all patients. The CRS was generally mild (Grade 1 or 2 only), characterized by fever and treated with tocilizumab and steroids. There were no reports of immune effector cell-associated neurotoxicity

syndrome (ICANS) attributed to LYL797. The most frequently reported Grade $\geq$ 3 related adverse events were pneumonitis (17%) and hypoxia (11%), as well as the expected cytopenia from lymphodepletion in 78% of patients. The index patient with pneumonitis had Grade 5 respiratory failure on Day 41. Subsequently, patients were treated aggressively at the first sign or symptom of pneumonitis with high-dose steroids with good result. Each case of pneumonitis has occurred between days 4 and 10. The adverse event of Grade $\geq$ 3 pneumonitis occurred only in patients with TNBC and lung metastases, resulting in the separation of dose escalation into two cohorts based upon lung involvement (lung primary, lung metastatic disease or pleural effusion). No dose-limiting toxicities occurred in patients without lung involvement. All patients are now receiving prophylactic therapy with dexamethasone to mitigate pneumonitis.

  - Translational data were reported on a subset of patients and include CAR T-cell expansion in peripheral blood, phenotypic analysis of T-cell exhaustion and stem-like markers, and on-study tumor biopsies to assess for CAR T-cell tumor infiltration. LYL797 CAR T-cell expansion was observed in peripheral blood samples at Day 60 in all patients assessed when the data were reported (n = 11), with peak expansion occurring between Days 8 and 11. Peak expansion was on average three-fold higher in patients receiving 150 x 10^6 cells compared to those receiving 50 x 10^6 cells. The exhaustion marker, TIGIT, was found only in a low proportion of LYL797 CAR T cells at Day 11 (n = 4) providing support for the role of c-Jun overexpression as an anti-exhaustion technology. A significant proportion of cells with stem-like and effector memory phenotypes were demonstrated at Days 11 and 22 following RNAseq transcriptomic analysis, supporting the role of Epi-R to preserve a stem-like phenotype. Nine evaluable on-treatment tumor biopsies collected between Days 21 and 30 after LYL797 infusion were assessed. LYL797 CAR T cells were present in all solid-tumor biopsies, indicating that LYL797 CAR T cells enhanced with our anti-exhaustion technology were able to infiltrate and persist in the solid tumor microenvironment. In addition, the tumor biopsies have features consistent with T cell-mediated tumor lysis, including T cell-rich inflammation with scattered tumor cells.

- Updated data from the ongoing Phase 1 trial in solid tumor indications, including the initiation of dose expansion, are expected in late 2024 to early 2025.
- An IND is expected to be filed in the second half of 2024 to initiate a Phase 1 trial of LYL797 in patients with relapsed/refractory multiple myeloma or CLL.

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

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

TIL have previously shown clinical benefit in patients with advanced melanoma and other solid tumors with high mutational burden. Published data from third-party TIL trials show that treating metastatic melanoma patients with TIL can result in complete and durable responses. Response rates to TIL therapy in patients with other advanced solid tumors such as lung, colorectal and breast have been much lower than those observed in advanced melanoma. Broad TIL efficacy has been limited by poor enrichment of tumor-reactive T cells and the poor quality and limited growth potential of expanded T cells. Failure to maintain polyclonality of TIL during production may also limit their ability to eradicate cancer cells given the inherent heterogeneous nature of solid tumors. LYL845 incorporates our Epi-R technology that has shown promising improvements in enhancing T-cell phenotypes reported in the literature to be associated with improved clinical outcomes (Krishna et al., Science, Dec. 2020), antitumor activity and increased polyclonality of TIL with stem-like qualities in nonclinical experiments. We received Orphan Drug Designation for LYL845 as a potential novel treatment for patients with advanced melanoma.

We are initially developing LYL845 for advanced melanoma, NSCLC and colorectal cancer (CRC). Based on our success with those indications, we may include patients with other solid tumors, potentially including head and neck, cervical, breast and pancreatic cancer.

- Enrollment in the Phase 1 clinical trial for LYL845 is ongoing. The study is designed to include patients with relapsed or refractory metastatic or locally advanced melanoma, NSCLC and CRC.

- The Phase 1 clinical trial is an open-label, dose-escalation and -expansion trial in patients with relapsed or refractory metastatic or locally advanced melanoma, NSCLC and CRC. The study will enroll at least 15 patients each with advanced melanoma, and relapsed or refractory NSCLC or CRC in the expansion phase of the study.
- Initial clinical and translational data from the Phase 1 trial of LYL845 in patients with advanced melanoma are expected in the second half of 2024.

LYL119 - A next-generation ROR1-targeted CAR T-cell product candidate incorporating Lyell's four stackable and complementary anti-exhaustion technologies designed for enhanced potency

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

LYL119 is being advanced with the goal of potentially creating even greater benefit for patients with ROR1-positive solid tumors.

- LYL119 is a ROR1-targeted CAR T-cell product enhanced with Lyell's four novel genetic and epigenetic reprogramming technologies: c-Jun overexpression, NR4A3 knockout, Epi-R manufacturing protocol and Stim-R™ T-cell activation technology.
- An IND application for LYL119 was cleared by the FDA.
- The Phase 1 trial is designed as an open label dose escalation and expansion trial in patients with ROR1 positive solid tumors and will initially enroll patients with ROR1 positive platinum-resistant ovarian cancer or endometrial cancer. Initial clinical data are expected in the second half of 2025.

Our Manufacturing Capabilities

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

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

We are currently producing clinical supply for our Phase 1 trials at our LyFE Manufacturing Center. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. While we believe this capacity is sufficient to support our pipeline programs into pivotal trials and, if approved, early commercialization, we are also advancing multiple strategic alternatives to innovate and scale manufacturing in the future. We are evaluating third-party manufacturing options as part of an overall CAR T-cell manufacturing strategy to build scale and reduce cost. For TIL, we are advancing our Epi-R P2 manufacturing protocol to shorten delivery time of TIL product to patients.

