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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from to

Commission File Number: 001-40502

Lyell Immunopharma, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☐
Emerging growth company	☒		

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

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

As of November 5, 2021, the registrant had 240,471,497 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, product candidates, planned nonclinical studies and clinical trials, results of nonclinical studies, 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 of our estimates regarding expenses, revenue opportunities, capital requirements and needs for additional financing;
- the scope, progress, results and costs of developing LYL797, LYL845 or any other product candidates we may develop, and conducting preclinical studies and clinical trials, including for LYL797 and LYL845;
- the timing and costs involved in obtaining and maintaining regulatory approval of LYL797, LYL845 or any other product candidates we may develop, and the timing or likelihood of regulatory filings and approvals, including our expectation to seek special designations for our product candidates for various diseases;
- our expectations regarding GSK’s plans for the NY-ESO-1 programs;
- our plans relating to commercializing LYL797, LYL845 or any other product candidates we may develop, if approved, including the geographic areas of focus and our ability to grow a sales force;
- the size of the market opportunity for LYL797, LYL845 or any other product candidates we may develop in each of the diseases we target;
- our reliance on third parties to conduct nonclinical research activities for LYL797, LYL845 or any other product candidates we may develop;
- the characteristics, safety, efficacy and therapeutic effects of LYL797, LYL845 or any other product candidates we may develop;
- our estimates of the number of patients in the United States who suffer from the diseases we target and the number of subjects that will enroll in our clinical trials;
- the progress and focus of our current and future clinical trials, and the reporting of data from those trials, including the timing thereof;
- the ability of our clinical trials to demonstrate the safety and efficacy of LYL797, LYL845 or any other product candidates we may develop, and other positive results;

- the success of competing therapies that are, or may become, available;
- developments relating to our competitors and our industry, including competing product candidates and therapies;
- our plans relating to the further development and manufacturing of LYL797, LYL845 or any other product candidates we may develop, including additional indications that we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our potential and ability to successfully manufacture and supply LYL797, LYL845 or any other product candidates we may develop for clinical trials and for commercial use, if approved;
- the rate and degree of market acceptance of LYL797, LYL845 or any other product candidates we may develop, as well as the pricing and reimbursement of LYL797, LYL845 or any other product candidates we may develop, if approved;
- our continued reliance on third parties to conduct additional clinical trials of LYL797, LYL845 or any other product candidates we may develop, and for the manufacture of our product candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights, including LYL797, LYL845 or any other product candidates we may develop;
- our ability to retain the continued service of our key personnel and to identify, hire, and then retain additional qualified personnel;
- our expectations regarding the impact of the COVID-19 pandemic on our business and operations, including clinical trials, manufacturing suppliers, collaborators, use of contract research organizations (CROs) and employees;
- our expectations regarding the period during which we will qualify as an emerging growth company under the 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 1. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 393,504	$ 140,406
Short-term marketable securities	225,417	472,213
Prepaid expenses and other current assets	12,226	4,928
Total current assets	631,147	617,547
Restricted cash	466	466
Long-term marketable securities	317,511	79,995
Other investments	83,448	83,448
Property and equipment, net	115,857	77,045
Right-of-use assets, net	47,236	47,010
Other non-current assets	2,669	2,769
Total assets	$ 1,198,334	$ 908,280
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,526	$ 9,396
Accrued liabilities and other current liabilities	25,058	28,021
Success payment liabilities	25,116	5,773
Deferred revenue	5,581	6,095
Total current liabilities	59,281	49,285
Operating lease liabilities, non-current	65,684	50,957
Deferred revenue, non-current	81,883	89,066
Other non-current liabilities	5,012	532
Total liabilities	211,860	189,840
Commitments and contingencies (Note 12)		
Convertible preferred stock, $0.0001 par value; zero and 195,021 shares authorized at September 30, 2021 and December 31, 2020, respectively; zero and 194,474 shares issued and outstanding at September 30, 2021 and at December 31, 2020, respectively	-	1,010,968
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000 and zero shares authorized at September 30, 2021 and December 31, 2020, respectively; zero shares issued and outstanding at September 30, 2021 and December 31, 2020	-	-
Common stock, $0.0001 par value; 500,000 and 264,905 shares authorized at September 30, 2021 and December 31, 2020, respectively; 239,789 and 15,570 shares issued and outstanding at September 30, 2021 and at December 31, 2020, respectively	24	2
Additional paid-in capital	1,487,171	41,357
Accumulated other comprehensive (loss) income	(65)	256
Accumulated deficit	(500,656)	(334,143)
Total stockholders' equity (deficit)	986,474	(292,528)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 1,198,334	$ 908,280

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ 2,755	$ 1,070	$ 7,828	$ 5,444
Operating expenses (income):				
Research and development	31,433	24,501	119,408	147,153
General and administrative	21,241	13,570	57,184	32,012
Other operating income, net	(758)	(158)	(1,526)	(1,308)
Total operating expenses	51,916	37,913	175,066	177,857
Loss from operations	(49,161)	(36,843)	(167,238)	(172,413)
Interest income	270	1,096	842	5,318
Other income (expense), net	16	28	(117)	1,480
Net loss	(48,875)	(35,719)	(166,513)	(165,615)
Other comprehensive (loss) gain:				
Net unrealized (loss) gain on marketable securities	(138)	(598)	(321)	139
Net comprehensive loss	$ (49,013)	$ (36,317)	$ (166,834)	$ (165,476)
Net loss attributed to common stockholders:				
Net loss	$ (48,875)	$ (35,719)	$ (166,513)	$ (165,615)
Deemed dividends upon repurchase of convertible preferred stock	-	-	-	(3,582)
Net loss attributed to common stockholders	$ (48,875)	$ (35,719)	$ (166,513)	$ (169,197)
Net loss per common share, basic and diluted	$ (0.20)	$ (2.57)	$ (1.66)	$ (13.40)
Weighted-average shares used to compute net loss per common share, basic and diluted	239,384	13,893	100,603	12,625

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

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	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 condensed consolidated financial statements.

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

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance as of June 30, 2020	194,474	$ 1,010,968	13,097	$ 1	$ 18,266	$ 1,191	$ (259,567)	$ (240,109)
Stock-based compensation	-	-	1,207	-	9,783	-	-	9,783
Other comprehensive loss	-	-	-	-	-	(598)	-	(598)
Net loss	-	-	-	-	-	-	(35,719)	(35,719)
Balance as of September 30, 2020	194,474	$ 1,010,968	14,304	$ 1	$ 28,049	$ 593	$ (295,286)	$ (266,643)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2019	152,116	$ 519,163	11,181	$ 1	$ 18,108	$ 454	$ (129,671)	$ (111,108)
Issuance of Series C convertible preferred stock, net of $533 in issuance costs	42,905	492,467	-	-	-	-	-	-
Issuance of common stock to strategic partners	-	-	275	-	1,004	-	-	1,004
Issuance of common stock for asset acquisition	-	-	688	-	4,000	-	-	4,000
Repurchase of convertible preferred stock	(547)	(662)	-	-	(3,582)	-	-	(3,582)
Issuance of common stock upon exercise of stock options	-	-	15	-	35	-	-	35
Repurchase of common stock	-	-	(2,032)	-	(11,806)	-	-	(11,806)
Stock-based compensation	-	-	4,177	-	20,290	-	-	20,290
Other comprehensive income	-	-	-	-	-	139	-	139
Net loss	-	-	-	-	-	-	(165,615)	(165,615)
Balance as of September 30, 2020	194,474	$ 1,010,968	14,304	$ 1	$ 28,049	$ 593	$ (295,286)	$ (266,643)

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

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

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (166,513)	$ (165,615)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	9,059	2,842
Stock-based compensation expense	41,023	20,290
Change in fair value of success payment liabilities	19,343	3,793
Change in fair value of warrants	199	(1,295)
Non-cash lease expense	1,486	4,694
Non-cash expense in connection with asset acquisition	-	3,529
Net amortization or accretion on marketable securities	1,434	67
Loss on property and equipment disposals	496	-
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(6,811)	(596)
Accounts payable	(8)	(616)
Accrued liabilities and other current liabilities	10,792	4,209
Deferred revenue	(7,697)	(5,444)
Other non-current liabilities	4,121	-
Net cash used in operating activities	(93,076)	(134,142)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(55,236)	(26,600)
Sales of property and equipment	40	-
Purchases of marketable securities	(539,541)	(723,487)
Sales and maturities of marketable securities	547,066	480,631
Purchases of other investments	-	(36,447)
Net cash used in investing activities	(47,671)	(305,903)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from initial public offering, net of issuance costs	391,802	-
Proceeds from issuance of convertible preferred stock, net of issuance costs	-	492,467
Proceeds from exercise of stock options	2,043	35
Payments for the repurchase of common stock	-	(11,806)
Payments for the repurchase of preferred stock	-	(4,244)
Net cash provided by financing activities	393,845	476,452
Net increase in cash, cash equivalents and restricted cash	253,098	36,407
Cash, cash equivalents and restricted cash at beginning of period	140,872	98,472
Cash, cash equivalents and restricted cash at end of period	$ 393,970	$ 134,879
Represented by:		
Cash and cash equivalents	$ 393,504	$ 134,413
Restricted cash	466	466
Total	$ 393,970	$ 134,879
SUPPLEMENTAL CASH FLOW INFORMATION		
Conversion of convertible preferred stock to common stock upon closing of initial public offering	$ 1,010,968	$ -
Purchases of property and equipment included in accounts payable and accrued liabilities	$ 5,432	$ 18,439
Operating lease right-of-use assets obtained in exchange for lease obligations	$ -	$ 30,475
Remeasurement of operating lease right of use asset for lease modification	$ 4,078	$ 2,963
Cash received for amounts related to tenant improvement allowances	$ 11,063	$ 2,705
Cash paid for amounts included in the measurement of lease liabilities	$ 5,658	$ 3,628

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

Lyell Immunopharma, Inc.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization

Lyell Immunopharma, Inc. (the “Company”) was incorporated in Delaware in June 2018. The Company is a T cell reprogramming company dedicated to the mastery of T cells to 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, acquire technology, enter into strategic collaboration and license arrangements, enable manufacturing activities in support of its product candidate development efforts, organize and staff the Company, 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 equivalent 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 condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”). The condensed consolidated financial statements include the accounts of Lyell Immunopharma, Inc. and its wholly-owned subsidiary. All significant intercompany transactions and balances are eliminated in consolidation.

