

**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 September 30, 2022

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

(State or other jurisdiction of
incorporation or organization)

201 Haskins Way
South San Francisco, California

(Address of principal executive offices)

83-1300510

(I.R.S. Employer Identification No.)

94080

(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, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 November 3, 2022, the registrant had 249,325,627 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 preclinical studies and clinical trials, results of preclinical studies, clinical trials, research and development costs, planned regulatory submissions, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “would,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “believe,” “estimate,” “predict,” “potential,” or “continue” or the negative of these terms or other similar expressions. Forward-looking statements contained in this 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 preclinical studies and clinical trials, including for LYL797, LYL845 and LYL119;
- the timing and costs involved in obtaining and maintaining regulatory approval of LYL797, LYL845, LYL119 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for our product candidates for various diseases;
- our 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 opportunity for LYL797, LYL845, LYL119 or any other product candidates we may develop in each of the diseases we target;
- our reliance on third parties to conduct preclinical research activities for LYL797, LYL845, LYL119 or any other product candidates we may develop;
- the characteristics, safety, efficacy and therapeutic effects of LYL797, LYL845, LYL119 or any other product candidates we may develop;
- our estimates of the number of patients in the United States who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- 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 demonstrate the safety and efficacy of LYL797, LYL845, LYL119 or any other product candidates we may develop, and other positive results;
- the success of competing therapies that are, or may become, available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- 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 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 of LYL797, LYL845, LYL119 or any other product candidates we may develop, 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 conduct additional clinical trials of LYL797, LYL845, LYL119 or any other product candidates we may develop, and for the manufacture of our product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights, including LYL797, LYL845, LYL119 or any other product candidates we may develop;
- our ability to retain the continued service of our key personnel and to identify, hire and then retain additional qualified personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations (CROs) and employees;
- our expectations regarding the impact of inflation, macroeconomic conditions and geopolitical conflicts on our business and operations, including on our manufacturing suppliers, collaborators, CROs and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the Jumpstart Our Business Startups Act of 2012 (the JOBS Act); 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 in the section titled “Risk Factors” 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)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 116,311	\$ 293,828
Marketable securities	531,821	320,966
Prepaid expenses and other current assets	11,613	11,492
Total current assets	659,745	626,286
Restricted cash	279	466
Marketable securities, non-current	102,519	283,531
Other investments	42,001	47,001
Property and equipment, net	125,727	120,098
Operating lease right-of-use assets	44,084	46,541
Other non-current assets	2,914	3,483
Total assets	\$ 977,269	\$ 1,127,406
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,795	\$ 3,207
Accrued liabilities and other current liabilities	23,568	29,057
Success payment liabilities	11,663	9,486
Deferred revenue ⁽¹⁾	11,191	4,988
Total current liabilities	51,217	46,738
Operating lease liabilities, non-current	64,636	66,650
Deferred revenue, non-current ⁽²⁾	37,163	79,665
Other non-current liabilities	4,227	4,566
Total liabilities	157,243	197,619
<i>Commitments and contingencies (Note 12)</i>		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 10,000 shares authorized at September 30, 2022 and December 31, 2021; zero shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, \$0.0001 par value; 500,000 shares authorized at September 30, 2022 and December 31, 2021; 249,240 and 242,738 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	25	24
Additional paid-in capital	1,589,080	1,515,748
Accumulated other comprehensive loss	(9,996)	(1,623)
Accumulated deficit	(759,083)	(584,362)
Total stockholders' equity	820,026	929,787
Total liabilities and stockholders' equity	\$ 977,269	\$ 1,127,406

(1) Including amounts from a related-party of \$11,191 and \$4,988 as of September 30, 2022 and December 31, 2021, respectively.

(2) Including amounts from a related-party of \$37,163 and \$79,665 as of September 30, 2022 and December 31, 2021, respectively.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue ⁽¹⁾	\$ 3	\$ 2,755	\$ 36,297	\$ 7,828
Operating expenses:				
Research and development	41,607	31,433	121,156	119,408
General and administrative	26,084	21,241	90,959	57,184
Other operating income, net	(1,251)	(758)	(3,544)	(1,526)
Total operating expenses	66,440	51,916	208,571	175,066
Loss from operations	(66,437)	(49,161)	(172,274)	(167,238)
Interest income, net	2,251	270	3,600	842
Other (expense) income, net	(1,068)	16	(1,047)	(117)
Impairment of other investments	(5,000)	—	(5,000)	—
Total other (loss) income, net	(3,817)	286	(2,447)	725
Net loss	(70,254)	(48,875)	(174,721)	(166,513)
Other comprehensive loss:				
Net unrealized loss on marketable securities	(1,645)	(138)	(8,373)	(321)
Comprehensive loss	\$ (71,899)	\$ (49,013)	\$ (183,094)	\$ (166,834)
Net loss per common share, basic and diluted	\$ (0.28)	\$ (0.20)	\$ (0.71)	\$ (1.66)
Weighted-average shares used to compute net loss per common share, basic and diluted	248,320	239,384	246,285	100,603

(1) Including related-party revenue of zero and \$2,640 for the three months ended September 30, 2022 and 2021, respectively, and \$36,299 and \$7,697 for the nine months ended September 30, 2022 and 2021, respectively.

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

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

Three Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of June 30, 2022	247,110	\$ 25	\$ 1,565,197	\$ (8,351)	\$ (688,829)	\$ 868,042
Issuance of common stock upon exercise of stock options	1,375	—	5,127	—	—	5,127
Stock-based compensation	650	—	19,123	—	—	19,123
Issuance of common stock in connection with restricted stock units, net of tax	105	—	(367)	—	—	(367)
Other comprehensive loss	—	—	—	(1,645)	—	(1,645)
Net loss	—	—	—	—	(70,254)	(70,254)
Balance as of September 30, 2022	249,240	\$ 25	\$ 1,589,080	\$ (9,996)	\$ (759,083)	\$ 820,026

Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2021	242,738	\$ 24	\$ 1,515,748	\$ (1,623)	\$ (584,362)	\$ 929,787
Issuance of common stock upon exercise of stock options	3,513	1	9,251	—	—	9,252
Stock-based compensation	2,600	—	63,561	—	—	63,561
Issuance of common stock under employee stock purchase plan	284	—	887	—	—	887
Issuance of common stock in connection with restricted stock units, net of tax	105	—	(367)	—	—	(367)
Other comprehensive loss	—	—	—	(8,373)	—	(8,373)
Net loss	—	—	—	—	(174,721)	(174,721)
Balance as of September 30, 2022	249,240	\$ 25	\$ 1,589,080	\$ (9,996)	\$ (759,083)	\$ 820,026

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

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

Three Months Ended September 30, 2021

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2021	—	\$ —	238,549	\$ 24	\$ 1,473,639	\$ 73	\$ (451,781)	\$ 1,021,955
Initial public offering costs	—	—	—	—	(39)	—	—	(39)
Issuance of common stock upon exercise of stock options	—	—	265	—	529	—	—	529
Stock-based compensation	—	—	975	—	13,042	—	—	13,042
Other comprehensive loss	—	—	—	—	—	(138)	—	(138)
Net loss	—	—	—	—	—	—	(48,875)	(48,875)
Balance as of September 30, 2021	—	\$ —	239,789	\$ 24	\$ 1,487,171	\$ (65)	\$ (500,656)	\$ 986,474

Nine Months Ended September 30, 2021

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	194,474	\$ 1,010,968	15,570	\$ 2	\$ 41,357	\$ 256	\$ (334,143)	\$ (292,528)
Proceeds from initial public offering, net of \$33,198 in issuance costs	—	—	25,000	2	391,800	—	—	391,802
Conversion of convertible preferred stock to common stock	(194,474)	(1,010,968)	194,474	20	1,010,948	—	—	1,010,968
Issuance of common stock upon exercise of stock options	—	—	776	—	2,043	—	—	2,043
Stock-based compensation	—	—	3,969	—	41,023	—	—	41,023
Other comprehensive loss	—	—	—	—	—	(321)	—	(321)
Net loss	—	—	—	—	—	—	(166,513)	(166,513)
Balance as of September 30, 2021	—	\$ —	239,789	\$ 24	\$ 1,487,171	\$ (65)	\$ (500,656)	\$ 986,474

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)

	Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (174,721)	\$ (166,513)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	63,561	41,023
Depreciation and amortization expense	12,979	9,059
Impairment of other investments	5,000	—
Change in fair value of success payment liabilities	2,177	19,343
Change in fair value of equity warrant	1,067	199
Non-cash lease expense	(1,104)	1,486
Net amortization and accretion on marketable securities	278	1,434
Loss on property and equipment disposals, net	97	536
Changes in operating assets and liabilities:		
Prepaid expenses, other current assets and other assets	(672)	(6,811)
Accounts payable	1,193	(8)
Accrued liabilities and other current liabilities	(5,836)	325
Deferred revenue	(36,299)	(7,697)
Operating lease liabilities, non-current	3,331	10,467
Other non-current liabilities	(339)	4,121
Net cash used in operating activities	(129,288)	(93,036)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(19,694)	(55,236)
Purchases of marketable securities	(346,647)	(539,541)
Sales and maturities of marketable securities	308,153	547,066
Net cash used in investing activities	(58,188)	(47,711)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of stock options	9,252	2,043
Proceeds from employee stock purchase plan	887	—
Taxes paid related to net share settlement of equity awards	(367)	—
Proceeds from initial public offering, net of issuance costs	—	391,802
Net cash provided by financing activities	9,772	393,845
Net (decrease) increase in cash, cash equivalents and restricted cash	(177,704)	253,098
Cash, cash equivalents and restricted cash at beginning of period	294,294	140,872
Cash, cash equivalents and restricted cash at end of period	\$ 116,590	\$ 393,970
Represented by:		
Cash and cash equivalents	\$ 116,311	\$ 393,504
Restricted cash	279	466
Total	\$ 116,590	\$ 393,970
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash received for amounts related to tenant improvement allowances	\$ 3,238	\$ 11,063
Cash paid for amounts included in the measurement of lease liabilities	\$ 8,136	\$ 5,658
Non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable and accrued liabilities	\$ 3,563	\$ 5,432
Remeasurement of operating lease right-of-use asset for lease modification	\$ 29	\$ 4,078
Conversion of convertible preferred stock to common stock upon closing of initial public offering	\$ —	\$ 1,010,968

The accompanying notes are an integral part of these 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 T-cell reprogramming company dedicated to the mastery of T cells to cure patients with solid tumors. The Company is building a multi-modality product pipeline. The Company’s primary activities since incorporation have been to develop T-cell therapies, perform research and development, enter into strategic collaboration and license arrangements, build manufacturing capabilities, enable manufacturing activities in support of its product candidate development efforts, acquire technology, organize and staff the Company, conduct business planning, establish its intellectual property portfolio, raise capital and provide general and administrative support for these activities.

Initial Public Offering

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

2. Basis of Presentation and Significant Accounting Policies

Basis of Presentation

The accompanying 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 are eliminated in consolidation. Certain prior period amounts in the condensed consolidated financial statements and accompanying notes have been reclassified to conform to the current period’s presentation.

The condensed consolidated balance sheet as of December 31, 2021 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, 2021.

Liquidity and Management’s Plan

The Company is currently working on a number of long-term 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 September 30, 2022 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 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, revenue recognition and accrued expenses. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

In June 2022, the Company recorded an adjustment to revenue related to a change in estimate in connection with the Collaboration and License Agreement, entered into in 2019 and amended in June 2020 and December 2021 (“GSK Agreement”) with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, “GSK”). The Company and GSK mutually agreed to conclude research activities on an undisclosed target for hematological cancers in June 2022. As a result, the Company decreased the related estimated project costs, which resulted in an increase in the measure of proportional cumulative performance. On October 24, 2022, GSK provided notice to the Company of its decision to terminate the GSK Agreement. The termination is effective on December 24, 2022.

This adjustment increased revenue by \$35.3 million, decreased net loss by \$35.3 million and resulted in a \$0.14 reduction in the Company’s basic and diluted net loss per common share for the nine months ended September 30, 2022.

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

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, 2021.

Recently Adopted Accounting Pronouncements

None.

3. License, Collaboration and Success Payment Agreements

Fred Hutch

License Agreement - In 2018, the Company entered into a license agreement with Fred Hutchinson Cancer Research Center (“Fred Hutch”) that grants the Company an exclusive, worldwide, sublicensable license under certain patent rights and a non-exclusive, worldwide, sublicensable license for certain technology, to research, develop, manufacture, improve and commercialize products and processes covered by such patent rights or incorporating such technology for all therapeutic uses for the treatment of human cancer.