Macroeconomic Environment

Our business and operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges such as the effects of the ongoing geopolitical conflicts in Ukraine, armed conflicts and turmoil in the Middle East, tensions in U.S.-China relations, inflationary pressures, fluctuations in the interest rate environment, instability in the banking industry, supply constraints and overall market volatility. Economic uncertainty may persist into the remainder of 2024, and the market dynamics discussed above and similar adverse conditions may negatively impact our business.

For a further discussion of trends, uncertainties and other factors that could impact our operating results, see the section entitled “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q.

Components of Results of Operations

Revenue

We have no products approved for sale and have never generated any revenue from product sales. In the future, we may generate additional revenue from collaborations, strategic alliances, licensing agreements, product sales, or a combination of these.

Operating Expenses

Research and Development

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

Research and development expenses also include non-cash expenses related to the change in the estimated fair value of the success payment obligations over their respective requisite service terms granted to Fred Hutchinson Cancer Center (Fred Hutch) and The Board of Trustees of the Leland Stanford Junior University (Stanford). As of December 31, 2022, Fred Hutch had provided the requisite service obligation to earn the potential success payment consideration under the continued collaboration. For the three and six months ended June 30, 2023 and future periods, the change in the Fred Hutch success payment liability fair value is recognized in other (expense) income, net, as the requisite service obligation had been met. See Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. 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.

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

Research and development activities account for a significant portion of our operating expenses. We anticipate that our research and development expenses will increase over the foreseeable future as we expand our research and development efforts including completing nonclinical studies, commencing planned clinical trials, conducting and completing current and planned clinical trials, seeking regulatory approvals of our product candidates, identifying new product candidates and incurring costs to acquire and license technology platforms. A change in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. Because we are early in our research and clinical development efforts of our product candidates, and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the nonclinical development, clinical development and commercialization of product candidates or whether, or when, we may achieve profitability.

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

- the number and scope of nonclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;

- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;
- the extent to which we establish additional collaboration or license agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

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

General and Administrative

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

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

Other Operating Income, Net

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

Interest Income, Net

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

Other (expense) income, net

Other (expense) income, net consists primarily of the change in fair value associated with our success payment liabilities to Fred Hutch and adjustments to the fair value of our marketable equity security that is publicly traded.

Impairment of Other Investments

Impairment of other investments consists of a reduction in the value of certain other investments.

Results of Operations

Three and Six Months Ended June 30, 2024 and 2023

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

	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
Revenue	$ 13	$ 27	$ (14)	$ 16	$ 92	$ (76)
Operating expenses:						
Research and development	40,261	47,471	(7,210)	83,435	92,101	(8,666)
General and administrative	12,256	19,030	(6,774)	25,750	38,309	(12,559)
Other operating income, net	(976)	(569)	(407)	(2,066)	(1,857)	(209)
Total operating expenses	51,541	65,932	(14,391)	107,119	128,553	(21,434)
Loss from operations	(51,528)	(65,905)	14,377	(107,103)	(128,461)	21,358
Interest income, net	6,364	5,264	1,100	13,183	9,761	3,422
Other (expense) income, net	(645)	(326)	(319)	445	774	(329)
Impairment of other investments	—	(2,923)	2,923	(13,001)	(12,923)	(78)
Total other income (loss), net	5,719	2,015	3,704	627	(2,388)	3,015
Net loss	$ (45,809)	$ (63,890)	$ 18,081	$ (106,476)	$ (130,849)	$ 24,373

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 June 30,			Six Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
Personnel	$ 15,979	$ 22,161	$ (6,182)	$ 32,453	$ 41,805	$ (9,352)
Facilities and technology	12,018	13,695	(1,677)	24,915	26,833	(1,918)
Research activities, collaborations and outside services	13,057	11,010	2,047	26,335	23,466	2,869
Success payments	(793)	605	(1,398)	(268)	(3)	(265)
Total research and development expenses	$ 40,261	$ 47,471	$ (7,210)	$ 83,435	$ 92,101	$ (8,666)

Research and development expenses were $40.3 million and $47.5 million for the three months ended June 30, 2024 and 2023, respectively. The $7.2 million decrease was primarily due to a $6.2 million reduction in personnel-related expenses, mainly due to a decrease in headcount associated with the Company's November 2023 reduction in workforce; a decrease of $1.7 million in facilities and technology costs primarily driven by the reduction in workforce and lower software implementation costs; and a decrease of $1.4 million associated with our success payment liabilities primarily driven by the change in our stock price. These decreases were partially offset by an increase of $2.0 million in research activities, collaborations and outside services primarily driven by clinical trials activity.

Research and development expenses were $83.4 million and $92.1 million for the six months ended June 30, 2024 and 2023, respectively. The $8.7 million decrease was primarily due to a $9.4 million reduction in personnel-related expenses mainly due to a decrease in headcount associated with the Company's November 2023 reduction in workforce; a decrease of $1.9 million in facilities and technology costs primarily driven by the reduction in workforce and lower software implementation costs; and a decrease of $0.3 million associated with our success payment liabilities primarily driven by the change in our stock price. These decreases were partially offset by an increase of $2.9 million in research activities, collaborations and outside services primarily driven by clinical trials activity.

General and Administrative Expenses

General and administrative expenses were $12.3 million and $19.0 million for the three months ended June 30, 2024 and 2023, respectively. The $6.8 million decrease was primarily due to a $6.5 million reduction in personnel costs, including a $4.5 million decrease in stock-based compensation expense, primarily related to significant awards being fully

expensed in the previous periods and a decrease of $2.0 million in personnel-related expenses mainly due to a decrease in headcount associated with the Company's November 2023 reduction in workforce.

General and administrative expenses were $25.8 million and $38.3 million for the six months ended June 30, 2024 and 2023, respectively. The $12.6 million decrease was primarily due to a $11.2 million reduction in personnel costs, including a $8.4 million decrease in stock-based compensation expense, primarily related to significant awards being fully expensed in the previous periods and a decrease of $2.8 million in personnel-related expenses mainly due to a decrease in headcount associated with the Company's November 2023 reduction in workforce. General and administrative expenses also decreased due to a reduction of $1.2 million in other administrative expenses.

Other Operating Income, Net

Other operating income, net was $1.0 million and $0.6 million for the three months ended June 30, 2024 and 2023, respectively, and $2.1 million and $1.9 million for the six months ended June 30, 2024 and 2023, respectively.