The condensed consolidated balance sheet as of December 31, 2020 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 condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and notes included in the prospectus the Company filed with the Securities and Exchange Commission on June 21, 2021 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus").

Use of Estimates

The preparation of the Company’s condensed consolidated financial statements in conformity with GAAP requires management to make judgments, estimates and assumptions that affect reported amounts and related disclosures. Specific accounts that require management estimates include, but are not limited to, stock-based compensation, valuation of success payments, revenue recognition and accrued expenses. Management bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could differ materially from those estimates.

Concentrations of Credit Risk and Off-Balance Sheet Risk

The Company maintains its cash and cash equivalents and restricted cash with high quality, accredited financial institutions. These amounts, at times, may exceed federally insured limits. The Company also makes short-term

investments in money market funds, U.S. Treasury securities, U.S. government agency securities 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 significant changes to the accounting policies during the nine months ended September 30, 2021, as compared to the significant accounting policies described in Note 2 of the “Notes to Financial Statements” in the Company’s audited financial statements included in the Prospectus, with the exception of revenue recognition related to licenses of intellectual property during the nine months ended September 30, 2021.

Revenue

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

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

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

3. Collaboration, License and Success Payment Agreements

Fred Hutch

In 2018, the Company entered into a license agreement with Fred Hutchinson Cancer Research Center (“Fred Hutch”) pertaining to certain patent rights. In 2018, the Company also entered into a research and collaboration agreement (“Fred Hutch Collaboration Agreement”), focused on research and development of cellular immunotherapy products and the Company recognized $1.1 million and $1.0 million of research and development expenses in connection with the Fred Hutch Collaboration Agreement for the three months ended September 30, 2021 and 2020, respectively, and $3.1 million and $3.0 million for the nine months ended September 30, 2021 and 2020, respectively.

In 2018, the Company also granted Fred Hutch rights to certain success payments. The potential payments for the Fred Hutch success payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the estimated per share fair value of the Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, relative to its original $1.83 per share issuance price. Upon the closing of the IPO, all shares of Series A convertible preferred stock then outstanding converted into an equivalent 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.

The estimated fair value of the success payments to Fred Hutch as of September 30, 2021 and December 31, 2020 was $21.7 million and $8.0 million, respectively. The success payment liability is estimated at fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Fred Hutch Collaboration Agreement. With respect to Fred Hutch success payment obligations, the Company recognized expense of $(0.8) million and $1.2 million for the three months ended September 30, 2021 and 2020, respectively, and $14.1 million and $3.8 million for the nine months ended September 30, 2021 and 2020, respectively. Expense associated with success payment obligations was recorded in research and development expense.

Stanford

In January 2019, the Company entered into a license agreement with The Board of Trustees of the Leland Stanford Junior University ("Stanford") pertaining to certain patent rights. In October 2020, the Company entered into a research and collaboration agreement with Stanford ("Stanford Collaboration Agreement"), focused on research and development of cellular immunotherapy products. The Company recognized $0.8 million and $2.3 million of research and development expenses in connection with the Stanford Collaboration Agreement for the three and nine months ended September 30, 2021, respectively. As the Stanford Collaboration Agreement was entered into in October 2020, no expense was recognized for the three and nine months ended September 30, 2020.

In October 2020, the Company also granted Stanford rights to certain success payments. The potential payments for the Stanford success payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the estimated per share fair value of the Series A convertible preferred stock, or any security into which such stock has been converted or for which it has been exchanged, relative to its original $1.83 per share issuance price. At the closing of the IPO, all shares of Series A convertible preferred stock then outstanding converted into an equivalent 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.

The estimated fair value of the success payments to Stanford as of September 30, 2021 and December 31, 2020 was $23.1 million and $8.9 million, respectively. The success payment liability is estimated at fair value at inception and at each subsequent reporting period and the expense is accreted over the service period of the Stanford Collaboration Agreement. With respect to Stanford success payment obligations, the Company recognized expense of $1.0 million for the three months ended September 30, 2021 and $5.2 million for the nine months ended September 30, 2021, which was recorded in research and development expense. As the rights to success payments were granted to Stanford in October 2020, no expense was recognized for the three and nine months ended September 30, 2020.

GSK

In 2019, the Company entered into a Collaboration and License Agreement, amended in June 2020 ("the GSK Agreement") with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, "GSK") for potential T cell therapies that apply the Company's platform technologies and cell therapy innovations with T cell receptors ("TCRs") or chimeric antigen receptors ("CARs") under distinct collaboration programs. The GSK Agreement has defined two initial collaboration targets and allows GSK to nominate seven additional targets through July 2024. The Company is expected to perform research and development services for each selected target up until a defined point (the "GSK Option Point"), at which time GSK will decide whether or not to exercise an option to obtain a license from the Company ("License Option") and take over the future development and commercialization. For each selected target, both parties will determine whether it will be developed under a Proof of Concept ("PoC") Development Program or Component Development Program. For a PoC Development Program, the Company is expected to conduct both preclinical and clinical development for the target and present clinical trial data to GSK in connection with their evaluation of whether to exercise the License Option. For a Component Development Program, the Company is obligated to perform preclinical studies only. Along with the research activities, the Company appoints 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. The Company is entitled to certain payments upon the achievement of specified development and sales milestones (for each selected target that is already within GSK's pipeline and meets certain criteria, the Company is eligible to receive up to an aggregate of approximately $400.0 million, and for each selected target that is not already within GSK's pipeline and meets certain criteria, the Company is eligible to receive up to an aggregate of approximately $900.0 million) and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK's pipeline and meet certain criteria, or from high single digit to low teens for all other targets. The Company is also entitled to potential milestone payments based on validating the Company's technology in a clinical setting up to an aggregate of approximately $200.0 million. Royalties and milestones are paid once per target, even if there is more than one Lyell innovation applied to a T cell therapy directed to that target. Any amounts received from GSK are generally non-refundable unless the Company terminates a collaboration target for safety or feasibility reasons and the funding received from GSK exceeds the costs incurred for the terminated target.

In connection with the GSK Agreement, in May 2019, the Company also entered into a Stock Purchase Agreement with GSK (the "GSK Stock Purchase Agreement"), pursuant to which the Company agreed to sell 30,253,189 shares of Series AA convertible preferred stock at a price of $6.78 per share. As of the issuance date, the estimated fair value of the Series AA convertible preferred stock was $4.84 per share, compared with the purchase price per share of $6.78. The difference of $58.6 million between the estimated fair value of the stock as of the issuance date and the purchase price was deemed to be additional consideration for the GSK Agreement. As a result, the total upfront payment for accounting purposes allocated to the GSK Agreement was $103.6 million.

Research and Development Services

The GSK Agreement was deemed to be within the scope of ASC 606 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, the 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 September 30, 2021, the transaction price was deemed to be $103.6 million, consisting of the upfront payment of $45.0 million under the GSK Agreement and the $58.6 million allocated from the GSK Stock Purchase Agreement. Other than the upfront payment and the amounts allocated from the GSK Stock Purchase Agreement, all other contingent consideration that may be earned under the GSK Agreement is subject to uncertainties including but not limited to target addition, research and investigational new drug enabling studies, initiation of clinical trials, and other related achievements. Consequently, the transaction price currently does not include any such contingent consideration that, if included, could result in a probable significant reversal of cumulative revenue when related uncertainties become resolved. The Company will re-evaluate the transaction price at each reporting period. If and when contingent consideration is included in the transaction price, it will be allocated to the two performance obligations proportionate to their SSPs and a cumulative 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 total estimated cost to complete. Incurred cost represents work performed, which corresponds with, and thereby best depicts, the transfer of control to the customer. The determination of the percentage of completion requires the Company to estimate the costs to complete the project. The Company makes a detailed estimate of the costs to complete, which is reassessed every reporting period based on the latest project plan and discussions with project teams. If a change in facts or circumstances occurs, the estimate will be adjusted, and the revenue will be recognized based on the revised estimate. The difference between the cumulative revenue recognized based on the previous estimate and the revenue recognized based on the revised estimate would be recognized as an adjustment to revenue in the period in which the change in estimate occurs.

The Company recognized revenue related to the research and development services for the two initial targets of $2.6 million and $1.1 million for the three months ended September 30, 2021 and 2020, respectively, and $7.7 million and $5.4 million for the nine months ended September 30, 2021 and 2020, respectively. Changes in deferred revenue during the nine months ended September 30, 2021 were as follows (in thousands):

Deferred revenue balance at December 31, 2020	$	95,161
Revenue recognized during the period previously recorded in deferred revenue		(7,697)
Deferred revenue balance at September 30, 2021	$	87,464

Exercise of the License Option

In April 2021, GSK exercised the License Option on NY-ESO-1 TCR with Gen-R, a Component Development Program, and will 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 actually 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 will update its assessment of whether an estimate of variable consideration is constrained and update the estimated transaction price accordingly.