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

Collaboration - 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 and the research is conducted in accordance with a research plan and budget approved by the parties. The Fred Hutch Collaboration Agreement has a six-year term. During 2021, one of the research plans on which the success payment service term is based was extended from January 31, 2022 to December 31, 2022. The Company incurred \$0.4 million and \$1.1 million in expense in connection with the Fred Hutch Collaboration Agreement for the three months ended September 30, 2022 and 2021, respectively, and \$1.4 million and \$3.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Success Payments - In 2018, the Company granted Fred Hutch rights to certain success payments, pursuant to the terms of the Fred Hutch Collaboration Agreement. The potential payments for the Fred Hutch success payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the estimated per share fair value of the Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, relative to its original \$1.83 per share issuance price. Upon the closing of the IPO, all shares of Series A convertible preferred stock then outstanding converted into an equal number of shares of common stock. 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	10x	20x	30x	40x	50x
Per share common stock price required for payment	\$ 18.29	\$ 36.58	\$ 54.86	\$ 73.15	\$ 91.44
Aggregate success payment(s) (in millions)	\$ 10	\$ 40	\$ 90	\$ 140	\$ 200

The success payments will be owed if the per share fair value of the Company's common stock on the contractually specified valuation measurement dates during the term of the success payment agreement equals or exceeds the above outlined multiples. The valuation measurement dates are triggered by the following events: the one-year anniversary of the Company's IPO and each two-year anniversary of the Company's IPO thereafter, the closing of a change in control transaction and the last day of the term of the success payment agreement, unless the term has ended due to the closing of a change of control transaction. As of September 30, 2022, 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 Fred Hutch as of September 30, 2022 and December 31, 2021 were \$7.7 million and \$8.5 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 Fred Hutch Collaboration Agreement. The success payment liability was \$7.2 million and \$6.4 million as of September 30, 2022 and December 31, 2021, respectively. With respect to the Fred Hutch Collaboration Agreement success payment obligations, the Company recognized expense of \$1.4 million and a decrease in success payment expense of \$(0.8) million for the three months ended September 30, 2022 and 2021, respectively, and success payment expense of \$0.8 million and \$14.1 million for the nine months ended September 30, 2022 and 2021, respectively.

Stanford

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

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

Collaboration Agreement - In October 2020, the Company entered into a research and collaboration agreement with Stanford ("Stanford Collaboration Agreement"), focused on research and development of cellular immunotherapy products. The Stanford Collaboration Agreement has a four-year term. The Company is committed to fund aggregate research performed by Stanford of \$12.0 million under the Stanford Collaboration Agreement, and the research will be conducted in accordance with a research plan and budget approved by the parties. The Company incurred \$0.8 million in expense in connection with the Stanford Collaboration Agreement for each of the three months ended September 30, 2022 and 2021, and \$2.3 million for each of the nine months ended September 30, 2022 and 2021.

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 10x to 50x based on a comparison of the estimated per share fair value of the Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, relative to its original \$1.83 per share issuance price. At the closing of the IPO, all shares of Series A convertible preferred stock then outstanding converted into an equal number of shares of common stock. 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	10x	20x	30x	40x	50x
Per share common stock price required for payment	\$ 18.29	\$ 36.58	\$ 54.86	\$ 73.15	\$ 91.44
Aggregate success payment(s) (in millions)	\$ 10	\$ 40	\$ 90	\$ 140	\$ 200

The success payments will be owed if the per share fair value of the Company's common stock on the contractually specified valuation measurement dates during the term of the success payment agreement equals or exceeds the above outlined multiples. The valuation measurement dates are triggered by the following events: the one-year anniversary of the Company's IPO and each two-year anniversary of the Company's IPO thereafter, the closing of a change in control transaction and the last day of the term of the success payment agreement, unless the term has ended due to the closing of a change of control transaction. As of September 30, 2022, 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 value of the success payments to Stanford as of September 30, 2022 and December 31, 2021 was \$8.9 million and \$9.9 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. The success payment liability was \$4.5 million and \$3.1 million as of September 30, 2022 and December 31, 2021, respectively. With respect to the Stanford Collaboration Agreement success payment obligations, the Company recognized expense of \$1.0 million for each of the three months ended September 30, 2022 and 2021, respectively, and \$1.4 million and \$5.2 million for the nine months ended September 30, 2022 and 2021, respectively.

GSK

In 2019, the Company entered into the GSK Agreement with GSK for potential T-cell therapies that apply the Company's platform technologies and cell therapy innovations with T-cell receptors ("TCRs") or chimeric antigen receptors ("CARs") under distinct collaboration programs. The GSK Agreement defined two initial collaboration targets and allows GSK to nominate seven additional targets through July 2024. The Company is expected to perform research and development services for each selected target up until a defined point (the "GSK Option Point"), at which time GSK will decide whether or not to exercise an option to obtain a license from the Company ("License Option") and take over the future development and commercialization. Selected targets may be developed as either a Proof of Concept ("PoC") Development Program or Component Development Program. For a PoC Development Program, the Company is expected to conduct both preclinical and clinical development for the target and present clinical trial data to GSK in connection with their evaluation of whether to exercise the License Option. For a Component Development Program, the Company is obligated to perform preclinical studies only. Along with the research activities, the Company appointed three representatives to the joint steering committee ("JSC") and is responsible for the manufacture of all compounds and products necessary for its research and development activities.

The Company received a non-refundable upfront payment of \$45.0 million under the GSK Agreement. In addition to the upfront payment, the Company is eligible to receive up to two one-time payments, totaling up to approximately \$200.0 million in aggregate for technology validation of the Company's cell therapy innovations. For each cell therapy target for which there has been a joint collaboration program, the Company is also entitled to receive up to approximately \$400.0 million in aggregate in development and sales milestones if the target is already within GSK's pipeline and meets certain criteria, up to approximately \$900.0 million in aggregate in development and sales milestones for all other targets, and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK's pipeline and meet certain criteria, or from high single digit to low teens for all other targets. Milestones are paid once per target, even if there is more than one of the Company's innovations applied to a T-cell therapy directed to that target. Any amounts received from GSK are generally non-refundable unless the Company terminates a collaboration target for safety or feasibility reasons and the funding received from GSK exceeds the costs incurred for the terminated target.

In connection with the GSK Agreement, in May 2019, the Company also entered into a Stock Purchase Agreement with GSK ("GSK Stock Purchase Agreement"), pursuant to which the Company agreed to sell 30,253,189 shares of Series AA convertible preferred stock at a price of \$6.78 per share, which was above the issuance date estimated

fair value of \$4.84 per share. The difference between the per share values resulted in \$58.6 million additional deemed consideration, bringing the total upfront payment of the GSK Agreement to \$103.6 million.

On October 24, 2022, GSK provided notice to the Company of its decision to terminate the GSK Agreement. The termination is effective on December 24, 2022. See Note 14, *Subsequent Events*, for additional details regarding termination of the GSK Agreement.

Research and Development Services

The GSK Agreement was deemed to be within the scope of Accounting Standards Codification (“ASC”) 606, *Revenue from Contracts with Customers*, because GSK engaged the Company to initially provide research and development services, which are outputs of its ongoing activities, in exchange for consideration.

The Company identified the following two distinct performance obligations: (i) research and development services related to the two initial collaboration targets, inclusive of the JSC participation and the manufacture of compounds necessary for providing the research and development services and (ii) a material right for GSK to nominate seven additional collaboration targets for which the Company will perform research and development services until the GSK Option Point.

To allocate revenue among the performance obligations, the Company determined standalone selling prices (“SSP”) of each obligation. For the research and development services, the SSP was calculated using a cost-plus margin approach. For the material right, SSP was calculated by reference to the underlying research and development services expected to be provided and the corresponding expected consideration. All amounts included in the transaction price are allocated to performance obligations proportionate to their SSPs.

As of December 31, 2020, the transaction price was deemed to be \$103.6 million, consisting of the upfront payment of \$45.0 million under the GSK Agreement and the \$58.6 million allocated from the GSK Stock Purchase Agreement. Other than the upfront payment and the amounts allocated from the GSK Stock Purchase Agreement, all other contingent consideration that may be earned under the GSK Agreement is subject to uncertainties including but not limited to additional target selections, research and investigational new drug enabling studies, initiation of clinical trials and other related achievements. Consequently, the transaction price currently does not include any such contingent consideration that, if included, could result in a probable significant reversal of cumulative revenue when related uncertainties become resolved. The Company re-evaluates the transaction price at each reporting period. If and when contingent consideration is included in the transaction price, it will be allocated to the two performance obligations proportionate to their SSPs and a cumulative catch up in revenue will be recorded for the portion of the services already completed. The remaining amounts will be deferred and recognized as the services are rendered.

The research and development services are transferred as the services are performed, with cost used as the measure of progress compared to the total estimated cost to complete. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. The determination of the percentage of completion requires the Company to estimate the costs to complete the project. The Company makes a detailed estimate of the costs to complete, which is reassessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate will be adjusted, and the revenue will be recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate would be recognized as an adjustment to revenue in the period in which the change in estimate occurs.

In June 2022, the Company recorded an adjustment to revenue related to a change in estimate in connection with the GSK Agreement due to GSK and the Company mutually agreeing to conclude research activities on an undisclosed target for hematological cancers. The change in estimate decreased the related estimated project costs, which resulted in an increase in the measure of proportional cumulative performance. This adjustment increased revenue by \$35.3 million, decreased net loss by \$35.3 million and resulted in a \$0.14 reduction in the Company’s basic and diluted net loss per common share for the nine months ended September 30, 2022.

The Company recognized revenue related to the research and development services related to the two initial targets of zero and \$2.6 million for the three months ended September 30, 2022 and 2021, respectively, and \$36.3 million and \$7.7 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022 and December 31, 2021, the Company had deferred revenue of \$48.4 million and \$84.7 million, respectively, related to this agreement. In light of the termination of the GSK Agreement, effective December 24, 2022, the Company expects all

research and development activities related to the collaboration thereunder to cease after such date. See Note 14, *Subsequent Events*, for additional details regarding termination of the GSK Agreement.

Exercise of the License Option

In April 2021, GSK exercised the License Option on LYL331 (NY-ESO-1 TCR with c-Jun), a Component Development Program, and agreed to assume sole responsibility for future development and commercialization of the program at its own cost and expense. The Company is entitled to the remaining development and sales milestones up to an aggregate of approximately \$400.0 million as well as the tiered royalties on future sales of all such products covered by the license granted pursuant to the License Option.

The exercise of the License Option was accounted for as a separate license contract for revenue recognition purposes. The Company identified one performance obligation, which was the license delivered to GSK upon the exercise of the License Option and transfer of information and data associated with the license. The Company concluded that the development milestone payments are solely dependent on GSK's performance and achievement of the specified events and are deemed to be not probable until such development milestones are achieved. Therefore, the remaining development milestones are fully constrained and excluded from the transaction price until the respective milestone is achieved. The Company also concluded that sales milestones and royalties relate predominantly to the license granted to GSK. Therefore, they also have been excluded from the transaction price and will be recognized when the related sales occur. At the end of each reporting period, the Company updates its assessment of whether an estimate of variable consideration is constrained and updates the estimated transaction price accordingly.

As of September 30, 2022, there were no contract assets or contract liabilities related to the license contract. None of the costs to obtain or fulfill the contract were capitalized. No license revenue was recognized for the three and nine months ended September 30, 2022 and 2021. As discussed above, the GSK Agreement will terminate in December 2022, in connection with which the Company's license to GSK also terminates. See Note 14, *Subsequent Events*, for additional details regarding termination of the GSK Agreement.

PACT

In June 2020, the Company entered into a commitment agreement ("PACT Commitment Agreement") with PACT Pharma, Inc. ("PACT") to jointly develop and test a next generation personalized anti-cancer T-cell therapy against solid tumors. The Company paid PACT an upfront non-refundable payment of \$50.0 million upon execution of the PACT Commitment Agreement. In November 2020, the parties agreed to suspend research and development activity under the PACT Commitment Agreement, and neither party would be required to conduct any further work under the development plan (including manufacturing development) nor incur any financial obligations (including milestone payments) that might otherwise arise, for as long as the parties continued to negotiate in good faith to resolve the issues that have arisen between them relating to the PACT Commitment Agreement.

In June 2020 in connection with the entry into the PACT Commitment Agreement, the Company also entered into a stock purchase agreement with PACT ("PACT SPA"), pursuant to which the Company purchased 17,806,901 shares of PACT Series C-1 convertible preferred stock at a purchase price of \$2.81 per share. As of the purchase date, the estimated fair value of the Series C-1 convertible preferred stock was \$2.05 per share, and the difference between the estimated fair value of the preferred stock as of the purchase date and the purchase price of \$13.6 million was deemed to be additional consideration for the PACT Commitment Agreement and recognized as research and development expense. As a result, the total upfront payment paid in connection with the PACT Commitment Agreement was \$63.6 million and was included in research and development expense. The remaining \$36.4 million associated with the PACT Series C-1 convertible preferred stock was recorded in other investments. In the fourth quarter of 2021, the Company fully impaired the remaining balance of \$36.4 million. See Note 5, *Other Investments*, for additional details regarding the PACT investment impairment.

In February 2021, the Company filed a demand for arbitration seeking, among other things, rescission of the PACT Commitment Agreement and the PACT SPA and recovery of the consideration paid thereunder. Arbitration hearings occurred in March and April 2022. In October 2022, the Company entered into a settlement agreement with PACT to resolve their outstanding legal dispute, which resulted in the Company obtaining ownership of approximately 80% of PACT's fully diluted shares. See Note 14, *Subsequent Events*, for additional details regarding the PACT settlement agreement.