Interest Income, Net

Interest income, net was $6.4 million and $5.3 million for the three months ended June 30, 2024 and 2023, respectively, and $13.2 million and $9.8 million for the six months ended June 30, 2024 and 2023, respectively. The increase in interest income, net was primarily driven by higher interest rates in 2024.

Other (expense) income, net

Other (expense) income, net was $(0.6) million and $(0.3) million for the three months ended June 30, 2024 and 2023, respectively, and $0.4 million and $0.8 million for the six months ended June 30, 2024 and 2023, respectively. Other (expense) income, net consists primarily of the change in fair value associated with our success payment liabilities to Fred Hutch and for the three and six months ended June 30, 2024, adjustments to the fair value of our marketable equity security investment that is publicly traded.

Impairment of Other Investments

Impairment of other investments was zero for the three months ended June 30, 2024 and $2.9 million for the three months ended June 30, 2023, which consisted of the full impairment of one of our other investments. Impairment of other investments was $13.0 million and $12.9 million for the six months ended June 30, 2024 and 2023, respectively, which consisted of the full impairment of one of our other investments for the six months ended June 30, 2024 and the full impairment of two of our other investments for the six months ended June 30, 2023. See Note 5, *Other Investments*, in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, for additional details regarding the impairments of other investments.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2024, we had $491.1 million in cash, cash equivalents and marketable securities. To date we have raised an aggregate of $1.4 billion in gross proceeds from sales of common stock and convertible preferred stock.

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.

On February 28, 2024, we entered into a sales agreement (Sales Agreement) with Cowen and Company, LLC (Cowen) acting as our sales agent, pursuant to which we may offer and sell shares of our common stock having an aggregate offering price of up to $150.0 million from time to time in a series of one or more at-the-market equity offerings. We will pay Cowen commissions of up to 3.0% of the gross proceeds of the sale, and reimbursement of certain expenses, under this agreement. Neither us nor Cowen is obligated to sell any shares and, to date, we have not made any sales under the Sales Agreement.

Future Funding Requirements

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

and our plans of operation. We are subject to the risks typically related to the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

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

- the scope, timing, progress, costs and results of discovery, nonclinical development and clinical trials for our current and future product candidates and any additional nonclinical studies;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing and outcome of regulatory review of any of our current and future product candidates;
- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- further investment to build additional manufacturing facilities or expand the capacity of our existing ones;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to maintain existing, and establish new, collaborations, licenses, product acquisitions or other strategic transactions and the fulfillment of our financial obligations under any such agreements, including the timing and amount of any success payment, future contingent payments, milestone, royalty or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company, including legal, accounting and other related expenses as well as costs relating to maintaining or expanding our operational, financial and management systems and compliance programs;
- addressing or responding to any potential disputes or litigation; and
- the extent to which we acquire or invest in businesses, products and technology platforms.

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

Material Cash Requirements

We continually evaluate our liquidity and capital resources to ensure that we can adequately and efficiently finance our operations. As of June 30, 2024, our material cash requirements consisted primarily of paying salaries and benefits, administering clinical trials, conducting research, improving our manufacturing capabilities, providing the technology and facilities necessary to support our operations, funding operating lease obligations and other payments related to our collaborative agreements. See Note 3, *License, Collaboration and Success Payment Agreements*, and Note 7, *Leases*, in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, for additional information.

Cash Flows

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

	Six Months Ended June 30,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	$ (80,110)	$ (85,373)
Investing activities	67,001	185,066
Financing activities	889	1,127
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (12,220)	$ 100,820

Operating Activities

During the six months ended June 30, 2024, net cash used in operating activities was $80.1 million, reflecting our net loss of $106.5 million, partially offset by $30.6 million of non-cash items primarily related to stock-based compensation expense of $17.4 million, the impairment of other investments of $13.0 million and depreciation and amortization expense of $9.9 million, partially offset by net amortization and accretion on marketable securities of $8.1 million and non-cash lease income of $1.0 million. Additionally, net operating assets and liabilities decreased $4.2 million primarily driven by a $3.1 million decrease in accrued liabilities and other current liabilities and a $0.6 million decrease in accounts payable.

During the six months ended June 30, 2023, net cash used in operating activities was $85.4 million, primarily reflecting our net loss of $130.8 million, partially offset by $46.2 million of non-cash items primarily related to stock-based compensation expense of $28.1 million, impairment of other investments of $12.9 million and depreciation and amortization of $10.1 million, partially offset by net amortization and accretion on marketable securities of $3.9 million and non-cash lease income of $0.8 million. Additionally, net operating assets and liabilities decreased $0.7 million primarily driven by a $3.6 million decrease in accrued liabilities and other current liabilities partially offset by a $2.4 million increase in accounts payable.

Investing Activities

During the six months ended June 30, 2024, cash provided by investing activities was $67.0 million, consisting primarily of net maturities and purchases of marketable securities.

During the six months ended June 30, 2023, cash provided by investing activities was $185.1 million, consisting of net maturities and purchases of marketable securities of $187.5 million offset by purchases of property and equipment of $2.5 million.

Financing Activities

During the six months ended June 30, 2024, cash provided by financing activities was $0.9 million, consisting of proceeds from the employee stock purchase plan of $0.8 million and proceeds from the exercise of stock options of $0.2 million, partially offset by taxes paid related to the net share settlement of equity awards of $0.1 million.

During the six months ended June 30, 2023, cash provided by financing activities was $1.1 million, consisting of proceeds from the employee stock purchase plan of $1.2 million and proceeds from the exercise of stock options of $0.1 million, partially offset by taxes paid related to the net share settlement of equity awards of $0.1 million.

Off-Balance Sheet Arrangements

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

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited Condensed Consolidated Financial Statements are prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these unaudited Condensed 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 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.