As of September 30, 2021, 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, 2021.

PACT

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

In June 2020 in connection with the entry into the PACT Agreement, the Company also entered into a stock purchase agreement with PACT ("PACT SPA"), pursuant to which the Company purchased 17,806,901 shares of 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 Agreement and recognized as research and development expense. As a result, the total upfront payment paid in connection with the PACT Agreement was $63.6 million and 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 February 2021, the Company filed a demand for arbitration seeking, among other things, rescission of the PACT Agreement and the PACT SPA and recovery of the consideration paid thereunder. An arbitration hearing has been scheduled to occur in March 2022.

NCI License Agreement

In December 2020, the Company entered into a license agreement with National Cancer Institute ("NCI") to access certain intellectual property for the development of treatment of human cancers. In connection with this agreement, the Company paid $100,000 upfront, and a prorated annual maintenance payment for 2020 of approximately $3,100, for total consideration of approximately $103,100, which was recorded in research and development expense for the year ended December 31, 2020. The Company is also required to pay NCI annual maintenance payments which, may be credited against earned royalties. Under the agreement, the Company may also be required to make certain prespecified

development milestone payments up to an aggregate of $3.1 million, and prespecified commercial milestone payments up to a maximum aggregate of $12.0 million for all licensed products. In June 2021, the Company entered into an amendment to the license agreement with NCI to include additional intellectual property and one additional inventor. In connection with this amendment, the Company paid $25,000 upfront, which was recorded in research and development expense. Under the amendment, the Company may also be required to pay prespecified additional development milestone payments that total $75,000.

4. Cash Equivalents and Marketable Securities

The fair value and amortized cost of cash equivalents and marketable securities by major security type as of September 30, 2021 and December 31, 2020 are as follows (in thousands):

	September 30, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 331,349	$ -	$ -	$ 331,349
U.S. Treasury securities	249,817	41	(97)	249,761
U.S. government agency securities	103,950	25	(14)	103,961
Corporate debt securities	230,724	6	(26)	230,704
Total cash equivalents and marketable securities	$ 915,840	$ 72	$ (137)	$ 915,775

Classified as:	Fair Value
Cash equivalents	$ 372,847
Short-term marketable securities	225,417
Long-term marketable securities	317,511
Total cash equivalents and marketable securities	$ 915,775

	December 31, 2020			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 50,513	$ -	$ -	$ 50,513
U.S. Treasury securities	202,674	27	-	202,701
U.S. government agency securities	205,558	207	(1)	205,764
Corporate debt securities	211,086	34	(11)	211,109
Total cash equivalents and marketable securities	$ 669,831	$ 268	$ (12)	$ 670,087

Classified as:	Fair Value
Cash equivalents	$ 117,879
Short-term marketable securities	472,213
Long-term marketable securities	79,995
Total cash equivalents and marketable securities	$ 670,087

As of September 30, 2021 and December 31, 2020 the fair value of securities held by the Company in an unrealized loss position was $312.5 million and $132.6 million, respectively, and as of September 30, 2021 and December 31, 2020, securities held by the Company in an unrealized loss position have been in the continuous loss position for less than 12 months. The Company determined that there was no material change in the credit risk of the above investments during the three and nine months ended September 30, 2021. As such, an allowance for credit losses has not been recognized. As of September 30, 2021, the Company does not intend to sell such securities, and it is not more-likely-than-not that the Company will be required to sell the securities prior to the recovery of the amortized cost basis. Gross realized gains and losses were *de minimis* for the three and nine months ended September 30, 2021 and 2020 and as a result, amounts reclassified out of accumulated other comprehensive (loss) income for the three and nine months ended September 30, 2021 and 2020 were also *de minimis*.

As of September 30, 2021 and December 31, 2020, all of the Company's marketable securities had a maturity date of two years or less, were available for use and were classified as available-for-sale.

5. Other Investments

From time to time, the Company makes minority ownership strategic investments. As of both September 30, 2021 and December 31, 2020, the aggregate carrying amounts of the Company's strategic investments in non-publicly traded companies were $83.4 million. These investments are measured at initial cost, minus impairment, if any, and plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. There were no adjustments recorded to the carrying amount for other investments for the three and nine months ended September 30, 2021 and 2020.

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

6. Fair Value Measurements

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

	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 331,349	$ -	$ -	$ 331,349
U.S. Treasury securities	-	249,761	-	249,761
U.S. government agency securities	-	103,961	-	103,961
Corporate debt securities	-	230,704	-	230,704
Equity warrant investment	-	-	1,124	1,124
Total financial assets	$ 331,349	$ 584,426	$ 1,124	$ 916,899
Financial liabilities:				
Success payment liabilities	$ -	$ -	$ 25,116	$ 25,116
Total financial liabilities	$ -	$ -	$ 25,116	$ 25,116

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Financial assets:				
Money market funds	$ 50,513	$ -	$ -	$ 50,513
U.S. Treasury securities	-	202,701	-	202,701
U.S. government agency securities	-	205,764	-	205,764
Corporate debt securities	-	211,109	-	211,109
Equity warrant investment	-	-	1,323	1,323
Total financial assets	$ 50,513	$ 619,574	$ 1,323	$ 671,410
Financial liabilities:				
Success payment liabilities	$ -	$ -	$ 5,773	$ 5,773
Total financial liabilities	$ -	$ -	$ 5,773	$ 5,773

The Company measures the fair value of money market funds based on quoted prices in active markets for identical assets or liabilities. The Level 2 marketable securities include U.S. Treasury and government agency securities and corporate debt securities. The Company's Level 2 securities are valued using third-party pricing sources. The pricing

services utilize industry standard valuation models. Inputs utilized include market pricing based on real-time trade data for the same or similar securities and other significant inputs derived from or corroborated by observable market data.

The Level 3 financial instruments include an equity warrant investment and success payment liabilities. The Company's Level 3 financial instruments are valued using valuation models which include the Black-Scholes model for valuing the equity warrant investment and a Monte Carlo simulation for the success payment liabilities. To determine the estimated fair value of the success payments, the Company uses a Monte Carlo simulation methodology which models the future movement of stock prices based on several key variables combined with empirical knowledge of the process governing the behavior of the stock price. The following variables were incorporated in the estimated fair value of the success payment liabilities: fair value of the Company's common stock (Series A convertible preferred stock, prior to IPO), expected volatility, risk-free interest rate and the estimated number and timing of valuation measurement dates on the basis of which payments may be triggered. The computation of expected volatility was estimated based on available information about the historical volatility of stocks of similar publicly traded companies for a period matching the expected term assumption.

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

	September 30, 2021	December 31, 2020
Fair value of common stock (Series A convertible preferred stock)	$ 14.80	$ 9.07
Risk-free interest rate	0.07% - 2.24%	0.10% - 1.52%
Expected volatility	75%	80%
Expected term (in years)	0.71 - 6.22	1.00 - 6.97

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

	September 30, 2021	December 31, 2020
Fair value of common stock (Series A convertible preferred stock)	$ 14.80	$ 9.07
Risk-free interest rate	0.07% - 2.24%	0.10% - 1.53%
Expected volatility	75%	80%
Expected term (in years)	0.71 - 8.00	1.00 - 8.75

The Company utilizes estimates and assumptions in determining the estimated success payment liabilities and associated expense. A small change in the valuation of the Company's 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, 2020	$ 1,323	$ 5,773
Change in fair value [(1)]	(199)	19,343
Balance at September 30, 2021	$ 1,124	$ 25,116

(1) The change in fair value associated with the equity warrant investment is recorded in other income (expense), net and the change in fair value associated with success 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, Seattle, Washington and Bothell, Washington with contractual periods expiring between December 2021 and March 2031. In addition to minimum rent, the leases require payment of real estate taxes,

insurance, common area maintenance charges and other executory costs. These additional charges are considered variable lease costs and are recognized in the period in which the costs are incurred.

The following table summarizes the Company's future minimum operating lease commitments, including expected lease incentives to be received, as of September 30, 2021 (in thousands):

Year ending December 31:		
2021 (remaining three months)	$	2,419
2022		10,698
2023		11,018
2024		11,347
2025		11,859
Thereafter		60,302
Total undiscounted lease payments		107,643
Less: imputed interest		(33,422)
Less: tenant improvement allowances		(6,993)
Total operating lease liabilities	$	67,228
Reported as of September 30, 2021:		
Short-term portion of lease liabilities (included in accrued liabilities and other current liabilities)	$	1,544
Operating lease liabilities, non-current		65,684
Total	$	67,228

The operating lease costs for all operating leases were $2.4 million and $2.9 million for the three months ended September 30, 2021 and 2020, respectively, and $7.1 million and $8.3 million for the nine months ended September 30, 2021 and 2020, respectively. The operating lease costs and total commitments for short-term leases were *de minimis* for the three and nine months ended September 30, 2021 and 2020. Variable lease costs for operating leases were $1.4 million and $0.5 million for the three months ended September 30, 2021 and 2020, respectively, and $3.7 million and $1.5 million for the nine months ended September 30, 2021 and 2020, respectively.

In May 2021, the Company entered into a sublease, whereby the Company agreed to sublease approximately 11,000 rentable square feet of its space in South San Francisco, California currently leased by the Company. The sublease commenced in August 2021, is classified as an operating lease and will expire in March 2031. The monthly fixed payment due to the Company is $0.1 million, subject to annual rent increases in accordance with the contract.

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 rentable 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 will be recognized over the term of the sublease. The sublease commenced in September 2021, is classified as an operating lease and will expire in March 2031. The monthly fixed payment due to the Company is $0.1 million, subject to annual rent increases in accordance with the contract.