4. Cash Equivalents and Marketable Securities

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

	September 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 42,608	\$ —	\$ —	\$ 42,608
U.S. Treasury securities	313,281	—	(6,972)	306,309
U.S. government agency securities	147,357	2	(1,716)	145,643
Corporate debt securities	235,749	1	(1,311)	234,439
Total cash equivalents and marketable securities	<u>\$ 738,995</u>	<u>\$ 3</u>	<u>\$ (9,999)</u>	<u>\$ 728,999</u>

Classified as:	Fair Value
Cash equivalents	\$ 94,659
Marketable securities	531,821
Marketable securities, non-current	102,519
Total cash equivalents and marketable securities	<u>\$ 728,999</u>

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	\$ 206,245	\$ —	\$ —	\$ 206,245
U.S. Treasury securities	290,909	2	(1,205)	289,706
U.S. government agency securities	93,864	2	(240)	93,626
Corporate debt securities	285,338	—	(182)	285,156
Total cash equivalents and marketable securities	<u>\$ 876,356</u>	<u>\$ 4</u>	<u>\$ (1,627)</u>	<u>\$ 874,733</u>

Classified as:	Fair Value
Cash equivalents	\$ 270,236
Marketable securities	320,966
Marketable securities, non-current	283,531
Total cash equivalents and marketable securities	<u>\$ 874,733</u>

The fair value of securities held by the Company in an unrealized continuous loss position for less than 12 months were \$507.3 million and \$602.9 million as of September 30, 2022 and December 31, 2021, respectively. The fair value of securities held by the Company in an unrealized continuous loss position for greater than 12 months were \$126.5 million and zero as of September 30, 2022 and December 31, 2021, respectively. As of September 30, 2022 and December 31, 2021, all of the Company's marketable securities had a maturity date of two years or less, were available for use and were classified as available-for-sale. 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 during the three and nine months ended September 30, 2022 and 2021. As such, an allowance for credit losses has not been recognized. Gross realized gains and losses were *de minimis* for the three and nine months ended September 30, 2022 and 2021 and as a result, amounts reclassified out of accumulated other comprehensive loss for the three and nine months ended September 30, 2022 and 2021 were also *de minimis*. See Note 6, *Fair Value Measurements*, for additional information regarding cash equivalents and marketable securities.

5. Other Investments

From time to time, the Company makes minority ownership strategic investments. As of September 30, 2022 and December 31, 2021, the aggregate carrying amounts of the Company's strategic investments in non-publicly traded

companies were \$42.0 million and \$47.0 million, respectively. These investments were measured at initial cost, minus impairment, if any, and plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer.

In connection with the preparation of the financial statements for the third quarter ended September 30, 2022, the Company performed a qualitative assessment of potential indicators of impairment and determined that indicators existed for one of the Company's other investments with a carrying amount of \$5.0 million. While there was no single event or factor, the Company considered the underlying company's operating cash flow requirements over the next year and liquid asset balances to fund those requirements and the underlying company's inability to raise funds as indicators of impairment. Due to these indicators, the Company assessed the valuation of the investment as of September 30, 2022 and determined the fair value to be negligible and the impairment to be other-than-temporary in nature. As a result, the Company recorded a \$5.0 million impairment expense for the investment for the third quarter ended September 30, 2022, which was recorded within impairment of other investments on the Condensed Consolidated Statement of Operations and Comprehensive Loss and as a reduction to the investment balance within other investments on the Condensed Consolidated Balance Sheet. There were no additional adjustments recorded to the carrying amount for other investments for the three and nine months ended September 30, 2022 and 2021.

In connection with the preparation of the financial statements for 2021, the Company performed a qualitative assessment of potential indicators of impairment and determined that indicators existed for its \$36.4 million investment in PACT Series C-1 convertible preferred stock. While there was no single event or factor, the Company considered PACT's operating cash flow requirements over the next year and liquid asset balances to fund those requirements and PACT's inability to raise funds as indicators of impairment. Due to these indicators, the Company assessed the valuation of the investment in PACT as of December 31, 2021 and determined the fair value to be negligible and the impairment to be other-than-temporary in nature. As a result, the Company recorded a \$36.4 million impairment expense for the PACT investment in the fourth quarter of 2021, which was recorded within impairment of other investments on the Consolidated Statement of Operations and Comprehensive Loss and as a reduction to the investment balance within other investments on the Consolidated Balance Sheet.

In November 2020, the Company made a strategic equity investment of \$13.0 million in Outpace Bio, Inc. ("Outpace"), a privately-held company, which represented a minority ownership interest at the time of the strategic investment. Outpace is engaged in the research and development of protein and cell technology platforms and has financed its activities via issuances of preferred stock. The Company determined that Outpace is a variable interest entity ("VIE") and the at-risk equity holders, as a group, lack the characteristics of a controlling financial interest. The Company does not have majority voting rights, representation on Outpace's board of directors or the power to direct the activities of this entity, and therefore it is not the primary beneficiary. As of both September 30, 2022 and December 31, 2021, the carrying value of the Company's investment in Outpace was \$13.0 million, which is recorded in other investments.

6. Fair Value Measurements

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

	September 30, 2022			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	\$ 42,608	\$ —	\$ —	\$ 42,608
U.S. Treasury securities	—	306,309	—	306,309
U.S. government agency securities	—	145,643	—	145,643
Corporate debt securities	—	234,439	—	234,439
Total financial assets	\$ 42,608	\$ 686,391	\$ —	\$ 728,999
Financial liabilities:				
Success payment liabilities	\$ —	\$ —	\$ 11,663	\$ 11,663
Total financial liabilities	\$ —	\$ —	\$ 11,663	\$ 11,663

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	\$ 206,245	\$ —	\$ —	\$ 206,245
U.S. Treasury securities	—	289,706	—	289,706
U.S. government agency securities	—	93,626	—	93,626
Corporate debt securities	—	285,156	—	285,156
Equity warrant investment	—	—	1,067	1,067
Total financial assets	\$ 206,245	\$ 668,488	\$ 1,067	\$ 875,800
Financial liabilities:				
Success payment liabilities	\$ —	\$ —	\$ 9,486	\$ 9,486
Total financial liabilities	\$ —	\$ —	\$ 9,486	\$ 9,486

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

The Level 3 financial instruments include an equity warrant investment and the success payment liabilities. For the quarter ended September 30, 2022, in conjunction with the impairment of one of the Company's other investments, the associated equity warrant investment's fair value was determined to be negligible. For the quarter ended September 30, 2022, the Company reduced the equity warrant investment's fair value from \$1.1 million to zero. See Note 5, *Other Investments*, for additional details regarding the impairment of the other investment. The Company's Level 3 financial instruments are valued using valuation models which include the Black-Scholes model for valuing the equity warrant investment and a Monte Carlo simulation for the success payment liabilities. To determine the estimated fair value of the success payment liabilities, the Company uses a Monte Carlo simulation methodology that models the future movement of stock prices based on several key variables combined with empirical knowledge of the process governing the behavior of the stock price. The following variables were incorporated in the estimated fair value of the success payment liabilities: fair value of the Company's common stock, expected volatility, the risk-free interest rate and the estimated number and timing of valuation measurement dates on the basis of which payments may be triggered. The computation of expected volatility was estimated based on available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption.

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

	September 30, 2022	December 31, 2021
Fair value of common stock	\$ 7.33	\$ 7.74
Risk-free interest rate	3.66% - 4.26%	0.19% - 1.88%
Expected volatility	80.0 %	75.0 %
Expected term (in years)	0.71 - 5.22	0.46 - 5.97

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

	September 30, 2022	December 31, 2021
Fair value of common stock	\$ 7.33	\$ 7.74
Risk-free interest rate	3.66% - 4.26%	0.19% - 1.88%
Expected volatility	80.0 %	75.0 %
Expected term (in years)	0.71 - 7.00	0.46 - 7.75

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

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

	Equity Warrant Investment	Success Payment Liabilities
Balance at December 31, 2021	\$ 1,067	\$ 9,486
Change in fair value ⁽¹⁾	(1,067)	2,177
Balance at September 30, 2022	\$ —	\$ 11,663

(1) The change in fair value associated with the equity warrant investment held is recorded in other (expense) income, net and the change in fair value associated with success payment liabilities is recorded in research and development expense.

7. Leases

The Company's lease portfolio is comprised of operating leases for laboratory, office and manufacturing facilities located in South San Francisco, California, 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, including expected lease incentives to be received, as of September 30, 2022 (in thousands):

Year Ending December 31:

2022 (remaining three months)	\$ 1,822
2023	11,018
2024	11,347
2025	11,859
2026	12,209
Thereafter	48,094
Total undiscounted lease payments	96,349
Less: imputed interest	(27,351)
Less: tenant improvement allowances	(1,523)
Total operating lease liabilities	\$ 67,475

Reported as of September 30, 2022:

Short-term portion of lease liabilities (included in accrued liabilities and other current liabilities)	\$ 2,839
Operating lease liabilities, non-current	64,636
Total	\$ 67,475

The operating lease costs for all operating leases were \$2.3 million and \$2.4 million for the three months ended September 30, 2022 and 2021, respectively, and \$7.0 million and \$7.1 million for the nine months ended September 30, 2022 and 2021, respectively. The operating lease costs and total commitments for short-term leases were *de minimis* for the three and nine months ended September 30, 2022 and 2021. Variable lease costs for operating leases were \$1.3 million and \$1.4 million for the three months ended September 30, 2022 and 2021, respectively, and \$3.8 million and \$3.7 million for the nine months ended September 30, 2022 and 2021, respectively. The weighted-average remaining lease terms for operating leases were 8.0 and 8.8 years as of September 30, 2022 and December 31, 2021, respectively. The weighted-average discount rates for operating leases were 8.5% and 8.4% as of September 30, 2022 and December 31, 2021, respectively.

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 and \$0.1 million for the three months ended September 30, 2022 and 2021, respectively, and \$0.6 million and \$0.1 million for the nine months ended September 30, 2022 and 2021, respectively.

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 13, *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 and \$0.2 million for the three months ended September 30, 2022 and 2021, respectively, and \$1.4 million and \$0.2 million for the nine months ended September 30, 2022 and 2021, respectively.

The Company’s sublease income is recognized within other operating income, net in the condensed consolidated statements of operations and comprehensive loss.

8. Convertible Preferred Stock

Upon the closing of the IPO, 194,474,431 shares of convertible preferred stock then outstanding converted into an equal number of shares of common stock. As of September 30, 2022 and December 31, 2021, no shares of convertible preferred stock were outstanding.

9. 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 September 30, 2022 and December 31, 2021, 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 September 30, 2022 and December 31, 2021, there were 249,239,833 shares and 242,738,350 shares of the Company’s common stock outstanding, respectively, excluding zero shares and 2,600,002 shares, respectively, of restricted stock awards (“RSAs”) outstanding that are subject to vesting requirements.

On August 4, 2022, the Company entered into an Equity Distribution Agreement with Goldman Sachs & Co. LLC (“Goldman Sachs”) and BofA Securities, Inc. (“BofA”), and together with Goldman Sachs, “the Agents”) with respect to an at-the-market offering program (the “Equity Distribution Agreement”). In accordance with the terms of the Equity Distribution Agreement, the Company may offer and sell from time to time through the Agents shares of the Company’s common stock having an aggregate offering amount of up to \$200.0 million (“the Placement Shares”). Sales of the Placement Shares, if any, will be made at prevailing market prices on Nasdaq at the time of sale, or as otherwise agreed with the Agents, by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415 of the Securities Act of 1933, as amended. The Company will pay commissions to the Agents of up to 3.0% of the gross proceeds of the sale of the Placement Shares sold under the Equity Distribution Agreement and reimburse the Agents for certain expenses. Neither the Company nor the Agents are obligated to sell any shares and, to date, the Company has not made any sales under the Equity Distribution Agreement.

10. 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, 2022, the Company reserved an additional 12,266,917 shares of common stock for issuance under the 2021 Plan representing 5% of

the total common shares outstanding as of December 31, 2021. On March 29, 2022, the Company filed with the Securities and Exchange Commission (“SEC”) a Form S-8 registering the additional shares. Under the 2021 Plan, the Company may grant incentive stock options, non-statutory stock options, RSAs, restricted stock units (“RSUs”), stock appreciation rights, performance awards and other stock-based awards. Terms of stock awards, including vesting requirements, are determined by the Company’s board of directors or by a committee authorized by the Company’s board of directors, subject to provisions of the 2021 Plan. The term of any stock option granted under the 2021 Plan cannot exceed ten years. Generally, awards granted by the Company vest over four years but may be granted with different vesting terms. In conjunction with adopting the 2021 Plan, the Company discontinued the 2018 Plan with respect to new equity awards.

As of September 30, 2022, 28,022,235 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, 2022, the Company reserved an additional 2,453,383 common shares for issuance under the 2021 ESPP representing 1% of the total common shares outstanding as of December 31, 2021. On March 29, 2022, the Company filed with the SEC a Form S-8 registering the additional shares. 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, no shares and 283,574 shares were issued during the three and nine months ended September 30, 2022, respectively, and none for the three and nine months ended September 30, 2021.

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 shall 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development	\$ 4,442	\$ 2,673	\$ 12,401	\$ 12,615
General and administrative	14,681	10,369	51,160	28,408
Total stock-based compensation expense	\$ 19,123	\$ 13,042	\$ 63,561	\$ 41,023

Stock-based compensation expense for the nine months ended September 30, 2021 includes the impact of an award accelerated in connection with the Company’s IPO resulting in stock-based compensation expense of \$2.6 million.

At September 30, 2022, total stock-based compensation cost related to unvested awards not yet recognized was \$114.9 million, which is expected to be recognized over a remaining weighted-average period of 2.48 years.

Restricted Stock Awards

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

	Number of Shares	Weighted-Average Value at Grant Date Per Share
Unvested shares as of December 31, 2021	2,600,002	\$ 0.0001
Vested	(2,600,002)	\$ 0.0001
Unvested shares as of September 30, 2022	<u>—</u>	<u>\$ —</u>

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, 2021	—	\$ —
RSUs granted	1,330,962	\$ 5.98
RSUs vested	(153,942)	\$ 5.98
RSUs forfeited or canceled	(187,766)	\$ 5.98
Unvested RSUs as of September 30, 2022	<u>989,254</u>	<u>\$ 5.98</u>

Stock Options

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

	Number of Stock Options	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding as of December 31, 2021	41,775,179	\$ 5.05	7.84	\$ 142,076
Granted	9,931,442	\$ 5.97		
Exercised	(3,512,765)	\$ 2.63		
Canceled or forfeited	(2,083,979)	\$ 6.07		
Options outstanding as of September 30, 2022	<u>46,109,877</u>	\$ 5.38	7.54	\$ 120,296
Options exercisable as of September 30, 2022	<u>26,446,733</u>	\$ 4.27	6.64	\$ 94,486

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

	Nine Months Ended September 30,	
	2022	2021
Risk-free interest rate	2.32 %	0.79 %
Expected volatility	85.6 %	78.7 %
Expected term (in years)	5.98	6.10
Expected dividend yield	0 %	0 %

The weighted-average grant date fair value of options granted for the nine months ended September 30, 2022 and 2021 were \$4.33 per share and \$6.55 per share, respectively.