There have been no material changes to our critical accounting policies and estimates as compared to those described in our Annual Report on Form 10-K for the year ended December 31, 2023 (Annual Report) other than our stock-based compensation policy for performance-based restricted stock units. For information related to our stock-based compensation policy for performance-based restricted stock units, see Note 2, *Summary of Significant Accounting Policies*, in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Interest Rate Risk

We had cash equivalents of $119.7 million as of June 30, 2024, which consisted of money market funds and highly liquid investments purchased with original maturities of three months or less from the purchase date. We also had fixed income marketable securities of $357.5 million as of June 30, 2024. The primary objective of our investment activities is to preserve capital to fund our operations, and we currently do not hedge our interest rate risk exposure. Because our fixed income marketable securities are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material effect on our unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. We had no debt outstanding as of June 30, 2024.

Foreign Currency Exchange Risk

All of our employees and operations are currently located in the United States and our expenses are generally denominated in U.S. dollars. We therefore are not currently exposed to significant market risk related to changes in foreign currency exchange rates. However, we have contracted with and may continue to contract with non-U.S. vendors who we may pay in their local currency. Our operations may be subject to fluctuations in foreign currency exchange rates in the future. To date, foreign currency transaction gains and losses have not been material to our unaudited Condensed Consolidated Financial Statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 10% change in exchange rates during any of the periods presented would not have a material effect on our unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and our clinical trial costs. We believe that inflation has not had a material effect on our unaudited Condensed Consolidated Financial Statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (Exchange Act). Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2024, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting during the quarter ended June 30, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we have been or may become involved in material legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not party to any legal proceedings material to our operations or of which any of our property is the subject, nor are we aware of any such proceedings that are contemplated by a government authority or otherwise. Regardless of outcome, any such proceedings or claims is subject to inherent uncertainties and can have an adverse impact on us because of defense and settlement costs, diversion of time and resources and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

Our business involves significant risks, some of which are described below. You should carefully consider the risks described below, as well as the other information contained in this Quarterly Report on Form 10-Q, including our unaudited Condensed Consolidated Financial Statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. The risk factors set forth below that are marked with an asterisk (*) contain substantive changes to the similarly titled risk factors included in, or did not appear as separate risk factors in, Item 1A of our Annual Report, which was filed with the SEC on February 28, 2024.

Summary of Risk Factors

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

- We are an early clinical stage biopharmaceutical company and have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing net losses for the foreseeable future.
- We operate in a rapidly evolving field and have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We currently have no products approved for sale and have never generated revenue from product sales. We may never generate revenue from product sales or achieve profitability.
- We will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Our success payment obligations in our success payment agreements may result in dilution to our stockholders or may be a drain on our cash resources to satisfy the payment obligations.
- We are early in our research and clinical development efforts for our product candidates. If we are unable to successfully develop, manufacture and commercialize product candidates or experience significant delays in doing so, our business may be harmed.
- Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use and expand our technology platforms to develop any product candidate.
- We currently have no marketing, sales or distribution infrastructure, and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Either of these commercialization strategies carries substantial risks to us.
- We currently manufacture drug products for our clinical trials ourselves. Delays in further qualifying or in receiving regulatory approvals for any manufacturing facility or product candidates, or in expanding our

manufacturing capacity or finding suitable third-party manufacturing partners, could delay our development plans and thereby limit our ability to generate product revenues.

- The manufacturing of cellular therapies is very complex. We are subject to a multitude of manufacturing risks, including risks associated with supply chain complexity related to patient materials, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates.
- If our sole clinical or commercial manufacturing facility or any of our potential contract manufacturing organizations are damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.
- We may rely on third parties to manufacture our product candidates, which subjects us to risks and could delay or prevent our development and/or commercialization, if approved, of our product candidates.
- Cell-based therapies rely on the availability of specialty raw materials, which may not be available to us on acceptable terms or at all.
- We rely on third parties to conduct, supervise and monitor a significant portion of our research and nonclinical studies and clinical trials for our product candidates, and, if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.
- We have in the past, and we may in the future, form or seek collaborations or strategic alliances or enter into additional licensing arrangements, and we may not realize the benefits of such alliances or licensing arrangements.
- We depend on the enrollment and retention of patients in our current and planned clinical trials for our product candidates. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our cellular therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approvals, commercialization or payor coverage of our product candidates.
- The results of research, nonclinical studies or earlier clinical trials are not necessarily predictive of future results, initial clinical results in a clinical trial may not be predictive of future results in the same clinical trial and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. If clinical trials of our product candidates fail to produce positive results or demonstrate satisfactory safety and efficacy, at the appropriate dose level or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- Clinical development involves a lengthy and expensive process with an uncertain outcome.
- Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.
- We have in-licensed a portion of our intellectual property from our partners. If we breach any of our license agreements with these partners, we could potentially lose the ability to continue the development and potential commercialization of one or more of our product candidates.

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

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

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

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

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

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

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

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

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our

financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, any of our quarterly or annual periods' results are not indicative of future operating performance.

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

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

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

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

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

We expect to expend substantial resources for the foreseeable future to advance and expand our research pipeline, conduct nonclinical studies and pursue clinical development and manufacturing of our product candidates. We also expect to continue to expend resources for the development of our technology platforms. These expenditures will include costs associated with research and development, potentially acquiring or licensing new technologies, conducting nonclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize. In addition, we may be required to make substantial payments related to our success payment agreements and other contingent consideration payments under our license and collaboration agreements. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably

estimate the actual amounts necessary to successfully complete the discovery, development and commercialization of our existing and potential product candidates, and other unanticipated costs may arise.

As of June 30, 2024, we had $491.1 million in cash, cash equivalents and marketable securities. As a result of expense timing, as well as diligent expense management, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our working capital and capital expenditure needs into 2027. However, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital to complete clinical development of any of our current programs.