8. Convertible Preferred Stock

In March 2020, the Company sold 42,905,042 shares of its Series C convertible preferred stock at a price of $11.49 per share for proceeds of $492.5 million, net of issuance costs of $0.5 million.

In March 2020, the Company repurchased 546,806 shares of its Series A convertible preferred stock from a related party for a purchase price of $4.2 million.

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

9. Stockholders' Equity

The Company amended and restated its certificate of incorporation effective June 2021, increasing the number of shares the Company has the authority to issue to 510.0 million shares, of which 500.0 million are common shares and 10.0 million shares are preferred stock.

Preferred Stock

The Company is authorized to issue 10,000,000 shares of preferred stock, par value $0.0001 per share. As of September 30, 2021, no shares of preferred stock were outstanding.

Common Stock

As of September 30, 2021 and December 31, 2020, there were 239,789,419 shares and 15,569,788 shares of the Company’s common stock outstanding, respectively, excluding 3,575,002 shares and 7,562,503 shares, respectively, of restricted stock awards (“RSAs”) outstanding that are subject to vesting requirements.

In March 2020, the Company repurchased 2,032,166 shares of its common stock from a related party for a purchase price of $11.8 million.

10. Stock-based Compensation

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 will automatically increase on January 1 of each year for a period of ten years, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to (1) 5% of the total number of shares of 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. Under the 2021 Plan, the Company may grant incentive stock options, non-statutory stock options, RSAs, restricted stock units, 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, 2021, 24.9 million 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 will automatically increase on

January 1 of each year for a period of ten years, beginning on January 1, 2022 and continuing through January 1, 2031, by the lesser of (1) 1% of the total number of shares of the Company's common stock outstanding on December 31 of the immediately preceding year, and (2) 4,940,000 shares; provided, however, that the Company's board of directors may act to provide a lesser increase in number of shares. The Company may specify offerings with durations not more than 27 months and may specify shorter purchase periods within each offering. No shares have been issued under the 2021 ESPP as of September 30, 2021.

2018 Equity Incentive Plan

In 2018, the Company established the 2018 Plan under which it may grant incentive stock options, non-statutory stock options, RSAs, restricted stock units, stock appreciation rights and other stock-based awards. Terms of stock awards, including vesting requirements, were 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 2018 Plan. The term of any stock option granted under the 2018 Plan cannot exceed ten years. Generally, awards granted by the Company vest over four years, but may 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,	
	2021	2020	2021	2020
Research and development	$ 2,673	$ 1,965	$ 12,615	$ 9,033
General and administrative	10,369	7,783	28,408	11,257
Total stock-based compensation expense	$ 13,042	$ 9,748	$ 41,023	$ 20,290

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, 2021, total stock-based compensation cost related to unvested awards not yet recognized was $122.5 million, which is expected to be recognized over a remaining weighted-average period of 2.46 years.

Restricted Stock Awards

A summary of the Company’s RSAs activity was as follows:

	Number of Shares	Weighted-Average Value at Grant Date Per Share
Unvested shares as of December 31, 2020	7,562,503	$ 0.0001
Vested	(3,968,751)	$ 0.0001
Forfeited	(18,750)	$ 0.0001
Unvested shares as of September 30, 2021	3,575,002	$ 0.0001

Stock Options

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

	Number of Stock Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding as of December 31, 2020	34,413,889	$ 3.33		
Granted	12,521,501	$ 9.00		
Exercised	(776,449)	$ 2.63		
Canceled or forfeited	(2,597,874)	$ 4.00		
Options outstanding as of September 30, 2021	43,561,067	$ 4.93	7.97	$ 432,916
Options exercisable as of September 30, 2021	24,397,665	$ 3.29	7.17	$ 280,840

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,	
	2021	2020
Risk-free interest rate	0.79%	0.99%
Expected volatility	79%	75%
Expected term (in years)	6.10	6.25
Expected dividend yield	0%	0%

The weighted-average grant date fair value of options granted for the nine months ended September 30, 2021 and 2020 was $6.55 per share and $3.21 per share, respectively.

11. Net Loss Per Share

Basic and diluted net loss per share attributed to common stockholders is calculated by dividing net loss attributed to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. The Company's potentially dilutive shares, which include preferred stock, unvested RSAs and options to purchase common stock, are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive. Potentially dilutive common shares have been excluded from the diluted net loss per common share computations in all periods presented because such securities have an anti-dilutive effect on net loss per common share due to the Company's net losses. There are no reconciling items used to calculate the weighted-average number of total common shares outstanding for basic and diluted net loss per common share.

As of September 30, 2021 and 2020 potentially dilutive securities were as follows:

	September 30,	
	2021	2020
Convertible preferred stock	-	194,474,431
Unvested RSAs	3,575,002	9,486,462
Options to purchase common stock	43,561,067	32,358,470
Total	47,136,069	236,319,363

12. Commitments and Contingencies

Collaboration and License Agreements

The Company has entered into certain collaboration and license agreements, including those identified in Note 3, *Collaboration, License and Success Payment Agreements* above, with third parties that include the funding of certain development, manufacturing and commercialization efforts with the potential for future milestone and royalty payments upon the achievement of pre-established developmental, regulatory and/or commercial milestones. The Company's obligation to fund these efforts is contingent upon continued involvement in the programs and/or the lack of any adverse events which could cause the discontinuance of the programs. Due to the nature of these agreements, the future potential payments are inherently uncertain, and accordingly no amounts have been recorded for the potential future achievement of these targets as of September 30, 2021 and December 31, 2020.

13. Related-Party Transactions

In September 2021, the Company entered into a sublease with Sonoma, with whom the Company has common stockholders with board seats. As a part of the sublease, a $4.6 million tenant improvement contribution payment was made by Sonoma, which will be recognized over the term of the sublease. As of September 30, 2021, accrued liabilities and other current liabilities of $0.5 million and other non-current liabilities of $4.1 million were in connection with the sublease with Sonoma. Income of $0.5 million and $1.2 million was recognized in other operating income, net for the three and nine months ended September 30, 2021, respectively. See Note 7, *Leases*, for more detail on the Sonoma sublease.

The Company is party to the GSK Agreement with GSK, who is a holder of more than 10% of the Company's equity. See Note 3, *Collaboration, License and Success Payment Agreements*. Deferred revenue of $5.6 million and $6.1 million as of September 30, 2021 and December 31, 2020, respectively, and deferred revenue, net of current portion of $81.9 million and $89.1 million as of September 30, 2021 and December 31, 2020, respectively, were in connection with the GSK Agreement. Revenue recognized in connection with the GSK agreement was $2.6 million and $1.1 million for the three months ended September 30, 2021 and 2020, respectively, and $7.7 million and $5.4 million for the nine months ended September 30, 2021 and 2020, respectively.

In March 2020, the Company repurchased 546,806 shares of its Series A convertible preferred stock and 2,032,166 shares of its common stock from a related party. See Note 8, *Convertible Preferred Stock* and Note 9, *Stockholders' Equity*.

14. Asset Acquisition

In May 2020, the Company completed the acquisition of 100% of the outstanding equity of Immulus, Inc. ("Immulus"), a company focused on developing technology platforms that enable the development and production of cell therapeutics. As consideration for the acquisition, the Company paid $3.5 million in cash and issued an aggregate of 688,463 shares of its common stock, with an estimated fair value of $4.0 million. The Company also incurred $0.5 million of direct expenses, for total consideration of $8.0 million.

The Company concluded the acquisition did not meet the accounting definition of a business as inputs were acquired, but no processes or outputs were acquired. Consequently, the Company accounted for the transaction as an asset acquisition with the value concentrated in IPR&D. The following table summarizes the fair value of assets acquired (in thousands):

Other assets	$	487
In-process research and development (IPR&D)		7,528
Total assets acquired	$	8,015

The amount allocated to the IPR&D asset was charged to research and development expenses for the nine months ended September 30, 2020 as this asset had no alternative future use at the time of the acquisition transaction.

In addition, the Company is also required to make milestone payments of up to $37.0 million to the former stockholders of Immulus upon successful completion of specified development milestones. Triggering of these milestones payments was not considered probable as of the date of the acquisition, and no expense has been recorded for these milestones for the three and nine months ended September 30, 2021 and 2020.

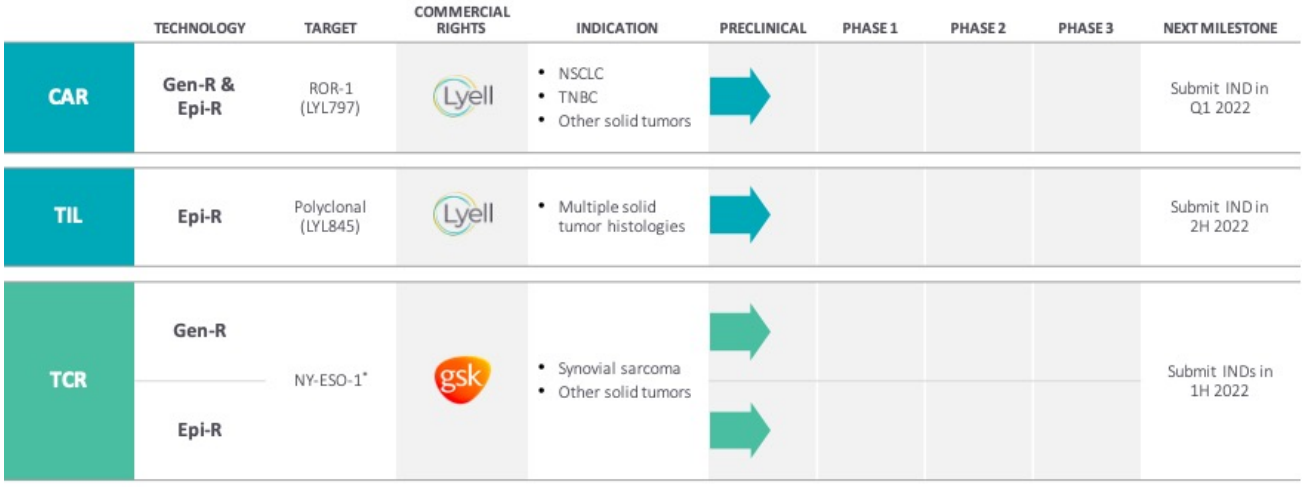
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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

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



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

We were incorporated in June 2018. Our primary activities to date have included developing T cell therapies, performing research and development, acquiring technology, entering into strategic collaboration and license agreements, enabling 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 to initiate clinical trials, raising capital and providing general and administrative support for these activities. All of our programs are currently in preclinical development, and we have not yet tested any product candidates in humans and do not have any products approved for sale. Since our inception, we have incurred net losses each year. Our net losses were $48.9 million and $35.7 million for the three months ended September 30, 2021 and 2020, respectively, and $166.5 million and $165.6 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $500.7 million. Our net losses resulted primarily from our research and development programs and, to a lesser extent, general and administrative costs associated with our operations.