11. Net Loss Per Share

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

Shares subject to options to purchase common stock, unvested RSAs and unvested RSUs were all excluded from consideration in the calculation of diluted net loss per share in all periods presented due to their anti-dilutive effects.

12. Commitments and Contingencies

Collaboration and License Agreements

The Company has entered into certain collaboration and license agreements, including those identified in Note 3, *License, Collaboration and Success Payment Agreements* above, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial milestones. The Company's obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events that could cause the discontinuance of the programs, including termination of such agreements. Due to the nature of these agreements, the future potential payments are inherently uncertain, and accordingly no amounts had been recorded for the potential future achievement of these targets as of September 30, 2022 and December 31, 2021.

13. Related-party Transactions

In September 2021, the Company entered into a sublease with Sonoma, 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, serves as a member of the board of directors of Sonoma, and he and certain holders of more than 5% of the Company's outstanding common stock are also stockholders of Sonoma. As a part of the sublease, a \$4.6 million tenant improvement contribution payment was made by Sonoma, which is recognized over the term of the sublease. As of September 30, 2022, there were accrued liabilities and other current liabilities of \$0.5 million and other non-current liabilities of \$3.6 million in connection with the sublease with Sonoma. Income of \$0.7 million and \$2.0 million, was recognized in other operating income, net for the three and nine months ended September 30, 2022, respectively, of which \$0.5 million and \$1.4 million was attributed to sublease income for the three and nine months ended September 30, 2022, respectively. See Note 7, *Leases*, for more detail on the Sonoma sublease.

The Company is party to the GSK Agreement, who is a holder of more than 10% of the Company's outstanding common stock. See Note 3, *License, Collaboration and Success Payment Agreements*. Deferred revenue of \$11.2 million and \$5.0 million as of September 30, 2022 and December 31, 2021, respectively, and deferred revenue, non-current of \$37.2 million and \$79.7 million as of September 30, 2022 and December 31, 2021, respectively, were in connection with the GSK Agreement. There was no revenue recognized in connection with the GSK agreement for the three months ended September 30, 2022. Revenue recognized in connection with the GSK agreement was \$2.6 million for the three months ended September 30, 2021, and was \$36.3 million and \$7.7 million for the nine months ended September 30, 2022 and 2021, respectively. As discussed above, in October 2022, GSK provided notice to the Company of its decision to terminate the GSK Agreement, effective December 24, 2022. See Note 14, *Subsequent Events*, for additional details regarding termination of the GSK Agreement.

14. Subsequent Events

On October 1, 2022, the Company entered into a settlement agreement with PACT, pursuant to which the parties agreed to resolve their outstanding legal dispute. In connection with the settlement agreement, the parties also entered into a stock purchase agreement, pursuant to which PACT issued shares of PACT's Series D convertible preferred stock to the Company in exchange for the Company's tender of its PACT Series C-1 convertible preferred stock and resolution of the arbitration. The issuance of PACT's Series D convertible preferred stock, which are non-voting, have limited conversion rights and carry no right to appoint directors, resulted in the Company's ownership increasing to approximately 80% of PACT's fully diluted shares outstanding. The settlement agreement also included the termination of the PACT Commitment Agreement to jointly develop a next generation anti-cancer T-cell therapy against solid tumors. The Company anticipates recording a legal settlement gain in the fourth quarter of 2022, subject to the valuation of the PACT Series D convertible preferred stock.

On October 24, 2022, GSK provided notice to the Company of its decision to terminate the GSK Agreement, effective December 24, 2022. The IND application for LYL132 was cleared in January 2022, though no patients have been treated, and the IND for LYL331 has not yet been submitted to the U.S. Food and Drug Administration. Lyell has discontinued any further work on these programs. The Company anticipates recognizing the outstanding deferred revenue balance of \$48.4 million as of September 30, 2022 in the fourth quarter of 2022.

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 T-cell reprogramming company dedicated to developing curative cell therapies for patients with solid tumors. We take a systematic, interrogative, cell biology-driven approach to overcome what we view as the two major barriers to successful Adoptive Cell Therapy (ACT) – T-cell exhaustion and lack of durable stemness – through the application of our proprietary *ex vivo* genetic and epigenetic reprogramming technologies. Our T-cell reprogramming technologies are designed to overcome loss of T-cell function attributable to an exhausted state, and to create populations of T cells with properties of durable stemness. T cells with properties of durable stemness have the ability to proliferate, persist and self-renew, as well as generate differentiated effector cell progenies to provide durable anti-tumor functionality.

Our technologies are designed to be applied in a target and modality agnostic manner to chimeric antigen receptor (CAR), tumor-infiltrating lymphocytes (TIL) and T-cell receptor (TCR) therapies to fundamentally improve the properties of T cells needed to eradicate solid tumors. We believe our autologous T-cell therapies will generate improved, durable clinical outcomes that are potentially curative for patients with solid tumors.

We are advancing a multi-modality product pipeline of promising living cell product candidates that incorporate our genetic and epigenetic reprogramming technologies and target solid tumor indications with high unmet need. Each of our programs provide opportunities to expand into additional indications beyond the patient populations we are initially targeting. Our lead product candidates are summarized in the table below:

Product Candidate/Modality	Target	Genetic Reprogramming		Epigenetic Reprogramming		Target Indications	Preclinical	Phase 1	Phase 2	Phase 3	Next milestone
		c-Jun	NR4A3	Epi-R™	Stim-R™						
LYL845 TIL	Polyclonal			✓		Melanoma CRC, NSCLC Other Solid Tumors					Initial data expected in 2024
LYL797 CAR T Cell	ROR-1	✓		✓		TNBC NSCLC Other Solid Tumors					Initial data expected in 1H 2024
LYL119 CAR T Cell	ROR-1	✓	✓	✓	✓	ROR1+ Solid Tumors					Submit IND in 1H 2024

Abbreviations: TIL, tumor infiltrating lymphocytes; CAR, chimeric antigen receptor; CRC, Colorectal Cancer; NSCLC, non-small cell lung cancer; TNBC, triple negative breast cancer

We were incorporated in June 2018. Our primary activities to date have included developing T-cell therapies, performing research and development, acquiring technology, entering into strategic collaboration and license agreements, building manufacturing capability, enabling and executing manufacturing activities in support of our product candidate development efforts, organizing and staffing the Company, business planning, establishing our intellectual property portfolio, preparing for and initiating clinical trials, raising capital and providing general and administrative support for these activities. We are early in our research and development efforts and just beginning clinical development of our product candidates. LYL797 and LYL845 are in Phase 1 clinical development, and LYL119 is in preclinical development. We do not have any products approved for sale.

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

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

Pipeline Programs and Operational Updates

Pipeline Programs

We are advancing three wholly-owned product candidates; two (LYL797 and LYL845) are in Phase 1 clinical development and an additional product candidate (LYL119) is in preclinical development.

LYL845 - TIL therapy designed to target multiple solid tumor indications, enhanced with Epi-R

LYL845 is an IV-administered autologous tumor infiltrating lymphocyte (TIL) product candidate enhanced with our Epi-R epigenetic reprogramming technology for patients with relapsed and/or refractory metastatic or locally advanced melanoma and select solid tumors. In preclinical studies, Epi-R maintains polyclonal populations of T cells that demonstrate properties of durable stemness and anti-tumor functionality. Durable stemness is the quality that enables T cells to self-renew, proliferate, persist and generate differentiated effector cell progeny.

TIL products are created by expanding T cells taken from the patient's own tumor. Previous clinical experiences suggest that the efficacy of adoptive transfer of *ex vivo* expanded TILs is largely driven by specific recognition of mutated tumor neoantigens specific to each patient. To date, broad efficacy of TIL therapies has been limited by variable and often poor product quality, lack of stemness or potential durability of expanded TILs and failure to maintain highly polyclonal and tumor-reactive TILs during production.

TIL products manufactured using our Epi-R reprogramming technology aim to overcome these challenges. Preclinical studies supporting the development of LYL845 suggest Epi-R technology improves TIL products by better preserving polyclonality and tumor-reactive clones, and maintaining properties of durable stemness, which leads to superior *ex vivo* cell expansion and product qualities.

We are initially developing LYL845 for patients with relapsed and/or refractory metastatic or locally advanced melanoma, non-small cell lung cancer (NSCLC) and colorectal cancer (CRC). Based on positive data in these initial indications, we intend to expand into additional tumor types.

- In October 2022, we announced that the U.S. Food and Drug Administration (FDA) cleared our Investigational New Drug (IND) application to initiate a Phase 1 clinical trial for LYL845.
- This Phase 1 clinical trial is designed to be an open-label, dose-escalation trial that initially enrolls patients with relapsed and/or refractory metastatic or locally advanced melanoma, with expansion cohorts planned for patients with melanoma, NSCLC and CRC. Initial data is expected in 2024.
- In November 2022, we have two presentations of preclinical data from LYL845 at the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC). The first highlights preclinical data demonstrating that Epi-R technology produces a polyclonal TIL product (LYL845) with a greater expansion success rate across hot and cold tumors, improved product phenotype and maintenance of TCR diversity. The second highlights preclinical data demonstrating that Epi-R technology produces a polyclonal TIL product (LYL845) with diverse tumor-reactive clones that have stem-like qualities and anti-tumor function.

LYL797 - CAR T-cell therapy targeting ROR1⁺ solid tumors, enhanced with genetic and epigenetic reprogramming technologies

We are applying our genetic reprogramming technology that overexpresses c-Jun and our epigenetic reprogramming protocol Epi-R, to our CAR T-cell product candidate, LYL797. LYL797 is an IV-administered CAR T-cell product candidate targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1), previously identified to differentially express in several cancer cell types. LYL797 contains a CAR with a 4-1BB/CD3z co-stimulatory domain, an optimized spacer 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 is enhanced with the overexpression of c-Jun and includes a proprietary optimized version of human EGFR (EGFR_{opt}) used for tagging the CAR T cells. LYL797 is manufactured utilizing our proprietary Epi-R technology.

We are initially developing LYL797 for the treatment of ROR1⁺ triple-negative breast cancer (TNBC) and NSCLC. Significant subsets of common cancers express ROR1, including TNBC (~60%) and NSCLC (~40%), and ROR1 expression is associated with poor prognosis. If successful, we anticipate expanding into other ROR1⁺ cancers, including potentially hormone receptor-positive breast cancer, ovarian and other solid tumors.

- The Phase 1 trial is designed to be an open-label dose-escalation and expansion trial that enrolls patients with relapsed/refractory TNBC or NSCLC who have failed at least two lines of therapy.
- Patient screening in the Phase 1 trial of LYL797 was initiated in late March; however, clinical site activation was initially slower than anticipated. We have undertaken several measures to accelerate administrative site activation activities and have also increased the number of sites that will participate in the trial. As a result, although site activations are now progressing well, enrollment has been slower than anticipated.
- Despite the accelerated pace of site activations, in order to present a meaningful dataset in terms of both the number of patients and duration of response to therapy, the timing of presentation of initial data is now expected to occur in the first half of 2024.
- In September 2022, we presented the first-in-human Phase 1 trial design for LYL797 at the European Society for Medical Oncology (ESMO) Congress 2022.

LYL119 - Second generation CAR T-cell therapy targeting ROR1⁺ solid tumors, further enhanced with additional genetic and epigenetic reprogramming technologies

We are applying new, stackable reprogramming technologies to LYL119, our second-generation investigational ROR1-targeting CAR T-cell product candidate. LYL119 is expected to be an IV-administered CAR T-cell product targeting receptor tyrosine kinase-like orphan receptor 1 (ROR1).

Preclinical data suggest that reducing NR4A3 expression in combination with c-Jun overexpression further limits T-cell exhaustion and provides durable ROR1 CAR T-cell functional activity compared to either strategy alone, which may further improve cellular immunotherapy against ROR1-expressing solid tumors. The combination of these two genetic reprogramming technologies is being incorporated in LYL119.

For LYL119, we also plan to incorporate our new stackable epigenetic reprogramming technology, Stim-R™. Stim-R optimizes signaling parameters during T-cell activation to generate more potent CAR T cells and can be combined with our Epi-R manufacturing protocol.

- In November 2022, we have two presentations at SITC describing these new reprogramming technologies: The first highlights preclinical data describing the effects of c-Jun overexpression in combination with NR4A3 gene knockout to enhance the functional activity of ROR1 CAR T cells. The second highlights preclinical data demonstrating that CAR T-cell products produced with Stim-R have improved polyfunctionality, persistence and anti-tumor activity and show reduced exhaustion, following repeated antigen stimulation *in vitro*.
- We expect to submit an IND for LYL119 in the first half of 2024.

Rejuvenation, the next innovation in T-cell reprogramming

We are working to advance another proprietary T-cell reprogramming technology that focuses on rejuvenation of antitumor T cells. While we believe that the epigenetic reprogramming of T cells to create cell populations with durable stemness holds great potential, new scientific developments are emerging that provide insight into additional opportunities to capture the potential of T-cell products enhanced with the required properties to cure cancer. There are two key cellular parameters as cells develop and differentiate over the life of an organism: cellular identity and age. Aging of adult stem cells is thought to play a central role in determining the effect of aging on organismal function. We and others have documented the impact of aging on T-cell function, which begins to decline after puberty, and at an increasingly

accelerated rate after age 65. Each T-cell clonotype can be renewed from a stem cell-like state, but self-renewal, proliferation, function, persistence and antitumor activity are thought to be impacted by aging. We are developing a rejuvenation method that maintains T-cell identity while reducing the epigenetic age of the cells.