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

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

We agreed to make success payments payable in cash or publicly-tradeable shares of our common stock at our discretion pursuant to our success payment agreements with Fred Hutch and Stanford. On each contractually prescribed measurement date, we may be required to make success payments based on increases in the per share fair value of our common stock. The total amount of success payments that we may become obligated to make is currently $400.0 million and may increase in the future due to amendments of our existing success payment agreements. For information related to our success payment obligations, see Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

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

Factors that may lead to increases or decreases in the estimated fair value of our success payment liabilities include, among others, changes in the value of the common stock, changes in volatility and changes in the risk-free rate. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP consolidated financial statements. See Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to the unaudited Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Risks Related to Our Business and Industry

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

We are early in our research and clinical development efforts for our product candidates. LYL797 and LYL845 are in Phase 1 clinical development, LYL119 is entering Phase 1 clinical development and our other proprietary TIL product candidate is currently in preclinical development. We have not yet demonstrated our ability to successfully complete any clinical trials (including any Phase 3 or other pivotal clinical trials), obtain regulatory approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We have invested substantial resources in developing our technology platforms and our product candidates, conducting nonclinical studies, commencing clinical trials and building our manufacturing facilities and capabilities, each of which will be required prior to any regulatory approval and commercialization. Our ability to generate revenue from product sales, which we do not expect will occur for several years, if ever, will depend heavily on the successful research and development and eventual commercialization of one or more product candidates in profitable indications and markets. The success of our efforts to identify, develop, manufacture and commercialize product candidates will depend on many factors, including the following:

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

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

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

We are seeking to identify and develop a broad pipeline of product candidates using our proprietary technology platforms. The scientific research that forms the basis of our efforts to develop product candidates with our technology platforms is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our technology platforms are both preliminary and limited. Additionally, although LYL797 and LYL845 are in, and LYL119 is entering, Phase 1 clinical development, our current clinical data are limited, and nonclinical data from murine tumor models and in vitro experiments with tumor cell lines may not translate into humans or may not accurately predict the safety and efficacy of our product candidates in humans. As a result, we are exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates.

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

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

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

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

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

Additionally, in the fourth quarter of 2023, we announced a reduction in workforce of approximately 25%. This reduction in force may yield unintended consequences and costs, such as difficulty retaining and motivating remaining

employees, increased difficulty in our day-to-day operations and loss of institutional knowledge and expertise and difficulty in attracting and hiring qualified employees in the future. We may also be subject to reputational risks and litigation risks and expenses and may not realize the savings or operational efficiencies anticipated, which could result in total costs and expenses that are greater than expected.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Manufacturing

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

We have built our own manufacturing facility in Bothell, Washington. The facility is designed to support the production of nonclinical and clinical development product candidates and early commercialization of products, and

ongoing facility and equipment qualification to support clinical production is required. If we are not able to further qualify our existing facility or the appropriate regulatory approvals for the facility are delayed, or if we are unable to otherwise expand our manufacturing capacity, we may be unable to manufacture sufficient quantities of our product candidates, if at all, which would limit our development activities and our opportunities for growth.

In addition, our manufacturing facility will be subject to ongoing, periodic inspection by the FDA, competent authorities of European Union (EU) Member States and other comparable regulatory authorities 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 modification or termination of or a hold on a clinical trial or may delay or prevent filing or approval of commercial marketing applications for our product candidates. We also may encounter problems with the following:

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

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

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

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

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

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

The process of successfully manufacturing products for clinical testing and commercialization may be particularly challenging, even if such products otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained

personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with microbes, viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated, unusable product or necessitate the closing of a manufacturing facility for an extended period of time to allow us to investigate and remedy the contamination. These types of contaminations could result in delays in the manufacture of products, which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

We intend to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP-compliant clinical trials on our product candidates properly and on time. For example, we are relying on CROs to conduct significant parts of our LYL797, LYL845 and planned LYL119 Phase 1 clinical trials. Negotiating budgets and contracts with CROs and study sites may result in delays to our development timelines and increased costs. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

We rely on these parties for execution of our nonclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with applicable GCPs. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations and requirements may require us to add patients to or repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal, state or foreign fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

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

The outside scientists and clinical trial investigators who conduct the research and development upon which portions of our product candidate pipeline depends are not our employees; rather, they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring

academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. These factors could adversely affect the timing of the clinical trials, the timing of receipt and reporting of clinical data, the timing of our IND submissions and comparable foreign applications and our ability to conduct our current and planned clinical trials. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to, and have an adverse effect on, our business.

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

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

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

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

We may form or seek further strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates, our research and any future product candidates that we may pursue. Such alliances will be subject to many of the risks set forth above. Moreover, any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that

dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex.

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

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

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

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

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

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

Our clinical trials compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. We may also encounter additional challenges and slower than anticipated enrollment in our clinical trials if any of our competitors obtain FDA approval before us in the same therapeutic areas as our product candidates.

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

Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

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

Patient enrollment depends on many additional factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- perceived risks and benefits of the product candidate under evaluation, including any perceived risks associated with genetically modified product candidates;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication that the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available approved or investigational therapies.

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

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

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

Risks Related to Regulation and Legal Compliance

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

We currently have no products approved for commercial sale, and we are in the first phase of clinical development of our product candidates. LYL797 and LYL845 are in Phase 1 clinical development, LYL119 is entering Phase 1 clinical development and our other proprietary TIL product candidate is currently in preclinical development. The future success of our business is substantially dependent on our ability to obtain regulatory approval for our product candidates for the indications we seek, and, if approved, to successfully commercialize one or more product candidates in a timely manner. Each of our programs and product candidates will require clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. We do not have any products that are approved for commercial sale, and we may never be able to develop or commercialize marketable products.

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

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of nonclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval. Furthermore, the regulatory approval process for novel product candidates, such as T-cell product candidates and next-generation T-cell programs, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates.

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

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

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

In addition to oversight by the FDA and by institutional review boards (IRBs) under guidelines promulgated by the National Institutes of Health (NIH), clinical trials such as those for LYL797 and LYL119, which evaluate T cells expressing a synthetic CAR and overexpressing c-Jun, 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 patients to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other comparable foreign regulatory authorities may ask for specific post-marketing requirements, and additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

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

The results of research, nonclinical studies or earlier clinical trials are not necessarily predictive of future results, initial clinical results in a clinical trial may not be predictive of future results in the same clinical trial and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. If clinical trials of our product candidates fail to produce positive results or demonstrate satisfactory safety and efficacy, at the appropriate dose level or at all, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.*