To date, we have funded our operations primarily from the issuance and sale of our convertible preferred stock in connection with private financings, the issuance and sale of our common stock in connection with our initial public offering (IPO) and, to a lesser extent, from a collaboration agreement, and we have not generated any revenue from product sales. From June 29, 2018 (inception) through September 30, 2021, we raised an aggregate of $1,405.7 million in gross proceeds from the sales of our convertible preferred stock in connection with private preferred stock financings and our common stock in connection with our IPO. As of September 30, 2021, we had cash, cash equivalents and marketable securities of $936.4 million. 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 2025.

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

- continue preclinical development of our current and future product candidates and initiate additional preclinical studies;
- commence clinical trials of our current and future product candidates;
- advance our Gen-R, Epi-R and cell rejuvenation technology platforms as well as other research and development efforts;
- attract, hire and retain qualified personnel;
- seek regulatory approval of our current and future product candidates;
- expand our manufacturing and process development capabilities;
- expand our operational, financial and management systems;
- acquire and license technology 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 believe it is critically important to own, control and continuously monitor all aspects of the cell therapy manufacturing process in order to mitigate risks the field has seen, including challenges in managing production, supply chain, patient specimen chain of custody and quality control. We made a strategic decision to invest substantial capital in building our own manufacturing facility to control our supply chain, maximize efficiencies in cell product production time, cost and quality and have the ability to rapidly incorporate disruptive advancements and new innovations. Controlling manufacturing also enables us to protect proprietary aspects of our Gen-R and Epi-R technology platforms. We view our manufacturing team and capabilities as a significant competitive advantage.

In 2019, we entered into two operating lease agreements for a combined approximately 73,000 square feet of space to develop a cell therapy manufacturing facility located in Bothell, Washington. This LyFE manufacturing center has a flexible and modular design allowing us to produce plasmid, viral vector and T cell product to control and de-risk the sequence and timing of production of the major components of our supply chain related to our product candidates. At full staffing and capacity, we expect to be able to manufacture approximately 500 infusions per year depending on product candidate mix. We believe this capacity is sufficient to support our pipeline programs through pivotal trials and, if approved, early commercialization. We have achieved operational readiness of our LyFE manufacturing center and we have successfully completed engineering runs at scale to supply product for our upcoming clinical trials. We anticipate the facility to be current Good Manufacturing Practices (cGMP) qualified by the end of 2021. We anticipate continued investment in our manufacturing facility and capabilities to support our operating strategy.

The global COVID-19 pandemic continues to evolve rapidly, and we will continue to monitor it closely. The extent of the impact of the COVID-19 pandemic on our business, operations and development timelines and plans remains uncertain and will depend on future developments that cannot be predicted at this time. Such developments include the continued spread of the Delta variant 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 (including boosters to vaccinations) are made available, the percentage of the population that becomes vaccinated and the effectiveness of the vaccines against Delta or other SARS-CoV-2 variants. While the implications of the COVID-19 pandemic on our operations remain uncertain, to date, we have not experienced delays in our discovery and preclinical development activities as a result of the COVID-19 pandemic. We have closely monitored the COVID-19 pandemic and have strived to follow recommended containment and mitigation measures, including the guidance from the Centers for Disease Control and Prevention (CDC) as well as the states of California and Washington and applicable counties. For most of the pandemic, essential laboratory and support employees worked in our facilities to continue and progress experiments. We implemented preventative measures at our facilities in order to minimize the risk of employee exposure to the virus. These measures include, requiring that each employee or contractor who enters a facility be fully vaccinated and agree to comply with social distancing, frequent hand washing and wearing masks. We also increased cleaning of high touch areas and provided hand sanitizing stations. We expect to continue such measures for the near foreseeable future. We will continue to actively monitor the situation related to the COVID-19 pandemic and may take further actions that alter our operations, including those that may be required by federal, state, or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

Our registration statement on Form S-1 related to our IPO was declared effective on June 16, 2021, and our common stock began trading on the Nasdaq Global Select Market on June 17, 2021. On June 21, 2021, we issued and sold 25,000,000 shares of common stock at an IPO price of $17.00 per share. We received $391.8 million in net proceeds, after deducting underwriting discounts and commissions of $29.8 million and offering expenses of $3.4 million. At the closing of the IPO, 194,474,431 shares of convertible preferred stock then outstanding converted into an equivalent number of shares of common stock.

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

Collaboration, License and Success Payment Agreements

Below is a summary of the key terms for certain of our collaboration and license agreements. For a more detailed description of these and our other collaboration, license and success payment agreements, see the section titled “Business—Collaboration, License and Success Payment Agreements” in the prospectus we filed with the Securities and Exchange Commission (SEC) pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (Securities Act) on June 21, 2021 (Prospectus), and Note 3 of the notes to unaudited condensed consolidated financial statements included under Part I, Item 1 of this Quarterly Report on Form 10-Q.

Fred Hutch

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

In December 2018, we entered into a research and collaboration agreement with Fred Hutch for the research and development of cellular immunotherapy products. Pursuant to this agreement, we are required to fund $12.0 million in research performed by Fred Hutch, and we recorded research and development expense of $1.1 million and $1.0 million for the three months ended September 30, 2021 and 2020, respectively, and $3.1 million and $3.0 million for the nine months ended September 30, 2021 and 2020, respectively.

We also entered into a letter agreement with Fred Hutch in December 2018, pursuant to which we may be required to make success payments (Fred Hutch Success Payments) up to an aggregate of $200.0 million based on increases in the fair market value of our Series A convertible preferred stock, or any security into which such stock has been converted or exchanged. All shares of Series A convertible preferred stock converted into shares of common stock upon the closing of our IPO. The potential Fred Hutch Success Payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the fair value of the Company's common stock relative to the original issuance price of $1.83 per share at pre-determined valuation measurement dates. The Fred Hutch Success Payments can be achieved over a maximum of nine years from the effective date of the agreement. The following table summarizes the potential success payments, which are payable in cash, cash equivalents or, at our discretion, publicly-tradeable shares of our common stock:

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 valuation measurement dates are triggered by the following events: the one-year anniversary of our IPO and each two-year anniversary of our IPO thereafter, the closing of a change in control transaction, and the last day of the term of the success payment agreement, unless the term has ended due to the closing of a change of control transaction.

The estimated fair value of the Fred Hutch Success Payments as of September 30, 2021 and December 31, 2020 was $21.7 million and $8.0 million, respectively. With respect to Fred Hutch Success Payments, we recognized expense of $(0.8) million and $1.2 million for the three months ended September 30, 2021 and 2020, respectively, and $14.1 million and $3.8 million for the nine months ended September 30, 2021 and 2020, respectively.

Stanford

In January 2019, we entered into an exclusive license agreement with The Board of Trustees of the Leland Stanford Junior University (Stanford) to access certain intellectual property for the development of CARs and TCRs. In connection with this agreement, we paid $400,000 in cash and issued Stanford 910,000 shares of our common stock, for total consideration of $3.0 million, which was recorded as research and development expense for the year ended December 31, 2019. We are also required to pay Stanford an annual maintenance fee on the second anniversary of the agreement date, and each anniversary thereafter until the date of the first commercial sale of a licensed product. Under the agreement, we may also be required to make certain prespecified development milestone payments up to an aggregate of $3.7 million for the first licensed product for each target, and prespecified commercial milestone payments up to an aggregate of $2.5 million for all licensed products.

In October 2020, we entered into a research and collaboration agreement with Stanford for the development of cellular immunotherapy products. Pursuant to this agreement, we are required to fund $12.0 million in research performed by Stanford, and we recorded research and development expense of $0.8 million for the three months ended September 30, 2021 and $2.3 million for the nine months ended September 30, 2021. There was no expense recorded associated with the research and collaboration agreement with Stanford for the three and nine months ended September 30, 2020.

We also entered into a letter agreement with Stanford in October 2020, pursuant to which we may be required to make success payments (Stanford Success Payments) up to an aggregate of $200.0 million based on increases in the fair market value of our Series A convertible preferred stock, or any security into which such stock has been converted or exchanged. All shares of Series A convertible preferred stock converted into shares of common stock upon the closing of our IPO. The potential Stanford Success Payments are based on multiples of increased value ranging from 10x to 50x based on a comparison of the fair value of the Company's common stock relative to the original issuance price of $1.83 per share at pre-determined valuation measurement dates. The Stanford Success Payments can be achieved over a maximum of nine years from the effective date of the agreement. The following table summarizes the potential success payments, which are payable in cash, cash equivalents or, at our discretion, publicly-tradeable shares of our common stock:

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 valuation measurement dates are triggered by the following events: the one-year anniversary of our IPO and each two-year anniversary of our IPO thereafter, the closing of a change in control transaction, and the last day of the term of the success payment agreement, unless the term has ended due to the closing of a change of control transaction.