Our Manufacturing Capabilities

We believe it is critically important to own, control and continuously monitor all aspects of the cell therapy manufacturing process in order to mitigate risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. We made a strategic decision to invest in building our own manufacturing facility to control our supply chain, maximize efficiencies in cell product production time, cost and quality, and have the ability to rapidly incorporate disruptive advancements and new innovations. Controlling manufacturing also enables us to protect proprietary aspects of our genetic and epigenetic reprogramming technologies. We view our manufacturing team and capabilities as a significant competitive advantage. Our manufacturing facility, LyFE™, is commissioned and qualified in compliance with the FDA's Current Good Manufacturing Practices (cGMP) and is designed to produce cell products at scale for our current and planned clinical trials across all of our programs.

COVID-19 Update

The global COVID-19 pandemic and its effects continue to evolve, and we continue to monitor it closely. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain and will continue to depend on certain developments, including the duration and spread of the outbreak, other next-level effects and the impact on our CROs, contract manufacturing organizations, clinical sites and other third parties with whom we do business, as well as the impact on regulatory authorities and our key scientific and management personnel.

There can be no assurance that we will be able to avoid materially adverse impacts from the effects of the COVID-19 pandemic. The effects of the COVID-19 pandemic may continue to negatively impact healthcare and hospital resources, including both front-line and administrative staff, which may delay enrollment in our current and planned clinical trials. Some patients may not be able to comply with clinical trial protocols due to potential quarantines, lack of healthcare support or potential interruptions of healthcare services, and we may be unable to obtain blood samples for testing. For example, limitations or modifications in surgery scheduling for oncology patients at collaborating institutions has limited and may continue to limit supply of patient tumor samples that we use in our research.

We have closely monitored the COVID-19 pandemic and have strived to follow recommended containment and mitigation measures, including the guidance from the Centers for Disease Control and Prevention (CDC) as well as the states of California and Washington and applicable counties. We implemented preventative measures at our facilities designed to minimize the risk of employee exposure to the virus, including the requirement that each employee or contractor who entered a facility be vaccinated. In addition, we encourage all individuals on-site to follow social distancing, frequent hand washing and masking recommendations. We continue to implement increased cleaning of high touch areas, provide hand sanitizing stations and provide for limited on-site contact tracing, if needed. We expect to continue such measures for the near foreseeable future, though employees have been returning to our facilities with mitigations in place to maintain a safe work environment. We will continue to actively monitor the situation related to the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

License, Collaboration and Success Payment Agreements

For a detailed description of our license, collaboration and success payment agreements, 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.

Components of Results of Operations

Revenue

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

To date, we have generated revenue primarily from the recognition of a portion of the upfront payment under the Collaboration and License Agreement, entered into in 2019 and amended in June 2020 and December 2021 (GSK Agreement) with GSK. GSK provided notice to the Company in October 2022 to terminate the GSK Agreement, effective in December 2022, and we do not expect further revenue from the collaboration thereunder after the termination is effective. See Note 14, *Subsequent Events*, 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 termination of the GSK Agreement.

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

Operating Expenses

Research and Development

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

Research and development expenses also include non-cash expenses related to the change in the estimated fair value of the liabilities associated with our success payments granted to Fred Hutchinson Cancer Research Center (Fred Hutch) and The Board of Trustees of the Leland Stanford Junior University (Stanford). 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 preclinical studies, commencing planned clinical trials, conducting and completing current and planned clinical trials, seeking regulatory approval of our product candidates, identifying new product candidates and incurring costs to acquire and license technology platforms. A change in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. Because we are early in our research and development efforts and just beginning clinical development of our product candidates, and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the preclinical development, clinical development and commercialization of product candidates or whether, or when, we may achieve profitability.

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

- the number and scope of preclinical and IND-enabling studies;
- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the cost and timing of manufacturing our product candidates;
- the phase of development of our product candidates;
- the efficacy and safety profile of our product candidates;

- the extent to which we establish additional collaboration or license agreements; and
- whether we choose to partner any of our product candidates and the terms of such partnership.

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

General and Administrative

General and administrative costs include personnel-related expenses, including stock-based compensation expense for personnel in executive, legal, finance and other administrative functions, 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 due to the increased costs of operating as a public company such as costs related to accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs.

Other Operating Income, Net

Other operating income, net, consists primarily of 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 changes in the fair value of an equity warrant investment held.

Impairment of Other Investments

Consists of a reduction in the value of certain other investments.

Results of Operations

Three and Nine Months Ended September 30, 2022 and 2021

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

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
Revenue	\$ 3	\$ 2,755	\$ (2,752)	\$ 36,297	\$ 7,828	\$ 28,469
Operating expenses:						
Research and development	41,607	31,433	10,174	121,156	119,408	1,748
General and administrative	26,084	21,241	4,843	90,959	57,184	33,775
Other operating income, net	(1,251)	(758)	(493)	(3,544)	(1,526)	(2,018)
Total operating expenses	66,440	51,916	14,524	208,571	175,066	33,505
Loss from operations	(66,437)	(49,161)	(17,276)	(172,274)	(167,238)	(5,036)
Interest income, net	2,251	270	1,981	3,600	842	2,758
Other (expense) income, net	(1,068)	16	(1,084)	(1,047)	(117)	(930)
Impairment of other investments	(5,000)	—	(5,000)	(5,000)	—	(5,000)
Total other (loss) income, net	(3,817)	286	(4,103)	(2,447)	725	(3,172)
Net loss	\$ (70,254)	\$ (48,875)	\$ (21,379)	\$ (174,721)	\$ (166,513)	\$ (8,208)

Revenue

Revenue was approximately zero and \$2.8 million for the three months ended September 30, 2022 and 2021, respectively. No additional research and development pursuant to the GSK Agreement was performed in the third quarter of 2022, which drove a decrease in revenue of \$2.8 million.

Revenue was \$36.3 million and \$7.8 million for the nine months ended September 30, 2022 and 2021, respectively, primarily related to the recognized portion of the upfront license fee pursuant to the GSK Agreement. The increase of \$28.5 million was primarily related to a \$35.3 million revenue adjustment due to a change in estimate in connection with the GSK Agreement due to a mutual agreement with GSK to conclude research activities on an undisclosed target for hematological cancers, offset by a decrease of \$6.8 million due primarily to fewer research and development activities under the GSK Agreement for the nine months ended September 30, 2022. The change in estimate decreased the related estimated project costs, which resulted in an increase in the measure of proportional cumulative performance. On October 24, 2022, GSK provided notice to the Company of its decision to terminate the GSK Agreement. The termination is effective on December 24, 2022 and we will not receive any future payments pursuant to the GSK Agreement. See Note 3, *License, Collaboration and Success Payment Agreements – GSK*, and Note 14, *Subsequent Events*, 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 about the termination of the GSK Agreement.

Research and Development Expenses

Research and development expenses were \$41.6 million and \$31.4 million for the three months ended September 30, 2022 and 2021, respectively. The increase of \$10.2 million was primarily due to an increase of \$3.0 million in personnel-related expenses primarily related to an increase in headcount; an increase of \$2.9 million in facilities and technology costs, primarily related to increased infrastructure to support our expansion in research and development, manufacturing capabilities and associated headcount growth; an increase of \$2.3 million in expense associated with our success payment liabilities to Fred Hutch and Stanford, primarily driven by the increase in the per share fair value of our common stock; and an increase of \$1.9 million in collaboration, research activities and outside services primarily driven by an increase in research and laboratory costs, partially offset by a reduction in collaboration and license fees.

Research and development expenses were \$121.2 million and \$119.4 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of \$1.7 million was primarily due to an increase of \$11.6 million in facilities and technology costs, primarily related to increased infrastructure to support our expansion in research and development, manufacturing capabilities and associated headcount growth; an increase of \$4.4 million in personnel-related expenses, that was primarily related to an increase in headcount to expand our research, development and manufacturing capabilities; and an increase of \$2.9 million in collaboration, research activities and outside services primarily driven by increases in research and laboratory costs and professional services offset by a reduction in collaboration and license fees; partially offset by a decrease of \$17.2 million in expense associated with our success payment liabilities to Fred Hutch and Stanford, primarily driven by the decrease in the per share fair value of our common stock.

General and Administrative Expenses

General and administrative expenses were \$26.1 million and \$21.2 million for the three months ended September 30, 2022 and 2021, respectively. The increase of \$4.8 million was primarily due to an increase of \$4.3 million in stock-based compensation expense, primarily related to new awards granted and the impact of awards modified in the prior periods. Additionally, corporate expenses increased by \$0.4 million due to costs associated with operating as a public company.

General and administrative expenses were \$91.0 million and \$57.2 million for the nine months ended September 30, 2022 and 2021, respectively. The increase of \$33.8 million was primarily due to an increase of \$22.8 million in stock-based compensation expense, primarily related to award modifications and new awards granted. Additionally, outside services increased by \$7.3 million, primarily due to certain arbitration costs, and corporate expenses increased by \$3.6 million due to costs associated with operating as a public company.

Other Operating Income, Net

Other operating income, net was \$1.3 million and \$0.8 million for the three months ended September 30, 2022 and 2021, respectively, and \$3.5 million and \$1.5 million for the nine months ended September 30, 2022 and 2021, respectively. The increases of \$0.5 million and \$2.0 million were due primarily to sublease income and operating fees related to our subleases.

Interest Income, Net

Interest income was \$2.3 million and \$0.3 million for the three months ended September 30, 2022 and 2021, respectively, and \$3.6 million and \$0.8 million for the nine months ended September 30, 2022 and 2021, respectively. The increases in interest income, net were primarily driven by higher interest rates in 2022.

Other (Expense) Income, Net

Other (expense) income, net was \$(1.1) million and approximately zero for the three months ended September 30, 2022 and 2021, respectively, and \$(1.0) million and \$(0.1) million for the nine months ended September 30, 2022 and 2021, respectively. The decrease in other (expense) income, net was due primarily to the decrease in fair value of the equity warrant investment held by the Company.

Impairment of Other Investments

For the three and nine months ended September 30, 2022, the \$5.0 million impairment consisted of the full impairment of one of our other investments. See Note 5, *Other Investments*, in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through the sale and issuance of convertible preferred stock, the sale of common stock in connection with our initial public offering (IPO) and business development activities. As of September 30, 2022, we had \$750.7 million in cash, cash equivalents and marketable securities. Since our inception, we have incurred significant operating losses. We have not yet commercialized any product candidates, and we do not expect to generate revenue from sales of any product candidates for a number of years, if ever. We had an accumulated deficit of \$759.1 million as of September 30, 2022. From June 29, 2018 (inception) through September 30, 2022, we raised an aggregate of \$1,405.7 million in gross proceeds from the sales of our convertible preferred stock.

On August 4, 2022, we entered into an Equity Distribution Agreement (the Equity Distribution Agreement) with Goldman Sachs & Co. LLC (Goldman Sachs) and BofA Securities, Inc. (BofA, and together with Goldman Sachs, the Agents) with respect to an at-the-market offering program. In accordance with the terms of the Equity Distribution Agreement, we may offer and sell from time to time through the Agents shares of our common stock having an aggregate offering amount of up to \$200.0 million (the Placement Shares). Sales of the Placement Shares, if any, will be made at prevailing market prices on Nasdaq at the time of sale, or as otherwise agreed with the Agents, by any method permitted by law deemed to be an “at-the-market offering” as defined in Rule 415 of the Securities Act of 1933, as amended. We will pay commissions to the Agents of up to 3.0% of the gross proceeds of the sale of the Placement Shares sold under the Equity Distribution Agreement and reimburse the Agents for certain expenses. Neither the Company nor the Agents are obligated to sell any shares and to date, we have not made any sales under the Equity Distribution 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 preclinical studies and clinical trials, developing new product candidates, establishing internal manufacturing capabilities and funding our operations generally. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our working capital and capital expenditure needs into 2026. 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 Equity Distribution 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, preclinical development and clinical trials for our current and future product candidates;
- the number of clinical trials required for regulatory approval of our current and future product candidates;
- the costs, timing and outcome of regulatory review of any of our current and future product candidates;

- the cost of manufacturing clinical and commercial supplies of our current and future product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- further investment to build additional manufacturing facilities or expand the capacity of our existing ones;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to maintain existing, and establish new, collaborations, licenses, product acquisitions or other strategic transactions and the fulfillment of our financial obligations under any such agreements, including the timing and amount of any success payment, future contingent, milestone, royalty or other payments due under any such agreement;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- addressing any potential interruptions or delays resulting from factors related to the COVID-19 pandemic;
- addressing or responding to any potential disputes or litigation; and
- the extent to which we acquire or invest in businesses, products and technology platforms.

Until such time as we complete preclinical and clinical development and receive regulatory approval of our product candidates and can generate significant revenue from product sales, if ever, we expect to finance our operations from the sale of additional equity or debt financings, or other capital which come in the form of strategic collaborations, licensing, or other arrangements. In the event that additional capital is required, we may not be able to raise it on terms acceptable to us, or at all. If we raise additional funds through the issuance of equity or convertible debt securities, including pursuant to the Equity Distribution 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 would restrict our operations. If we raise funds through strategic collaboration, licensing, or other arrangements, we may relinquish significant rights or grant licenses on terms that are not favorable to us. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic, actual or perceived changes in interest rates and economic inflation, and otherwise. If we are unable to raise additional capital when desired, our business, results of operations and financial condition would be adversely affected.