Success in research, nonclinical studies and early clinical trials does not ensure that later clinical trials will generate similar results and otherwise provide adequate data to demonstrate the efficacy and safety of an investigational product. Clinical trials may show that one or more of our product candidates are not safe or effective, in which event we may need to abandon development of such product candidates. For example, adverse events of pneumonitis were reported with the initial data from the Phase 1 clinical trial of LYL797 released in June 2024, and dose escalation in the trial has been separated into two cohorts including patients with and without lung involvement. All patients now receive prophylactic therapy with dexamethasone to mitigate pneumonitis. If we are unable to find the appropriate cell dose level for patients with or without lung involvement that can demonstrate satisfactory safety and efficacy, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the clinical trial for LYL797. In fact, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in early- and late-stage clinical trials, even after seeing promising results in earlier nonclinical studies or clinical trials. Thus, even if the results from our initial research, nonclinical activities or early clinical results appear positive, we do not know whether the current Phase 1 or subsequent 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, and results in one indication may not be predictive of results for the same product candidate in another indication. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials. Additionally, even if clinical trials show promising early results, clinical trials of the same product candidate in another indication may fail to show similar results, and market acceptance of our product candidate, if approved, may be limited.

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

We are in the first phase of clinical development of our product candidates. LYL797 and LYL845 are in Phase 1 clinical development, LYL119 is entering Phase 1 clinical development and our second proprietary TIL product candidate is currently in preclinical development. The risk of failure of our product candidates is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

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

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

application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

To date, we have not fully enrolled or completed any clinical trials required for the approval of our product candidates. We may experience delays in initiating, enrolling or conducting our current and planned clinical trials, and we do not know whether clinical trials will begin or enroll patients on time, will need to be redesigned, will achieve expected enrollment rates or will be completed on schedule, if at all. Identifying candidate patients with ROR1+ tumors for the LYL797 and LYL119 clinical studies and obtaining sufficient and specific tumor tissues for the LYL845 clinical study are necessary to support our Phase 1 clinical trials. Our inability to identify candidates with ROR1+ tumors or obtain specific tumor tissues or sufficient amounts of tumor tissues in a timely manner or at all could delay or preclude our ability to execute and complete the clinical trials. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including in connection with:

- inability to generate sufficient nonclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in reaching agreement with the FDA or other regulatory authorities, including comparable foreign regulatory authorities, as to the design or implementation of our clinical trials;
- obtaining regulatory authorization to commence a clinical trial;
- reaching an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- obtaining IRB approval at each trial site or positive ethics committees opinions;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with applicable regulatory requirements, including the FDA's and comparable foreign regulatory authorities' GCP requirements, or other applicable regulatory requirements;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of product candidates for use in clinical trials; or
- suspensions or terminations by IRBs or ethics committees of the institutions at which such trials are being conducted, by the Data Safety Monitoring Committee for such trial or by the FDA or other regulatory authorities, including comparable foreign regulatory authorities, due to a number of factors, including those described above.

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

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

product sales and generate revenues. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

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

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not continue the development of nor receive approval to market any product candidates, which could prevent us from ever generating product revenues or achieving profitability. For example, previous clinical trials utilizing CAR T cells to treat hematologic tumors have shown an increased risk of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome, and approved CAR T products carry a boxed warning concerning the risk of developing secondary T-cell malignancies. Serious adverse events of pneumonitis that were not expected were reported for patients treated in our LYL797 Phase 1 clinical trial. Adverse events may also be associated with the lymphodepletion or IL-2 regimen utilized with cellular therapies. If additional adverse events or other side effects are observed in any of our clinical trials that are atypical of, or more severe than, the known side effects of cellular therapies, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. If such effects are more severe, less reversible than we expect or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of any of our product candidates, which could result in the delay or denial of regulatory approval by the FDA or other regulatory authorities.

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 patients to complete the trial or result in potential product liability claims.

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

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

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

Interim, topline or preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available or as we make changes to our manufacturing processes and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our nonclinical studies and clinical trials, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Further, modifications or improvements to our manufacturing processes for a therapy may result in changes to the characteristics or behavior of the product candidate that could cause our product candidates to perform differently and affect the results of our ongoing clinical trials. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available.

From time to time, we may also disclose preliminary or interim data from our nonclinical studies and clinical trials. Preliminary or interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. If the interim, topline or preliminary data we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any of our potential product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

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

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

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

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

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory authority or enforcement authority may, among other things:

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

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

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

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

We have received Orphan Drug Designation (ODD) for LYL845 in the United States, and we may seek ODD in other regions or indications in the future, or for other product candidates. We may not be able to obtain or maintain ODD for any product candidates, and we may be unable to take advantage of the benefits associated with ODD, including the potential for market exclusivity. If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our lead compounds before us, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.*

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

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

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

We may not be able to obtain any future ODDs that we apply for and receiving ODDs does not guarantee that we will be able to successfully develop our product candidates. There is no guarantee that we will be able to maintain any ODDs that we receive. ODDs may be revoked if the FDA finds that the request for designation contained an untrue statement of a material fact or omitted material information, or if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request. Moreover, even if we were able to receive and maintain ODDs, we may ultimately not receive any period of regulatory exclusivity if our product candidates are approved. For example, we may not receive orphan product regulatory exclusivity if the indication for which we receive FDA regulatory approval is different than the ODD. ODD exclusivity may be lost if we are unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan exclusivity for any of our current or future product candidates, that exclusivity may not effectively protect the product candidate, if approved, from competition as different products can be approved for the same condition or products that are the same as ours can be approved for different conditions. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the regulatory authority concludes that the latter product is clinically superior by means of greater effectiveness, greater safety or providing a major contribution to patient care. If another sponsor receives approval for such product before we do, we would be prevented from launching our product for the orphan indication during the period of marketing exclusivity unless we can demonstrate clinical superiority.

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

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

We may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any product candidates for which we obtain marketing approval. The healthcare laws that may affect us include: the federal fraud and

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

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

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

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

In addition, there continues to be heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs. For example, President Biden issued an executive order in July 2021 supporting legislation to enact drug pricing reforms and, in response, the U.S. Department of Health and Human Services (HHS) released a Comprehensive Plan for Addressing High Drug Prices in September 2021 with specific legislative and administrative policies that Congress could enact to help improve affordability of, and access to, prescription drugs. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law, which among other things: (i) directs HHS to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law, and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Additionally, the IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in the ACA marketplaces through plan year 2025. The IRA

also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions started taking effect progressively in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be effectuated, but it is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration’s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare and Medicaid Services (CMS) Innovation Center, which will be evaluated on their ability to lower the cost of drugs, promote accessibility and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act of 1980 (Bayh-Dole Act). On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights that for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. For additional detail on healthcare reform that may affect our business, see “Healthcare Reform” in the business section of our Annual Report.