The estimated fair value of the Stanford Success Payments as of September 30, 2021 and December 31, 2020 was $23.1 million and $8.9 million, respectively. With respect to Stanford Success Payments, we recognized expense of $1.0 million for the three months ended September 30, 2021 and $5.2 million for the nine months ended September 30, 2021. There was no expense recorded associated with the Stanford Success Payments for the three and nine months ended September 30, 2020.

GSK Collaboration Agreement

In May 2019, we entered into a collaboration agreement with GlaxoSmithKline Intellectual Property (No. 5) Limited and Glaxo Group Limited (together, GSK), amended in June 2020 (GSK Agreement), for potential T cell therapies that apply our platform technologies and cell therapy innovations to TCRs or CARs under distinct collaboration programs. Pursuant to the GSK Agreement, we received an upfront payment of $45.0 million which was recorded as deferred revenue and revenue is recognized as the research and development services are rendered. For potential TCR or CAR therapies that are the subject of a collaboration program under the GSK Agreement, we are responsible for certain research and development activities, at our cost, up to GSK’s option point. These are expensed as research and development as incurred. Generally, each party is responsible for its own cost and expense to conduct each collaboration program. In April 2021, GSK exercised its option to the NY-ESO-1 TCR with Gen-R program and GSK will assume responsibility for future research and development of this program at its cost and expense. We are eligible to receive up to two one-time payments, totaling approximately $200.0 million in aggregate, for technology validation of Lyell’s cell therapy innovations. For each cell therapy target for which there has been a joint collaboration program, we also could receive up to approximately $400.0 million in aggregate in development and sales milestones for a target that is already within GSK’s pipeline and meets certain criteria, up to approximately $900.0 million in aggregate in development and sales milestones for all other targets, and tiered royalties on a per-product basis ranging from low to high single digits for targets that are already within GSK’s pipeline and meet certain criteria, or from high single digit to low teens for all other targets. Royalties and milestones are paid once per target, even if there is more than one Lyell innovation applied to a T cell therapy directed to that target.

NCI License Agreement

In December 2020, we entered into a license agreement with National Cancer Institute (NCI) to access certain intellectual property for the development of treatment of human cancers. In connection with this agreement, we paid $100,000 upfront, and a prorated annual maintenance payment for 2020 of approximately $3,100, for total consideration of approximately $103,100, which was recorded in research and development expense for the year ended December 31, 2020. We are also required to pay NCI annual maintenance payments which may be credited against earned royalties. Under the agreement, we may also be required to make certain prespecified development milestone payments up to an aggregate of $3.1 million, and prespecified commercial milestone payments up to a maximum aggregate of $12.0 million for all licensed products. In June 2021 we entered into an amendment to the license agreement with NCI to include additional intellectual property and one additional inventor. In connection with this amendment, we paid $25,000 upfront, which was recorded in research and development expense. Under the amendment, we may also be required to pay prespecified additional development milestone payments that total $75,000.

Components of Operating Results

Revenue

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

To date, we have generated revenue primarily from the recognition of a portion of the upfront payment under the GSK Agreement that we entered into in May 2019. As we continue to conduct research under the GSK Agreement, we will recognize revenue based upon our estimate of the progress made as well as potential future license revenue. In the future, we may generate additional revenue from other collaborations, strategic alliances, licensing agreements, product sales, or a combination of these.

Operating Expenses (income)

Research and Development

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

Research and development expenses also include non-cash expense related to the change in the estimated fair value of the liabilities associated with our success payments granted to Fred Hutch and Stanford. See Note 3 of the notes to the unaudited condensed consolidated financial statements included under 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. See the subsection titled “—Critical Accounting Policies and Significant Judgments and Estimates—Success Payments” included in the Prospectus.

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

Research and development activities account for a significant portion of our operating expenses. We anticipate that our research and development expenses will increase over the foreseeable future as we expand our research and development efforts including completing preclinical studies, commencing clinical trials, completing clinical trials, seeking

regulatory approval of our product candidates, identifying new product candidates, and incurring costs to acquire and license technology or technology platforms. A change in the outcome of any of these variables could mean a significant change in the costs and timing associated with the development of our product candidates. Because all of our product candidates are still in preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the preclinical development, clinical development and commercialization of product candidates or whether, or when, we may achieve profitability.

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

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

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

General and Administrative

General and administrative costs include personnel-related expenses, including stock-based compensation expense, for personnel in executive, legal, finance and other administrative functions, 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 sales of property and equipment.

Interest Income

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

Other Income (Expense), Net

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

Deemed Dividends Upon Repurchase of Convertible Preferred Stock

For the nine months ended September 30, 2020, deemed dividends upon repurchase of convertible preferred stock consists of the amount by which the cash paid for the repurchase of convertible preferred stock exceeded the carrying value of such convertible preferred stock.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

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

	Three Months Ended September 30,		
	2021	2020	Change
Revenue	$ 2,755	$ 1,070	$ 1,685
Operating expenses (income):			
Research and development	31,433	24,501	6,932
General and administrative	21,241	13,570	7,671
Other operating income, net	(758)	(158)	(600)
Total operating expenses	51,916	37,913	14,003
Loss from operations	(49,161)	(36,843)	(12,318)
Interest income	270	1,096	(826)
Other income, net	16	28	(12)
Net loss and net loss attributed to common stockholders	$ (48,875)	$ (35,719)	$ (13,156)

Revenue

Revenue was $2.8 million and $1.1 million for the three months ended September 30, 2021 and 2020, respectively, primarily related to the recognized portion of the upfront license fee pursuant to the GSK Agreement. The increase of $1.7 million in revenue for the three months ended September 30, 2021, compared to the same period in 2020, was primarily due to progress in research and development activities under the GSK Agreement.

Research and Development Expenses

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

	Three Months Ended September 30,		
	2021	2020	Change
Personnel	$ 13,447	$ 11,707	$ 1,740
Facilities and technology	10,919	5,581	5,338
Collaborations, research activities and outside services	6,958	5,977	981
Success payments	109	1,236	(1,127)
Total research and development expenses	$ 31,433	$ 24,501	$ 6,932

Research and development expenses were $31.4 million and $24.5 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $6.9 million was primarily due to:

- an increase in facilities and technology costs of $5.3 million primarily related to additional infrastructure to support the expansion of our research and development, manufacturing capabilities and associated headcount growth;
- an increase in personnel-related expenses of $1.7 million, which was primarily related to an increase in headcount to expand our research and development and manufacturing capabilities;
- an increase in collaboration, research activity and outside service expenses of $1.0 million, primarily due to expense associated with new sponsored research agreements; partially offset by
- a decrease of $1.1 million associated with our Fred Hutch and Stanford success payments liabilities primarily due to the decrease in the per share fair value of our common stock.

General and Administrative Expenses

General and administrative expenses were $21.2 million and $13.6 million for the three months ended September 30, 2021 and 2020, respectively. The increase of $7.7 million was primarily due to an increase in outside services and corporate expenses of $3.5 million, which was primarily attributable to the costs associated with operating as a public company. Additionally, personnel-related expenses increased by $3.8 million primarily due to an increase in headcount to support operations and a $2.6 million increase in stock-based compensation expense primarily related to new awards granted.

Interest Income

Interest income was $0.3 million and $1.1 million for the three months ended September 30, 2021 and 2020, respectively. The decrease of $0.8 million was primarily due to lower interest rates on cash, cash equivalents and marketable securities balances.

Comparison of the Nine Months Ended September 30, 2021 and 2020

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

	Nine Months Ended September 30,		
	2021	2020	Change
Revenue	$ 7,828	$ 5,444	$ 2,384
Operating expenses (income):			
Research and development	119,408	147,153	(27,745)
General and administrative	57,184	32,012	25,172
Other operating income, net	(1,526)	(1,308)	(218)
Total operating expenses	175,066	177,857	(2,791)
Loss from operations	(167,238)	(172,413)	5,175
Interest income	842	5,318	(4,476)
Other (expense) income, net	(117)	1,480	(1,597)
Net loss	$ (166,513)	$ (165,615)	$ (898)
Deemed dividends upon repurchase of convertible preferred stock	-	(3,582)	3,582
Net loss attributed to common stockholders	$ (166,513)	$ (169,197)	$ 2,684

Revenue

Revenue was $7.8 million and $5.4 million for the nine months ended September 30, 2021 and 2020, respectively, primarily related to the recognized portion of the upfront license fee pursuant to the GSK Agreement. The increase of $2.4 million in revenue for the nine months ended September 30, 2021, compared to the same period in 2020, was primarily due to progress in research and development activities under the GSK Agreement.