Material Cash Requirements

We continually evaluate our liquidity and capital resources to ensure that we can adequately and efficiently finance our operations. As of September 30, 2022, our material cash requirements consisted primarily of paying salaries and benefits, administering clinical trials, providing the technology and facilities necessary to support our operations, operating lease obligations, potential success payments to Fred Hutch and Stanford 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):

	Nine Months Ended September 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	\$ (129,288)	\$ (93,036)
Investing activities	(58,188)	(47,711)
Financing activities	9,772	393,845
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>\$ (177,704)</u>	<u>\$ 253,098</u>

Operating Activities

During the nine months ended September 30, 2022, net cash used in operating activities was \$129.3 million, primarily reflecting our net loss of \$174.7 million, a decrease of \$38.6 million in net operating assets and liabilities primarily driven by a \$36.3 million decrease in deferred revenue due to non-cash revenue recognized and a \$5.8 million decrease in accrued liabilities and other current liabilities, offset by a \$3.3 million increase in operating lease liabilities. These decreases were partially offset by \$84.1 million of non-cash expenses primarily related to stock-based compensation of \$63.6 million, depreciation and amortization of \$13.0 million and impairment of other investments of \$5.0 million.

During the nine months ended September 30, 2021, net cash used in operating activities was \$93.0 million, primarily reflecting our net loss of \$166.5 million, an increase of \$0.4 million in net operating assets primarily driven by a \$7.7 million decrease in deferred revenue due to non-cash revenue recognized, partially offset by a \$4.1 million increase in other non-current liabilities related to deferred lease income for the nine months ended September 30, 2021. These decreases were partially offset by \$73.1 million of non-cash expenses, primarily related to stock-based compensation of \$41.0 million, \$19.3 million for revaluation of our success payment liabilities to Fred Hutch and Stanford, depreciation and amortization of \$9.1 million and \$1.5 million of non-cash lease expense.

Investing Activities

During the nine months ended September 30, 2022, cash used in investing activities was \$58.2 million, consisting of net maturities, sales and purchases of marketable securities of \$38.5 million and purchases of property and equipment of \$19.7 million. During the nine months ended September 30, 2021, cash used in investing activities was \$47.7 million, consisting of purchases of property and equipment of \$55.2 million partially offset by net maturities, sales and purchases of marketable securities of \$7.5 million.

Financing Activities

During the nine months ended September 30, 2022, cash provided by financing activities was \$9.8 million, consisting of proceeds from the exercise of stock options of \$9.3 million and proceeds from the employee stock purchase plan of \$0.9 million, partially offset by \$0.4 million in taxes paid related to the net share settlement of equity awards. During the nine months ended September 30, 2021 cash provided by financing activities was \$393.8 million, consisting of \$391.8 million in net proceeds from the sale of our common stock in our IPO and proceeds from the exercise of stock options of \$2.0 million.

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

We are an “emerging growth company,” as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statement, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have elected to use the

extended transition period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. We will be a “large accelerated filer” as of December 31, 2022 and as a result, we will no longer be an emerging growth company as of that date.

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.

Except for the change in estimates related to the GSK Agreement as described in this Quarterly Report on Form 10-Q, Part I, Item 1, Note 2, *Basis of Presentation and Significant Accounting Policies – Use of Estimates*, 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, 2021.

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 \$94.7 million as of September 30, 2022, which consisted of money market funds and highly liquid investments purchased with original maturities of three months or less from the purchase date. We also had marketable securities of \$634.3 million as of September 30, 2022. The primary objective of our investment activities is to preserve capital to fund our operations. Because our marketable securities are primarily short-term in duration, we believe that our exposure to interest rate risk is not significant, and a hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material effect on our 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 September 30, 2022.

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 condensed consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We believe a hypothetical 1% change in exchange rates during any of the periods presented would not have a material effect on our 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 September 30, 2022, 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 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 September 30, 2022, 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 September 30, 2022 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. For example, although not material to our operations, in February 2021 we filed a demand for arbitration to, among other things, seek rescission of the agreements we entered into with PACT in June 2020 and recover the consideration paid to PACT thereunder. Arbitration hearings occurred in March and April 2022. In October 2022, we entered into a settlement agreement with PACT to resolve the outstanding legal dispute, in connection with which we also entered into a stock purchase agreement for the issuance of PACT's Series D convertible preferred stock in exchange for the tender of previously acquired PACT Series C-1 convertible preferred stock and resolution of the arbitration. The acquisition of PACT's Series D convertible preferred stock resulted in our ownership increasing to approximately 80% of PACT's fully diluted shares outstanding. See Note 14, *Subsequent Events*, 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 PACT settlement.

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

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

Item 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.

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 will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We are early in our research and development efforts and just beginning clinical development of our product candidates. Besides LYL797 and LYL845, which are in Phase 1 clinical development, all of our other proprietary product candidates are currently in preclinical development. We also do not have any products approved for sale. If we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be harmed.
- Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.

- Our cellular therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.
- The results of research, preclinical studies or earlier clinical trials are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- Clinical development involves a lengthy and expensive process with an uncertain outcome.
- We 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 intend to manufacture at least a portion of our product candidates ourselves. Delays in receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our ability to generate product revenues.
- The manufacturing of cellular therapies is very complex. We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates.
- We have in the past, and we may in the future, form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- Our business could continue to be adversely affected by the effects of health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations.
- 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.

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 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. As of September 30, 2022, we had an accumulated deficit of \$759.1 million.

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

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

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

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

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

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

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

- successfully complete our research activities to identify the technologies and product candidates to further investigate in clinical trials;
- successfully complete development activities, including the necessary clinical trials;
- complete and submit regulatory submissions to the 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 preclinical 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 preclinical studies and clinical trials and potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. We will also need to make significant expenditures to develop a commercial organization capable of sales, marketing and distribution for any products, if any, that we intend to sell ourselves in the markets in which we choose to commercialize. In addition, we may be required to make substantial payments related to our success payment agreements and other contingent consideration payments under our license and collaboration agreements. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the discovery, development and commercialization of our potential product candidates, and other unanticipated costs may arise.

As of September 30, 2022, we had approximately \$750.7 million in cash, cash equivalents and marketable securities. Certain clinical trial expenses projected for 2022 are now expected to be incurred in 2023. 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 2026. 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 potential worsening 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 resulting from the COVID-19 pandemic, actual or perceived changes in interest rates and economic inflation and the current or anticipated impact of geopolitical instability. If adequate funds are not available to us on a timely basis, including pursuant to the Equity Distribution Agreement, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

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

We agreed to make success payments payable in cash or publicly-tradeable shares of our common stock at our discretion pursuant to our success payment agreements with Fred 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 consolidated balance sheets. Under GAAP, we are required to estimate the fair value of these liabilities as of each quarter end and changes in the estimated fair value are accreted to research and development expense over the service period of the collaboration agreement. Factors that may lead to increases or decreases in the estimated fair value of this liability include, among others, changes in the value of the common stock, changes in volatility and changes in the risk-free rate. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP consolidated financial statements. See Note 3, *License, Collaboration and Success Payment Agreements*, in the accompanying notes to the unaudited condensed consolidated financial statement 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 development efforts and just beginning clinical development of our product candidates. If we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be harmed.

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

- timely and successful completion of our preclinical 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 build a pipeline of product candidates.

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. We are not aware of any FDA approved therapeutics utilizing similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our technology platforms are both preliminary and limited. Additionally, although LYL797 and LYL845 are in Phase 1 clinical development, we have not tested any of our product candidates in humans yet, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans or may not accurately predict the safety and efficacy of our product candidates in humans. As a result, we are exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates.

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

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, manufacturing, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors and our inability to find suitable replacements could result in

delays in product development and harm our business. We conduct substantially all of our operations at our facilities in the San Francisco, Seattle and Bothell metropolitan areas. These regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity that vests over time. The value to employees of equity incentives that vest over time may be significantly affected by factors beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

Any 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 the PACT Commitment Agreement and the PACT SPA and recovery of the consideration paid thereunder. In October 2022, we entered into a settlement agreement with PACT to resolve the outstanding legal dispute. See Note 14, *Subsequent Events*, for additional details regarding the outcome of our arbitration with PACT. 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.

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

Our business could continue to be adversely affected by health epidemics, including the COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of potential clinical trial sites or other business operations. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting employees, patients, communities and business operations, as well as the United States and international economy and financial markets. In this regard, the COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business-related activities have occurred, supply chains have been disrupted and manufacturing and clinical development activities have been impacted.

Remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the COVID-19 pandemic could materially and adversely affect our operations. Following guidance from federal, state and local authorities, we had previously implemented policies that restrict the number and nature of employees who can be on site, and versions of such policies may continue for an indefinite period. We have also implemented preventative measures at our facilities, including requiring that each employee or contractor who enters a facility be vaccinated. In addition, we encourage all individuals on-site to follow social distancing, frequent hand washing and masking recommendations. In connection with these and potential future measures, we may be subject to claims based upon, arising out of or related to the COVID-19 pandemic and our actions and responses thereto, including any determinations that we have made and may make in the future with respect to our on-site operations. Further, current and future government restrictions as well as our remote work policies may materially and adversely impact productivity, disrupt our business and delay our preclinical studies and clinical trial plans, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. We continue to evaluate the impact that the COVID-19 pandemic may have on our ability to effectively conduct our business operations as planned. However, there can be no assurance that we will be able to avoid materially adverse impacts from the evolving effects of the COVID-19 pandemic. The COVID-19 pandemic may continue to negatively impact healthcare and hospital resources, including both front-line and administrative staff, which may delay enrollment in our current and planned clinical trials. Some patients may not be able to comply with clinical trial protocols due to potential quarantines, lack of healthcare support or potential interruptions of healthcare services, and we may be unable to obtain blood samples for testing. For example, limitations or modifications in surgery scheduling for oncology patients at collaborating institutions has limited and may continue to limit supply of patient tumor samples that we use in our research.

The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain and will depend on future developments that cannot be predicted at this time. Such developments include the continued spread of the Omicron variants and subvariants in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants that may prove especially contagious or virulent, the ultimate duration of the pandemic and the resulting impact on our clinical trial plans, CROs, contract manufacturing organizations and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel, and the effectiveness of actions taken globally to contain and treat the disease, including the rate at which vaccinations or boosters are made available, the percentage of the population that becomes vaccinated or boosted and the effectiveness of the vaccines or boosters against Omicron, its subvariants or other SARS-CoV-2 variants. We do not yet know the full extent of potential delays or impacts on our business, our planned preclinical studies or clinical trials, healthcare systems or the global economy as a whole. The foregoing and other continued disruptions to our business as a result of the evolving effects of the COVID-19 pandemic could materially and adversely affect our business, results of operations, financial condition and cash flows. Furthermore, the effects of the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

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

The global credit and financial markets have experienced extreme volatility and disruptions (including as a result of the COVID-19 pandemic and actual or perceived changes in interest rates and economic inflation), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability and swings in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate

market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, including disruption to enrollment within our ongoing trials and our ability to purchase necessary supplies on acceptable terms, if at all. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

Risks Related to Manufacturing

We intend to manufacture most of each product candidate ourselves. Delays in commissioning and receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our ability to generate product revenues.

We have built our own manufacturing facility in Bothell, Washington. The facility is designed to support the production of preclinical and 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 qualify the facility or the appropriate regulatory approvals for the facility are delayed, we may be unable to manufacture sufficient quantities of our product candidates, if at all, which would limit our development activities and our opportunities for growth.

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

- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- 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, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

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

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

Developing commercially viable manufacturing processes for cellular therapies is a difficult and uncertain task and requires significant expertise and capital investment. We are developing and implementing manufacturing processes for our product candidates. In particular, for autologous cell therapies, the starting material is the patient's own cells, which inherently adds complexity and variability to the manufacturing process, and we have not yet manufactured a cellular therapy for a patient with cancer. In addition, 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 products candidates to patients could be delayed. In addition, the complexities of utilizing a patient's own cells as the starting material requires that we have suitable cells capable of yielding a viable cellular therapy product, which may not be possible for severely immune-compromised or heavily pre-treated patients.

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

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

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

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

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

If we are unable to develop or scale our own manufacturing, we may have to rely on third parties to manufacture our product candidates, which subjects us to risks and could delay or prevent our development and/or commercialization, if approved, of our product candidates.

If we are unable to develop or scale our own manufacturing capabilities for our product candidates, we will be reliant on third parties to manufacture our product candidates. We may be unable to identify manufacturers for our product candidates or the materials required to develop the cellular therapy on acceptable terms or at all because the number of potential manufacturers is limited. Engaging a third-party manufacturer will require testing and regulatory interactions, and a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any. Our third-party manufacturers may be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

Furthermore, the facilities used by manufacturers are subject to ongoing periodic unannounced inspections by the FDA and corresponding state agencies to ensure strict compliance with government regulations and corresponding foreign standards, and we do not have control over third-party manufacturers' compliance with cGMPs for the manufacture of our product candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to obtain and/or maintain regulatory approval for our product candidates manufactured in these facilities. In addition, we have no control over the ability of our third-party manufacturers to maintain adequate control, quality assurance and qualified personnel required to meet our clinical and commercial needs, if any. If the FDA or a comparable foreign regulatory authority does not approve the manufacture of our product candidates at these facilities or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that any approvals we have obtained could be revoked, which would adversely affect our business and reputation.