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

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

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

Similarly, a significant trend in the healthcare industry is cost containment. Governmental authorities have announced initiatives to control the cost of prescription drugs through the use of march-in rights under the Bayh-Dole Act, and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. For additional detail on healthcare reform that may affect our cost containment, see “Healthcare Reform” in the business section of our Annual Report. As such, cost containment reform efforts may result in an adverse effect on our operations. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates will be physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

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

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

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

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

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

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

In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut and Utah—have enacted comprehensive data privacy and security laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct or delete certain personal data and to opt-out of certain data processing activities, such as targeted advertising, profiling and automated decision-making. The exercise of these rights may impact our business and ability to advance our product candidates effectively. Certain states also impose more stringent requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, CCPA), applies to personal data of consumers, business representatives and employees who are California

residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines of up to $7,500 per intentional violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability.

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

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

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

In addition to data privacy and security laws, we are or may become contractually subject to industry standards adopted by industry groups. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

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

Risks Relating to Our Intellectual Property

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

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

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office (USPTO) and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. There is also no assurance that all

potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. We may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity, enforceability or patentability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity, enforceability or patentability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

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

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

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

United States patent applications containing or that at any time contained a claim not entitled to a priority date before March 16, 2013 are subject to the “first to file” system implemented by the America Invents Act (2011). The first to file system requires us to be cognizant going forward of the time from invention to filing of a patent application. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product candidate.

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first nonprovisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent’s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. While the patent term of certain patents can also be extended with respect to a specific product to recapture time lost in clinical trials and regulatory review by the FDA, a patent’s life also can be shortened by a terminal disclaimer over an earlier filed patent

or patent application. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing infringing products made using our inventions in other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful, the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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

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

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

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

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

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

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

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

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

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

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

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

Our product candidates may also require specific formulations, manufacturing methods or technologies to work effectively and efficiently, and these rights may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms; such failure would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

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

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

We have acquired or licensed, or may require in the future, intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). For example, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

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

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual

property rights, to protect our or our partners' trade secrets or to determine the validity or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid. In patent litigation in the United States, defendant counterclaims alleging noninfringement, invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert noninfringement, invalidity or unenforceability of a patent. The outcome following legal assertions of noninfringement, unpatentability, invalidity and unenforceability is unpredictable. With respect to the validity of patent rights, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of unpatentability, invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

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

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments.

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

We may in the future be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological

achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

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

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- permit stockholders to take actions only at a duly called annual or special meeting and not by unanimous written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend certain provisions of the bylaws; and

- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

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

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

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

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

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

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

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

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal control. Section 404 of the Sarbanes-Oxley Act (Section 404) requires that we evaluate and determine the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. Our independent registered public accounting firm is also required to attest to the effectiveness of our internal control over financial reporting. These assessments need to include the disclosure of any material weaknesses in such internal control. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis. We and our independent auditors have previously identified a material weakness in our internal control over financial reporting, and we cannot assure you that we will not identify other material weaknesses in the future.

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

General Risk Factors

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

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

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

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

- the timing and results of nonclinical studies and clinical trials for our product candidates;
- failure or discontinuation of any of our product development and research programs;
- the success of existing or new competitive product candidates or technologies;
- results of clinical trials or regulatory approvals of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes including those concerning patent applications, issued patents, or other proprietary rights;
- labor discord or disruption, geopolitical events and tensions, social unrest, war, armed conflicts and turmoil, terrorism, political instability, acts of public violence, boycotts, hostilities and social unrest and health pandemics;
- the level of expenses related to any of our research programs or clinical development programs;
- actual or anticipated changes in our estimates as to our financial results or development timelines;
- whether our financial results, forecasts and development timelines meet the expectations of securities analysts or investors;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- market conditions in the healthcare sector;

- general economic, industry and market conditions beyond our control, such as inflationary pressures, the interest rate environment, labor shortages and supply chain constraints, instability in the banking industry and other macroeconomic factors and associated economic downturn; and
- the other factors described in this “Risk Factors” section.

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

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

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

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

At any time, sales of a substantial number of shares of our common stock in the public market could occur, or there could be a perception in the market that the holders of a large number of shares of common stock intend to sell shares, and any such event could reduce the market price of our common stock. As of June 30, 2024, we have 255,948,333 shares of common stock outstanding. Substantially all of the shares of our common stock outstanding and shares issued upon the exercise of stock options outstanding under our equity incentive plans, subject to applicable securities law restrictions, may be able to be sold in the public market.

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

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

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

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

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

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

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

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

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

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

Under the Tax Act, as modified by the CARES Act, our net operating losses (NOLs) generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOLs is

limited to 80% of taxable income. There is variation in how states have responded and may continue to respond to the Tax Act and CARES Act. In addition, under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past, including as a result of our initial public offering (IPO), and may experience future ownership changes as a result of subsequent shifts in our stock ownership (some of which may be outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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

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

Our reliance on third parties could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, clinical research and development and other functions. We also rely on third-party service providers to provide other products, services or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their data privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, we cannot assure you that our data protection efforts and our investment in information technology will detect all vulnerabilities on a timely basis, prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs, and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal data), which could result in financial, legal, business and reputational harm to us. For example, any such event

that leads to unauthorized access, use or disclosure of personal data, including personal data regarding our clinical trial patients or employees, could harm our reputation directly, compel us to comply with potentially costly federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, including expending significant resources or modifying our business practices such as our clinical trial activities, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. We take steps designed to detect, mitigate and remediate vulnerabilities in our information systems. However, we may not detect and remediate all such vulnerabilities, including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident, and we may need to expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against any security incidents.

Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data or to notify relevant stakeholders, including affected individuals, regulators and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

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

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

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

During the second quarter of 2024, none of our directors or executive officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement as defined in Item 408(a) and (c) of Regulation S-K, respectively.

Item 6. Exhibits.

Exhibit Number	Description	Form	File Number	Exhibit/ Appendix Reference	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation.	S-8	333-257249	4.1	06/21/2021	
3.2	Amended and Restated Bylaws.	10-Q	001-40502	3.2	11/07/2023	
4.1	Form of Common Stock Certificate.	S-1/A	333-256470	4.1	06/09/2021	
4.2	Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated March 5, 2020.	S-1	333-256470	4.2	05/25/2021	
10.1*	Lyell Immunopharma, Inc. Non-Employee Director Compensation Policy.					X
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a).					X
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a).					X
32.1*«	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350.					X
101.INS	XBRL Instance Document.	The XBRL instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					X

* Filed herewith.

« The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Lyell Immunopharma, Inc.

Date: August 7, 2024

By: /s/ CHARLES NEWTON

Charles Newton

Chief Financial Officer

(Principal Financial and Accounting Officer)

Exhibit 10.1

Lyell Immunopharma, Inc.
Non-Employee Director Compensation Policy
Adopted by the Board of Directors: November 11, 2019
Last Amended and Restated: April 24, 2024, to be effective June 14, 2024

Effective Date: June 14, 2024

Each member of the Board of Directors (the " ***Board***") of Lyell Immunopharma, Inc. (the " ***Company***") who is a non- employee director of the Company (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service. Unless otherwise defined herein, capitalized terms used in this Policy will have the meaning given to such terms in the Company's 2021 Equity Incentive Plan or if such plan is no longer in use, the meaning given to such terms or any similar terms in the primary successor to such plan (in either case, the "***Plan***").

This Policy is amended and restated effective upon June 14, 2024 (the " ***Effective Date***").

Annual Cash Compensation

Each Eligible Director will receive the cash compensation described below. The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash retainer fees are vested upon payment.

1. Annual Board Service Retainer:

   a. All Eligible Directors other than Lead Director/Chair: $50,000
   b. Lead Director: $80,000
   c. Chair: $85,000

2. Annual Committee Service Retainer (Chair):

   a. Chair of the Audit Committee: $20,000
   b. Chair of the Compensation Committee: $15,000
   c. Chair of the Nominating and Corporate Governance Committee: $10,000

3. Annual Committee Service Retainer (Non-Chair):

   a. Audit Committee: $10,000
   b. Compensation Committee: $7,500
   c. Nominating and Corporate Governance Committee: $5,000

Equity Compensation

Each Eligible Director will be eligible to receive the equity compensation set forth below. The equity compensation below will be granted under the Plan and the Company's standard form of Option Agreement most recently approved by the Board or the Compensation Committee. All Options granted under this Policy will be Nonstatutory Stock Options, with a maximum term of ten years from the date of grant and an exercise price per share equal to 100% of the Fair Market Value of the underlying Common Stock on the date of grant.

1. Appointment Grant. Without any further action of the Board, each person who is elected or appointed for the first time to be an Eligible Director will automatically, upon the date of his or her initial election or appointment to be an Eligible Director, be granted the lesser of (i) a Nonstatutory Stock Option to purchase shares of Common Stock calculated to have a Black-Scholes value of $500,000 on the date of grant, rounded to the nearest whole number; and (ii) a Nonstatutory Stock Option to purchase 260,000 shares of Common Stock (an "***Appointment Grant"***). Each

Appointment Grant will vest as to one thirty-sixth (1/36th) of the shares of Common Stock subject to the Appointment Grant on a monthly basis following the Appointment Grant's grant date on the same day of the month as such grant date (or on the last day of the month, if there is no corresponding day in such month), subject to the Eligible Director remaining in Continuous Service through the applicable vesting date.

2. Annual Grant. Without any further action of the Board, at the close of business on the date of each annual meeting of stockholders of the Company (each, an "***Annual Meeting***"), each person who is then an Eligible Director will automatically be granted the lesser of (i) a Nonstatutory Stock Option to purchase shares of Common Stock calculated to have a Black-Scholes value of $300,000 on the date of grant, rounded to the nearest whole number; and (ii) a Nonstatutory Stock Option to purchase 130,000 shares of Common Stock (an "***Annual Grant***"). Each Annual Grant will vest as to all of the shares of Common Stock subject to the Annual Grant on the earlier of (a) the date of the next Annual Meeting that occurs following the grant date of the Annual Grant (or the date immediately prior to such date if the Eligible Director's service as a director ends at such Annual Meeting due to the director's failure to be re-elected or the director not standing for re-election); or (b) the first anniversary of the grant date of the Annual Grant, subject to the Eligible Director remaining in Continuous Service through the vesting date.

Change in Control

Notwithstanding anything to the contrary in this Policy, in the event of a Change in Control, each Eligible Director will fully vest in his or her then-outstanding Company equity awards as of immediately prior to the Change in Control, including, without limitation, any equity awards granted under this Policy, provided that the Eligible Director continues to be an Eligible Director through immediately prior to the date of such Change in Control.

Eligible Director Compensation Limit

Notwithstanding anything to the contrary in this Policy, the cash compensation and equity compensation that each Eligible Director is eligible to receive under this Policy shall be subject to the limits set forth in Section 3(d) of the Plan.

Ability to Decline Compensation

An Eligible Director may decline all or any portion of his or her compensation under this Policy by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be.

Expenses

The Company will reimburse Eligible Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Eligible Director timely submits to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Amendment

This Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee.

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Lynn Seely, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Lyell Immunopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2024

By: /s/ LYNN SEELY

Lynn Seely, M.D.

President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Charles Newton, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Lyell Immunopharma, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 7, 2024

By: /s/ CHARLES NEWTON

Charles Newton

Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), each of the undersigned hereby certifies in her or his capacity as an officer of Lyell Immunopharma, Inc, Inc. (the "Company"), that, to the best of her or his knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 7, 2024

By: /s/ LYNN SEELY

Lynn Seely, M.D.

President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2024

By: /s/ CHARLES NEWTON

Charles Newton

Chief Financial Officer
(Principal Financial and Accounting Officer)