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2021	2020	Change
Personnel	$ 46,120	$ 36,716	$ 9,404
Facilities and technology	27,916	16,536	11,380
Collaborations, research activities and outside services	26,029	90,108	(64,079)
Success payments	19,343	3,793	15,550
Total research and development expenses	$ 119,408	$ 147,153	$ (27,745)

Research and development expenses were $119.4 million and $147.2 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease of $27.7 million was primarily due to:

- a decrease in collaboration, research activity, and outside service expenses of $64.1 million, primarily due to the commitment agreement upfront payment to PACT of $63.6 million, consisting of the $50.0 million upfront payment and $13.6 million deemed to be the difference between the purchase price of the preferred stock shares we purchased from PACT and the associated value of the preferred shares, and $7.5 million in acquired in-process research and development expense related to the asset acquisition of Immulus, Inc. (Immulus), recorded for the nine months ended September 30, 2020. These decreases were offset by a $3.4 million increase to direct costs associated with collaboration agreements as well as a $2.2 million increase related to consulting and temporary labor; partially offset by

- an increase of $15.6 million associated with our Fred Hutch and Stanford success payments liabilities, primarily due to the increase in the per share fair value of our common stock;

- an increase in facilities and technology costs of $11.4 million, primarily related to increased infrastructure to support the expansion of our research and development, manufacturing capabilities and associated headcount growth; and

- an increase in personnel-related expenses of $9.4 million, including $3.6 million of stock-based compensation expense, which was primarily related to an increase in headcount to expand our research and development and manufacturing capabilities.

General and Administrative Expenses

General and administrative expenses were $57.2 million and $32.0 million for the nine months ended September 30, 2021 and 2020, respectively. The increase of $25.2 million was primarily attributable to an increase in personnel-related expenses of $19.2 million due to an increase in headcount to support our operations and an increase of $17.2 million in stock-based compensation expense, primarily related to award modifications, accelerations and new awards granted. Additionally, outside services and corporate expenses increased by $5.5 million primarily due to the costs associated with operating as a public company.

Interest Income

Interest income was $0.8 million and $5.3 million for the nine months ended September 30, 2021 and 2020, respectively. The decrease of $4.5 million was primarily due to lower interest rates on cash, cash equivalents and marketable securities balances.

Other Income (Expense), Net

For the three and nine months ended September 30, 2021, other income (expense), net, consisted primarily of the changes in fair value of an equity warrant investment.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through the sale of convertible preferred stock and the sale of common stock in connection with our IPO. From June 29, 2018 (inception) through September 30, 2021, we raised an aggregate of $1,405.7 million in gross proceeds from the sales of our convertible preferred stock in connection with preferred stock financings and common stock in connection with our IPO. As of September 30, 2021, we had $936.4 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 $500.7 million as of September 30, 2021.

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 2025. However, we anticipate that we will need to raise additional capital in the future to fund our operations, including the further development of our product candidates and commercialization of any approved product candidates. We are subject to the risks typically related to the development of new products, and we may encounter

unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business.

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

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

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

and worldwide resulting from the ongoing COVID-19 pandemic and otherwise. If we are unable to raise additional capital when desired, our business, results of operations and financial condition would be adversely affected.

Cash Flows

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

	Nine Months Ended September 30,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	$ (93,076)	$ (134,142)
Investing activities	(47,671)	(305,903)
Financing activities	393,845	476,452
Net increase in cash, cash equivalents and restricted cash	$ 253,098	$ 36,407

Operating Activities

During the nine months ended September 30, 2021, net cash used in operating activities was $93.1 million, consisting primarily of our net loss of $166.5 million, partially offset by non-cash adjustments to reconcile net loss to net cash used in operating activities of $73.0 million. These adjustments consisted primarily of stock-based compensation expense of $41.0 million, $19.3 million for revaluation of our success payment liabilities to Fred Hutch and Stanford, depreciation and amortization expense of $9.1 million and $1.5 million in non-cash lease expense. Additionally, net operating assets and liabilities increased $0.4 million, which included $7.7 million of non-cash revenue recognized partially offset by $4.1 million increase in other non-current liabilities related to deferred lease income for the nine months ended September 30, 2021.

During the nine months ended September 30, 2020, net cash used in operating activities was $134.1 million, consisting primarily of our net loss of $165.6 million, partially offset by non-cash adjustments to reconcile net loss to net cash used in operating activities of $33.9 million. These adjustments consisted primarily of stock-based compensation expense of $20.3 million, non-cash expense in connection with an asset acquisition of $3.5 million, non-cash lease expense of $4.7 million, $3.8 million for revaluation of our success payment liabilities to Fred Hutch, and depreciation and amortization of $2.8 million, partially offset by the change in fair value of an equity warrant investment of $1.3 million. Additionally, net operating assets and liabilities decreased $2.4 million, which included $5.4 million of non-cash revenue recognized for the nine months ended September 30, 2020.

Investing Activities

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 purchases, sales and maturities of marketable securities of $7.5 million.

During the nine months ended September 30, 2020, cash used in investing activities was $305.9 million, consisting of net purchases of marketable securities of $242.9 million, purchases of other investments of $36.4 million and purchases of property and equipment of $26.6 million.

Financing Activities

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 $2.0 million in proceeds from the exercise of stock options.

During the nine months ended September 30, 2020, cash provided by financing activities was $476.5 million, consisting of $492.5 million in net proceeds from the sale of our convertible preferred stock, partially offset by the repurchase of preferred and common stock of $16.1 million.

Contractual Obligations and Commitments

There have been no material changes outside the ordinary course of business to our contractual obligations and commitments as compared to those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” set forth in the Prospectus.

Off-Balance Sheet Arrangements

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

JOBS Act Accounting Election

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

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements, as well as the reported revenue and expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies and estimates as compared to those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” set forth in the Prospectus, with the exception of revenue recognition related to licenses of intellectual property in the nine months ended September 30, 2021.

Revenue

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

In applying the ASC 606 framework, we must apply judgment to determine the nature of the promises within a revenue contract and whether those promises represent distinct performance obligations. In determining the transaction price, we do not include amounts subject to uncertainties unless it is probable that there will be no significant reversal of cumulative revenue when the uncertainty is resolved. Milestone and other forms of variable consideration that we may earn are

subject to significant uncertainties of research and development related achievements, which generally are deemed to be not probable until such milestones are actually achieved. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Additionally, we develop assumptions that require judgment to determine the standalone selling price of each performance obligation identified in the contract. We then allocate the total transaction price to each performance obligation based on the estimated standalone selling prices of each performance obligation, for which we recognize revenue as or when the performance obligations are satisfied. At the end of each subsequent reporting period, we re-evaluate the variable consideration and any related constraint and, if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis.

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

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

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, cash equivalents and restricted cash of $394.0 million as of September 30, 2021, which consisted of bank deposits, money market funds and highly liquid investments purchased with original maturities of three months or less from the purchase date. We also had marketable securities of $542.9 million as of September 30, 2021. The primary objective of our investment activities is to preserve capital to fund our operations while earning a low-risk return. Because our marketable securities are primarily short-term in duration and subject to minimal interest rate risk, we do not believe that a change in interest rates would have a material negative impact on the value of our investment portfolio and on our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. We had no debt outstanding as of September 30, 2021.

Foreign Currency Exchange Risk

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

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and in the future our clinical trial costs. We believe that inflation has not had a material effect on our 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, 2021, 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) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of September 30, 2021, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

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, 2021 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. An arbitration hearing has been scheduled to occur in March 2022. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business.

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

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

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 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 a preclinical biopharmaceutical company and have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing net losses for the foreseeable future.
- We operate in a rapidly evolving field and have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional capital to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- We are early in our research and development efforts and all of our product candidates are still in preclinical development. If we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be harmed.
- Our product candidates and technology platforms are based on novel technologies that are unproven and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval and we may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.
- Our cellular therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our inability to achieve regulatory approval, commercialization or payor coverage of our product candidates.
- The results of research, preclinical studies or earlier clinical trials are not necessarily predictive of future results. Any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- Clinical development involves a lengthy and expensive process with an uncertain outcome.
- We intend to manufacture at least a portion of our product candidates ourselves. Delays in commissioning and receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our ability to generate product revenues.

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

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

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

- Our business could be adversely affected by the effects of health epidemics, including the 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 Relating to Our Financial Condition, Limited Operating History and Need for Additional Capital

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

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We are a preclinical biopharmaceutical company, and we do not have any products approved by regulatory authorities and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. Since our inception, we have not generated any revenue from product sales and have incurred significant net losses. Our net losses were $48.9 million and $35.7 million for the three months ended September 30, 2021 and September 30, 2020, respectively, and $166.5 million and $165.6 million for the nine months ended September 30, 2021 and 2020, respectively. Substantially all of our net losses since inception have resulted from our research and development programs and general and administrative costs associated with our operations. As of September 30, 2021, we had an accumulated deficit of $500.7 million.

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

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

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

- commence clinical trials of our current and future product candidates;

- advance our Gen-R, Epi-R and cell rejuvenation technology platforms as well as other research and development efforts;
- attract, hire and retain qualified personnel;
- seek regulatory approval of our current and future product candidates;
- expand our manufacturing and process development capabilities;
- expand our operational, financial and management systems;
- acquire and license technology 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, preparing 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 U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other agencies and obtain regulatory approval for indications for which there is a commercial market;
- obtain coverage and adequate reimbursement from third parties, including government and private payors;
- set commercially viable prices for our products, if any;
- develop manufacturing and distribution processes for our product candidates;
- develop commercial quantities of our products at acceptable cost levels;
- establish and maintain adequate supply of our product candidates, including the starting materials and reagents needed;
- complete our own manufacturing facility such that we can maintain the supply of our product candidates in a manner that is compliant with global legal requirements or to the extent necessary, establish and maintain manufacturing relationships with reliable third parties;
- achieve market acceptance of our products, if any;
- attract, hire and retain qualified personnel;
- protect our rights in our intellectual property portfolio;
- develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
- find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

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

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

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

uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the discovery, development and commercialization of our potential product candidates and other unanticipated costs may arise.