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

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

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

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

In addition, those suppliers may not have the capacity to support commercial products manufactured by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection, or medical crises such as widespread contamination. We may not be able to contract with these companies on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing. In addition, some raw materials are currently available from a single supplier, or a

small number of suppliers. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. These factors could cause the delay of studies or trials, regulatory submissions, required approvals or commercialization of product candidates that we develop, cause us to incur higher costs and prevent us from commercializing our product candidates successfully.

Risks Related to Our Dependence on Third Parties

We intend to rely on third parties to conduct, supervise and monitor a significant portion of our research and preclinical 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 contract research organizations (CROs), to conduct GCP-compliant clinical trials on our product candidates properly and on time. For example, we are relying on a CRO to conduct a significant part of our LYL797 Phase 1 clinical trial. 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. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted or subject to delay as a result of the continuing effects of the COVID-19 pandemic, including due to staff shortages at the CRO, clinical site or other vendor or reallocation of resources due to the pandemic.

In addition, any third parties conducting our clinical trials or preclinical 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 is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials or preclinical 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 preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials are conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to 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 or state 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 to 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 their third-party research institutions for research and development and early clinical testing of our product candidates. These scientists and institutions may have other commitments or conflicts of interest, which could limit our access to their expertise and harm our ability to leverage our technology platforms.

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

The outside scientists who conduct the research and development upon which portions of our product candidate pipeline depends are not our employees; rather, they serve as either independent contractors or the primary investigators under research collaboration agreements that we have with their sponsoring academic or research institution. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. These factors could adversely affect the timing of the clinical trials, the timing of receipt and reporting of clinical data, the timing of our IND submissions and our ability to conduct 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 in the future, 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 entered into a research and development collaboration with GlaxoSmithKline (GSK) for our NY-ESO-1 program and other potential product opportunities and, in October 2022, GSK informed us that it was terminating the agreement and discontinuing its development of product candidates targeting NY-ESO-1, including the second generation product candidates incorporating our genetic and epigenetic reprogramming technologies (LYL132 and LYL331). Such termination of the GSK Agreement may adversely affect our business, financial condition and our results of operations.

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

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

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

We have entered into, and may desire to enter into in the future, collaborations, licenses or other strategic transactions for the acquisition of products or business opportunities, in each case where we believe such arrangement will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. For example, we entered into a collaboration agreement and stock purchase agreement with PACT Pharma, Inc. (PACT) in June 2020 and, in February 2021, we filed a demand for arbitration seeking to, among other things, rescind the agreements with PACT and recover the consideration paid thereunder. In October 2022, the Company entered into a settlement agreement with PACT to resolve their outstanding legal dispute. See Note 14, *Subsequent Events*, 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 regarding the PACT arbitration and settlement agreement. 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 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, patient withdrawal or adverse events. These types of developments could cause us to delay the trial or halt further development. For example, enrollment for the Phase 1 trial of LYL797 has been slower than anticipated, and we now anticipate the presentation of our initial LYL797 clinical data to occur in the first half of 2024.

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

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

Patient enrollment depends on many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- eligibility criteria for the trial;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- perceived risks and benefits of the product candidate under evaluation, including any perceived risks associated with genetically modified product candidates;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the risk that patients enrolled in clinical trials will drop out of the trials before the administration of our product candidates or trial completion;
- the availability of competing clinical trials;
- the availability of such patients during the COVID-19 pandemic;
- the availability of new drugs approved for the indication the clinical trial is investigating; and
- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

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

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

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

Risks Related to Regulation and Legal Compliance

We are just beginning the 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 just beginning the clinical development of our product candidates. Besides LYL797 and LYL845, which are in Phase 1 clinical development, all of our other proprietary product candidates are currently in preclinical development. The future success of our business is substantially dependent on our ability to obtain regulatory approval for our product candidates for the indications we seek, and, if approved, to successfully commercialize one or more product candidates in a timely manner. Each of our programs and product candidates will require clinical development, regulatory approval, obtaining manufacturing supply, capacity and expertise, building a commercial organization or successfully outsourcing commercialization, substantial investment and significant marketing efforts before we generate any revenue from product sales. We may never be able to develop or commercialize marketable products.

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

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

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

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

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

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

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

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

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

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

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

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

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

The clinical testing that will be required for any product candidates we choose to advance is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our 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 preclinical and clinical trials.

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

To date, we have not fully enrolled or completed any clinical trials required for the approval of our product candidates. We may experience delays in initiating, enrolling or conducting our current and planned clinical trials, and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned, will achieve expected

enrollment rates or will be completed on schedule, if at all. For example, obtaining sufficient and specific tumor tissues will be needed for our planned Phase 1 clinical trial of LYL845 in multiple solid tumor indications. Our inability to obtain the specific tumor tissues or sufficient amount of tumor tissues in a timely manner or at all could delay or preclude our ability to initiate the planned clinical trial. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including in connection with:

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

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

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

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

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

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

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

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

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

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

From time to time, we may also disclose preliminary or interim data from our preclinical studies and clinical trials. Preliminary or interim data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between

preliminary or interim data and final data could significantly harm our business prospects. Additionally, disclosure of preliminary or interim data by us or by our competitors could result in volatility in the price of our common stock.

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

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

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

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

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

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

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

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by us, the institutional review boards for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial or the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or a regulatory authority concludes that the financial

relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

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

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

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

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations, as well as, for the manufacture of certain of our product candidates, the FDA's cGTPs for the use of human cellular and tissue products to prevent the introduction, transmission or spread of communicable diseases. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs, cGTPs and adherence to commitments made in any approved marketing application. Accordingly, we 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 actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against

companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also required that companies enter into consent decrees and/or imposed permanent injunctions under which specified promotional conduct is changed or curtailed.

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

- issue warning letters;
- issue, or require us to issue, safety-related communications, such as safety alerts, field alerts, “Dear Doctor” letters to healthcare professionals, or import alerts;
- impose civil or criminal penalties;
- suspend, limit, or withdraw regulatory approval;
- suspend any of our preclinical studies and clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- 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. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

We may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any product candidates for which we obtain marketing approval. The healthcare laws that may affect us include: the federal fraud and abuse laws, including the federal anti-kickback, and false claims and civil monetary penalties laws; federal data privacy and security laws, including the Health Insurance Portability and Accountability Act, as amended by the Health Information Technology for Economic and Clinical Health Act; and federal transparency laws related to ownership and investment interests and payments and/or other transfers of value made to or held by physicians (including doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report

information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction.

Ensuring that our operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom are compensated in the form of stock options for consulting services provided, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, disgorgement, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and/or oversight if a corporate integrity agreement or similar agreement is executed to resolve allegations of non-compliance with these laws and the curtailment or restructuring of operations. In addition, violations may also result in reputational harm, diminished profits and 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 on Form 10-K for the year ended December 31, 2021.

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, allowing the ACA to remain in effect in its current form, 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 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 the U.S. Department of Health and Human Services (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 will also extend 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 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. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be effectuated but is likely to have a significant impact on the pharmaceutical industry. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, assuming FDA approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental, nor investigational. Assuming we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Additionally, we or our collaborators may develop companion diagnostic tests for use with our product candidates. We or our collaborators will be required 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. Third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. As such, cost containment reform efforts may result in an adverse effect on our operations. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates will be physician-administered, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used.

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

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

Separately, in response to the COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. In February 2022, the FDA resumed on-site inspections of domestic manufacturing facilities, subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, in April 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized or deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory

activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Relating to Our Intellectual Property

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

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

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

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

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

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

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

In addition, our registered or unregistered trademarks or trade names may be challenged, infringed or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first nonprovisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. 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 U.S. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing.

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

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

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

Our commercial success depends, in part, on us and our partners not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries,

including patent infringement lawsuits, interference or derivation proceedings, oppositions, and inter partes and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing, and may develop, product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products, methods of making or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

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

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

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

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

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

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

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

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

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

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

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

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

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

We have acquired or licensed, or may require in the future, intellectual property rights that have been generated through the use of U.S. government funding or grant. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government

action is necessary to meet requirements for public use under federal regulations (also referred to as “march-in rights”). The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

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

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

Interference, derivation or opposition proceedings provoked by third parties, brought by us or our partners, or brought by the USPTO or any non-U.S. patent authority, may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, inter partes review, post-grant review or other 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 in the U.S. Even if we are successful in the relevant proceedings, we may incur substantial costs, and the time and attention of our management and scientific personnel could be diverted from other activities. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question and/or may require us to pay the other party attorneys’ fees. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of

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

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

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

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

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

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

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

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

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

Risks Related to Ownership of Our Common Stock

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

Provisions in our amended and restated certificate of incorporation and bylaws may discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions may also prevent or

frustrate attempts by our stockholders to replace or remove our management. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our organizational documents:

- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered three-year terms;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- authorize our board of directors to issue shares of preferred stock and determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval;
- permit stockholders to take actions only at a duly called annual or special meeting and not by unanimous written consent;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings;
- authorize our board of directors, by a majority vote, to amend certain provisions of the bylaws; and
- require the affirmative vote of at least 66 2/3% or more of the outstanding shares of common stock to amend many of the provisions described above.

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

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

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

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

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

Furthermore, to prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended (Securities Act). However, these provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Any person purchasing or otherwise acquiring or holding any interest in shares of our capital stock is deemed to have received notice of and consented to the foregoing provisions. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds more favorable for disputes with us or with our directors, officers, other employees or agents or our other stockholders, which may discourage such lawsuits against us and such other persons, or

may result in additional expense to a stockholder seeking to bring a claim against us. Alternatively, if a court were to find this choice of forum provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, results of operations and financial condition.

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

As a public company, we 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. This assessment needs to include the disclosure of any material weaknesses in such internal control. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements will not be prevented or detected on a timely basis.

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

Although we believe that we have remediated this material weakness by hiring additional accounting and financial reporting personnel and have not identified any material weaknesses in connection with the finalization of our consolidated financial statements as of and for the year ended December 31, 2021, we cannot assure you that we will not identify other material weaknesses in the future.

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

General Risk Factors

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

Pursuant to Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with our second filing of an Annual Report on Form 10-K with the SEC. When we lose our status as an “emerging growth company” and become a “large accelerated filer” as of December 31, 2022, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff.

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

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

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. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

The market price of our common stock may 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 preclinical studies and clinical trials for our product candidates;
- failure or discontinuation of any of our product development and research programs;
- the success of existing or new competitive product candidates or technologies;
- results of clinical trials or regulatory approvals of our competitors;
- commencement or termination of collaborations for our product development and research programs;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- developments or disputes including those concerning patent applications, issued patents, or other proprietary rights;
- the impact of the COVID-19 pandemic on our business and on global economic conditions;
- labor discord or disruption, geopolitical events, social unrest, war, including repercussions of the recent military conflict between Russia and Ukraine, terrorism, political instability, acts of public violence, boycotts, hostilities and social unrest and other 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; 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 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 September 30, 2022, we have 249,239,833 shares of common stock outstanding, with zero shares of restricted stock awards outstanding that are subject to vesting requirements. 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 and excluding shares of restricted stock that will remain unvested, may be able to be sold in the public market.

Moreover, holders of shares of our common stock will have rights, subject to conditions, to require us to file registration statements with the SEC covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. 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 August 2022, we entered into an Equity Distribution Agreement pursuant to which we may offer and sell, from time to time, up to \$200.0 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 Equity Distribution 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.

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

We are currently an “emerging growth company” as defined in the JOBS Act and expect to maintain such status through the end of fiscal year 2022. While we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404, not being required to comply with the auditor requirements to communicate critical audit matters in the auditor’s report on the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different from the information that is available with respect to other public companies. We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

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

Effective December 31, 2022, we will no longer be an “emerging growth company,” and the reduced reporting requirements applicable to “emerging growth companies” will no longer apply, which will increase our costs as a result of being a public company and demands on management.

Effective December 31, 2022, we will no longer be classified as an “emerging growth company” as defined in the JOBS Act. As such, we will incur significant additional expenses that we did not previously incur in complying with the Sarbanes-Oxley Act and rules implemented by the SEC. As we prepare for no longer being classified as an “emerging growth company,” the cost of compliance with Section 404 has required, and will continue to require, us to incur substantial accounting expense and expend significant management time on compliance-related issues as we implement additional corporate governance practices and comply with reporting requirements, which could divert management attention and adversely affect our business, operating results and financial condition. Moreover, if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

Furthermore, investor perceptions of our company may suffer if, in the future, material weaknesses are found, and this could cause a decline in the market price of our stock. Irrespective of compliance with Section 404, any failure of our internal control over financial reporting could have a material effect on our stated operating results. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting or financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm.

In addition, as a “large accelerated filer,” we will be required to hold a say-on-pay vote and a say-on-frequency vote at our 2023 annual meeting of stockholders. As a result, we expect that we will require additional attention from management with respect to our disclosures and will incur increased costs, which could include higher legal fees, accounting fees, consultant fees and fees associated with investor relations activities, among others, and, as a result, our business, operating results and financial condition could be adversely affected.

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

consuming and costly. For example, the rules and regulations applicable to us as a public company have made it more expensive for us to obtain director and officer liability insurance. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

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

Under the Tax Cuts and Jobs Act of 2017 (the Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), our 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 in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past, including as a result of our IPO, and may experience ownership changes as a result of our 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. For example, California recently imposed limits on the usability of California state NOLs and tax credits to offset California taxable income in tax years beginning after December 31, 2019 and before January 1, 2022. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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

Our internal computer systems, and those of our partners, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

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

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

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

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from our Initial Public Offering of Common Stock

In June 2021, we completed our IPO, pursuant to which we issued and sold 25,000,000 shares of our common stock at price to the public of \$17.00 per share. The shares were registered pursuant to a registration statement on Form S-1 (File No. 333-256470) that was declared effective on June 16, 2021. As a result of our IPO, we raised a total of approximately \$391.8 million in net proceeds after deducting underwriting discounts and commissions of \$29.8 million and offering expenses of \$3.4 million. Goldman Sachs & Co. LLC, BofA Securities, J.P. Morgan and Morgan Stanley acted as joint book-running managers for the IPO. Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents and investments. No payments were made from our net proceeds directly or indirectly to our officers or directors, to persons owning 10% or more of any class of our equity securities or to any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for services on our board. We are holding a significant portion of the balance of the net proceeds from the offering in money market funds and short-term investments.

The proceeds from the IPO have been used to fund ongoing operations, including the development of our product candidates and our clinical trials and research programs, and for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from the IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 21, 2021 (the Prospectus). We cannot predict with certainty all of the particular uses for the net proceeds from our IPO, or the amounts that we will actually spend on the uses set forth in the Prospectus and above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to access additional financing, the relative success and cost of our research, preclinical and clinical development programs and whether we are able to enter into future collaboration and licensing arrangements. As a result, our management will continue to have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from our IPO.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

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.	S-8	333-257249	4.2	06/21/2021		
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	Notice and Acceptance of Amendment to Stock Options between the Registrant and Elizabeth Homans, dated August 4, 2022.	10-Q	001-40502	10.2	08/04/2022		
10.2	Offer Letter by and between the Registrant and Rahsaan W. Thompson, dated September 12, 2022.					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*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350.					X	
32.2*	Certification of 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 and Exhibit 32.2 that accompany 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.

September 12, 2022

Rahsaan W. Thompson Electronic delivery

Re: Offer of Employment by Lyell Immunopharma, Inc.

Dear Rahsaan:

I am very pleased to confirm our offer to you of employment with Lyell Immunopharma, Inc. (the “**Company**”). The opportunity to work with you to build one of the world’s great companies whose goal is nothing less than to develop curative therapies for solid tumors is one I am thrilled to have, and I know that your contributions will help ensure that we will achieve our ambitions.

1. **Position.** I am delighted to offer you a position as Chief Legal Officer. Your proposed start date is September 28, 2022. You will be responsible for overseeing the legal organization and will report to Elizabeth Homans, CEO. Your role is categorized as a Traveler and you will be authorized to be onsite up to 3 days per week depending on Company requirements. You will be based out of our South San Francisco, California office. The Company may change your position, duties, and work location from time to time in its discretion.

2. **Cash Compensation.**

(a) **Starting Salary.** Your starting salary will be \$460,000 per year, less payroll deductions and withholdings, paid on the Company’s normal payroll schedule. As a full-time exempt salaried employee, you will be expected to work the Company’s normal business hours as well as additional hours as required by the nature of your work assignments, and you will not be entitled to overtime compensation. Your salary will be subject to annual review and may or may not be adjusted in the Company’s sole discretion.

(b) **Sign-on Bonus Advance.** The Company will pay you a sign-on bonus advance of \$150,000, less applicable tax and other withholding, within thirty (30) days after your start date (the “**Sign-On Bonus Advance**”). You will earn 100% of the Sign-On Bonus Advance if you remain continuously employed with the Company through the one-year anniversary of your Start Date. If your employment with the Company terminates for any reason (other than for Good Reason or without Cause, as such terms are defined in the Officer Severance Plan) prior to the one-year anniversary of your Start Date, you authorize the Company to consider any unearned portion of the Sign-On Bonus Advance as a payroll advance and to deduct it from any amounts owed to you by the Company, including, without limitation, any accrued but unpaid salary and any unreimbursed business expenses. You agree to repay, within thirty (30) days of your last day of employment with the Company, any unearned portion of the Sign-On Bonus Advance previously paid to you by the Company in advance of becoming earned.

(c) **Target Annual Bonus.** In addition, you will be eligible to earn an annual incentive bonus of up to 50% of your base salary for the fiscal year of the Company (which runs from January 1st to December 31st) during which you commence employment, based on the achievement of performance objectives to be determined by the Company’s Board of Directors (the “**Board**”) or the Compensation Committee of the Board (the “**Committee**”) in its sole

discretion. Any bonus for the fiscal year in which your employment begins will be prorated, based on the number of days you are employed by the Company during that fiscal year. Thereafter, you will be eligible to receive an annual bonus in such amount and upon such terms as shall be determined by the Board or the Committee, in its sole discretion. If you remain on the same standard work hours and have a change to your base salary during the fiscal year, any bonus earned will be calculated based on your target bonus and base salary as of December 31 of that fiscal year. Any bonus for a fiscal year will be paid within 3 months after the close of that fiscal year, and you must be employed on the day that your bonus (if any) is paid in order to earn the bonus. Therefore, if your employment is terminated either by you or the Company for any reason prior to the bonus being paid, you will not have earned the bonus and no partial or prorated bonus will be paid. The determinations of the Board or the Committee with respect to your bonus will be final and binding.

3. **Benefits.** In addition, you will be eligible to participate in regular health insurance, bonus and other employee benefit plans established by the Company for its employees from time to time. The Company reserves the right to change or otherwise modify, in its sole discretion, the preceding terms of employment.

4. **Equity.** We will recommend to the Board of Directors of the Company or the Committee that you be granted an option to purchase up to 715,000 shares of Common Stock of the Company (the "**Option**"). The Option will be granted under the Company's 2021 Equity Incentive Plan, as amended (the "**Plan**") and associated form of stock option agreement and will have an exercise price equal to the fair market value of the Company's Common Stock on the date such grant is approved by the Committee. The Option will be subject to the terms and conditions of the Plan and your grant agreement. The Option will vest at the rate of twenty five percent (25%) of the shares at the end of your first anniversary with the Company, and an additional 1/48th of the total shares subject to the Option per month thereafter, so long as you remain employed by the Company. However, the grant of such option by the Company is subject to the Committee's approval and this promise to recommend such approval is not a promise of compensation and is not intended to create any obligation on the part of the Company. Further details on the Plan and any specific option grant to you will be provided upon approval of such grant by the Committee.

5. **Severance Payments/COBRA.** Your employment relationship with the Company is at will, as described below. However, in the event of a qualifying termination of your employment, you will be eligible to receive severance benefits as set forth in that certain Officer Severance Plan, while in effect and as amended from time to time by the Board or the Committee.

6. **Company Policies.** You will be expected to abide by Company rules and policies (including but not limited to the Company's Code of Business Conduct and Ethics, Insider Trading Policy, Whistleblower and Complaint Policy and Lyell Workplace Policies), as adopted or modified by the Company from time to time.

7. **Confidentiality.** As an employee of the Company, you will have access to certain confidential information of the Company and you may, during the course of your employment, develop certain information or inventions that will be the property of the Company. To protect the interests of the Company, you will need to sign the Company's standard "Employee Invention Assignment and Confidentiality Agreement" as a condition of your employment. We wish to impress upon you that we do not want you to, and we hereby direct you not to, bring with you any

confidential or proprietary material of any former employer or to violate any other obligations you may have to any former employer. Rather, you will be expected to use only that information which is generally known and used by persons with training and experience comparable to your own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by the Company. You agree that you will not bring onto Company premises, or upload onto any Company systems, any unpublished documents, information or property belonging to any former employer or other person to whom you have an obligation of confidentiality.

8. **No Breach of Obligations to Prior Employers.** You represent that your signing of this offer letter, agreement(s) concerning stock options granted to you, if any, under the Plan (as defined above), and the Company's Employee Invention Assignment and Confidentiality Agreement and your commencement of employment with the Company will not violate any agreement currently in place between yourself and current or past employers. You hereby represent that you have disclosed to the Company any contract you have signed that may restrict your activities on behalf of the Company.

9. **Conflicting Obligations.** Other than as may be set forth in a Consulting Agreement with Gritstone bio, Inc. approved and acknowledged by the Company, during the period that you render services to the Company, you agree to not engage in any employment, business or activity that is in any way competitive with the business or proposed business of the Company. You will disclose to the Company in writing any other gainful employment, business or activity that you are currently associated with or participate in that competes with the Company. You will not assist any other person or organization in competing with the Company or in preparing to engage in competition with the business or proposed business of the Company.

10. **At Will Employment.** While we look forward to a long and profitable relationship, should you decide to accept our offer, you will be an at-will employee of the Company, which means the employment relationship can be terminated by either of us at any time, with or without prior notice, and with or without cause. Any statements or representations to the contrary (and, indeed, any statements contradicting any provision in this letter) should be regarded by you as ineffective. Further, your participation in any stock option or benefit program is not to be regarded as assuring you of continuing employment for any particular period of time. Any modification or change in your at-will employment status may only occur by way of a written employment agreement signed by you and the Chief Executive Officer of the Company.

11. **Background Check.** This offer is contingent upon satisfactory verification of criminal, education, driving and/or employment background and reference checks. This offer can be rescinded based upon data received in this verification.

12. **Work Authorization.** Please note that because of employer regulations adopted in the Immigration Reform and Control Act of 1986, within three (3) business days of starting your new position you will need to present documentation demonstrating that you have authorization to work in the United States.

13. **COVID-19 Vaccination.** This position requires you to work onsite at the Company's facilities, and the Company requires that all employees working in its facilities

(including attending in-person meetings and events) be fully vaccinated against Covid-19 (except as required by applicable law). Therefore, this offer is contingent upon satisfactory proof that you are fully vaccinated from COVID-19, subject to reasonable accommodations for medical or religious reasons, and/or as otherwise required by applicable law. The Company considers you fully vaccinated once 14 days have passed since you received either the second dose in a two-dose COVID-19 vaccine series or a single-dose COVID-19 vaccine. Acceptance of this offer of employment is contingent on you maintaining a fully vaccinated status (including any vaccine boosters) against COVID-19 and providing vaccination attestation in our Human Resources Information System (UltiPro/UKG). The vaccine (including any vaccine booster) must have been FDA approved, have emergency use authorization from the FDA, or, for persons fully vaccinated outside of the U.S., be listed as approved by the World Health Organization or for emergency use by the World Health Organization.

14. **Governing Law and Arbitration.** This Agreement shall be governed by the law of the State of California. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of California. To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this letter Agreement, your employment with the Company, or the termination of your employment, shall be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. § 1-16, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes before a single arbitrator (available upon request and also currently available at <http://www.jamsadr.com/rules-employment-arbitration/>). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** In addition, all claims, disputes, or causes of action under this section, whether by you or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class or representative proceeding, nor joined or consolidated with the claims of any other person or entity. The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative or class proceeding. To the extent that the preceding sentences regarding class claims or proceedings are found to violate applicable law or are otherwise found unenforceable, any claim(s) alleged or brought on behalf of a class shall proceed in a court of law rather than by arbitration. This paragraph shall not apply to any action or claim that cannot be subject to mandatory arbitration as a matter of law, including, without limitation, claims brought pursuant to the California Private Attorneys General Act of 2004, as amended, the California Fair Employment and Housing Act, as amended, and the California Labor Code, as amended, to the extent such claims are not permitted by applicable law(s) to be submitted to mandatory arbitration and the applicable law(s) are not preempted by the Federal Arbitration Act or otherwise invalid (collectively, the "**Excluded Claims**"). In the event you intend to bring multiple claims, including one of the Excluded Claims listed above, the Excluded Claims may be filed with a court, while any other claims will remain subject to mandatory arbitration. You will have the right to be represented by legal counsel at any arbitration proceeding. Questions of whether a claim is subject to arbitration under this agreement shall be decided by the arbitrator. Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the

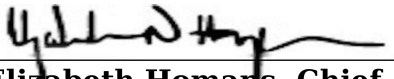
arbitrator. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this letter agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

15. **Entire Agreement.** This letter, together with your Employee Invention Assignment and Confidentiality Agreement, constitutes the entire agreement between you and the Company with respect to the subject matter hereof and supersedes all prior offers, negotiations and agreements, if any, whether written or oral, relating to such subject matter. Modifications or amendments to this agreement, other than those changes expressly reserved to the Company's discretion in this letter, must be made in a written agreement signed by you and an officer of the Company. If any provision of this offer letter agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this offer letter agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law. You acknowledge that neither the Company nor its agents have made any promise, representation or warranty whatsoever, either express or implied, written or oral, which is not contained in this agreement for the purpose of inducing you to execute the agreement, and you acknowledge that you have executed this agreement in reliance only upon such promises, representations and warranties as are contained herein.

16. **Acceptance.** This offer will remain open until September 16, 2022. If you decide to accept our offer, and I hope you will, please sign the enclosed copy of this letter in the space indicated and return to the People team. We also ask that you sign and return to the People team the Employee Invention Assignment and Confidentiality Agreement that is enclosed. Your signature will acknowledge that you have read and understood and agreed to the terms and conditions of this offer letter and the attached documents, if any. Should you have anything else that you wish to discuss, please do not hesitate to call me.

We look forward to the opportunity to welcome you to the Company.

Very truly yours,



Elizabeth Homans, Chief

I have read and understood this offer letter and hereby acknowledge, accept and agree to the terms as set forth above and further acknowledge that no other commitments were made to me as part of my employment offer except as specifically set forth herein.

DocuSigned by:

A6B4865DE41B456...

Rahsaan
W. Thompson

Date signed: 9/12/2022

**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, Elizabeth Homans, certify that:

1. I have reviewed this 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)) 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) 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
 - (c) 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: November 8, 2022

By:

/s/ ELIZABETH HOMANS

Elizabeth Homans

**Chief Executive Officer
(Principal Executive Officer)**

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

In connection with the Quarterly Report of Lyell Immunopharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; 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: November 8, 2022

By:

/s/ ELIZABETH HOMANS

Elizabeth Homans

**Chief Executive Officer
(Principal Executive Officer)**