As of September 30, 2021, we had approximately $936.4 million in cash, cash equivalents and short-term marketable securities. 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 2025. 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 in order 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 and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or delay, limit, reduce or terminate our establishment of sales, marketing and distribution capabilities or other activities that may be necessary to commercialize our product candidates.

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

We agreed to make success payments payable in cash or publicly-tradeable shares of our common stock at our discretion pursuant to our success payment agreements with Fred Hutchinson Cancer Research Center (Fred Hutch) and The Board of Trustees of the Leland Stanford Junior University (Stanford). 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 or additional success payment agreements that we may enter into in the future. For information related to our success payment obligations, see Note 3 of the notes to unaudited condensed consolidated financial statements included under 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 U.S. generally accepted accounting principles (GAAP), we are required to estimate the fair value of these liabilities as of each quarter end and changes in the estimated fair value are accreted to research and development expense over the service period of the collaboration agreement. Factors that may lead to increases or decreases in the estimated fair value of this liability include, among others, changes in the value of the common stock, changes in volatility and changes in the risk-free rate. As a result, our operating results and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and from year to year and may reduce the usefulness of our GAAP consolidated financial statements. As of September 30, 2021 and December 31, 2020, the estimated fair values of the liabilities associated with the Fred Hutch success payments were $21.7 million and $8.0 million, respectively, and as of September 30, 2021 and December 31, 2020, the estimated fair values of the liabilities associated with the Stanford success payments were $23.1 million and $8.9 million, respectively.

Risks Related to Our Business and Industry

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

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

- timely and successful completion of our preclinical studies and research activities to identify and develop product candidates to investigate in clinical trials;
- submission of INDs to the FDA to proceed with clinical trials, or comparable applications to foreign regulatory authorities that allow the commencement of our planned or future clinical trials for our product candidates;
- completion of preclinical studies and successful enrollment and completion of clinical trials in compliance with Good Clinical Practice (GCP) requirements with positive results;
- the 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 from our TIL program;
- manufacturing our product candidates at an acceptable cost;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;

- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other marketed therapies;
- maintaining compliance with regulatory requirements, including the cGMP requirements;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

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

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

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

Given the novelty of our technology platforms, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of relevant experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our technology platforms, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. There can be no assurance as to the length of clinical development, 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. For example, in September 2021, Dr. Rick Klausner, who founded our company, resigned from his position as Executive Chairman and ceased to be an employee effective

October 1, 2021. While Dr. Klausner continues to serve as Chair of our Board of Directors, he is currently on a medical leave of absence and is not expected to return until early 2022. We conduct substantially all of our operations at our facilities in the San Francisco and Seattle metropolitan areas. These regions are headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options or other equity incentives that vest over time may be significantly affected by factors beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain, and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

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

We may in the future become subject to legal proceedings and claims that arise in the ordinary course of business, such as claims brought by third parties in connection with commercial disputes or employment claims made by our current or former employees. Litigation or adversarial proceedings might result in substantial costs and may divert management’s attention and resources, which might seriously harm our business, reputation, overall financial condition and operating results. Insurance might not cover such claims, might not provide sufficient payments to cover all the costs to resolve one or more such claims and might not continue to be available on terms acceptable to us. A claim brought against us that is uninsured or underinsured could result in unanticipated costs, thereby harming our business.

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

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

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

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

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

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

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

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 have implemented policies that enable some of our employees to work in the research laboratories and for other employees to work remotely, and such policies may continue for an indefinite period. We have also implemented various safety protocols for all on-site personnel, including requiring that each employee or contractor who enters a facility be fully vaccinated and agree to comply with social distancing, frequent hand washing and wearing masks. In connection with these and potential future measures, we may be subject to claims based upon, arising out of or related to COVID-19 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, the effects of current and future governmental shelter-in-place orders and our remote work policies may materially and adversely impact productivity, disrupt our business and delay our preclinical study and future 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 evolving effects of the COVID-19 pandemic may have on our ability to effectively conduct our business operations as planned, and while to date, we have not experienced delays in our discovery and preclinical development activities as a result of the COVID-19 pandemic, there can be no assurance that we will be able to avoid materially adverse impacts from the evolving effects of the COVID-19 pandemic. For example, our preclinical study and future clinical trial plans may be materially and adversely affected by the COVID-19 pandemic. In this regard, site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic, which may delay enrollment in our future global clinical trials, and some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, and we may be unable to obtain blood samples for testing.

The 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 Delta variant 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 are made available, the percentage of the population that becomes vaccinated and the effectiveness of the vaccines against Delta 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 evolving effects of the COVID-19 pandemic could heighten the risks in certain of the other risk factors described herein.

Risks Related to Manufacturing

We intend to manufacture at least a portion of our product candidates ourselves. Delays in commissioning and receiving regulatory approvals for our manufacturing facility could delay our development plans and thereby limit our ability to generate product revenues.

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

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

- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials or key contractors; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, EMA, or other comparable regulatory agencies.

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

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

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

Developing commercially viable manufacturing processes for cellular therapies is a difficult and uncertain task and requires significant expertise and capital investment. We are developing and implementing manufacturing processes for our product candidates. In particular, for autologous cell therapies the starting material is the patient's own cells, which inherently adds complexity and variability to the manufacturing process, and we have not yet manufactured a cellular therapy for a patient with cancer. In addition, we have only recently completed construction of our Bothell, Washington manufacturing facility. 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 ongoing COVID-19 pandemic or otherwise, our clinical trials or regulatory approval may be delayed. We may also have to write off inventory, incur other charges and expenses for supply of product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. In addition, parts of the supply chain may have long lead times or may come from a small number of suppliers. If we are not able to appropriately manage our supply chain our ability to successfully produce our product candidates could be delayed or harmed. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

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

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

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

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

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

If we are unable to develop or scale 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 our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We do not currently have the ability to independently conduct any clinical trials. We intend to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as contract research organizations (CROs), to conduct GCP-compliant clinical trials on our product candidates properly and on time. Negotiating budgets and contracts with CROs and study sites may result in delays to our development timelines and increased costs. While we will control only certain aspects of these third parties' activities, nevertheless, we will be responsible for ensuring that each of our trials are conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development.

Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

We rely on our third-party research institution collaborators for some research capabilities. However, the research we are funding constitutes only a small portion of the overall research of each research institution. Other research being conducted by these institutions may at times receive higher priority than research on the programs we are funding. We

typically have less control of the research, clinical trial protocols and patient enrollment than we might with activity led by our employees.

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

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

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

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

- the collaborator may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

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

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

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

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

We have entered into, and may desire to enter into in the future, collaborations, licenses or other strategic transactions for the acquisition of products or business opportunities, in each case where we believe such arrangement will complement or augment our existing business. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. For example, we entered into a collaboration agreement and stock purchase agreement with PACT Pharma, Inc. (PACT) in June 2020 and, in February 2021, we filed a demand for arbitration seeking to, among other things, rescind the agreements with PACT and recover the consideration paid thereunder. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates or programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive benefit/risk profile. Any delays in entering into new strategic alliance agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

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

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

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

Our clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates, and this competition reduces the number and types of patients available to us, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Moreover, enrolling patients in clinical trials for diseases in which there is an approved standard of care is challenging, as patients will first receive the applicable standard of care. Many patients who respond positively to the standard of care do not enroll in clinical trials. This may limit the number of eligible patients able to enroll in our clinical trials who have the potential to benefit from our product candidates and could extend development timelines or increase costs for these programs. Patients who fail to respond positively to the standard of care treatment will be eligible for clinical trials of unapproved drug candidates. However, these prior treatment regimens may render our therapies less effective in clinical trials.

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

Patient enrollment depends on many factors, including:

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

- clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

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

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

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

Risks Related to Regulation and Legal Compliance

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

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

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

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

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

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

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

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

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

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

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

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

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

product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

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

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

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

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

To date, we have not completed any clinical trials required for the approval of our product candidates. We may experience delays in initiating or conducting any future clinical trials, and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned, will achieve expected enrollment rates or will be completed on schedule, if at all. For example, obtaining sufficient and specific tumor tissues will be needed for the anticipated TIL clinical trial. Our inability to obtain the specific tumor tissues or sufficient amount of tumor tissues could delay the clinical trial. There can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical trials of any of our product candidates on clinical hold in the future. Clinical trials can be delayed, suspended or terminated for a variety of reasons, including in connection with:

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

- obtaining IRB or ethics committee approval at each trial site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with applicable regulatory requirements, including the FDA's GCP requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- adding a sufficient number of clinical trial sites;
- 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 future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market our product candidates, which would significantly harm our business, financial condition, results of operations and prospects.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that 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, 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, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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

We may be subject to broadly applicable healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research, market, sell and distribute any product candidates for which we obtain marketing approval. The healthcare laws that may affect us include: the federal fraud and abuse laws, including the federal anti-kickback, and false claims and civil monetary penalties laws; federal data privacy and security laws; and federal transparency laws related to ownership and investment interests and payments and/or other transfers of value made to or held by physicians (including doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals and, beginning in 2022, information regarding payments and transfers of value provided to and other healthcare professionals during the previous year. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction.

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

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

In the United States and some foreign jurisdictions there have been, and continue to be, several legislative and regulatory changes and proposed reforms of the healthcare system in an effort to contain costs, improve quality and expand access

to care. In the United States, there have been and continue to be a number of healthcare-related legislative initiatives, as well as executive, judicial and Congressional challenges to existing healthcare laws that have significantly affected, and could continue to significantly affect, the healthcare industry. For example, 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, some of which have been successful, create considerable uncertainties for all businesses involved in healthcare, including our own. 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. 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. 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.

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.

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

We intend to engage CROs and other third parties to conduct our planned preclinical studies or clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO or clinical site or other vendor staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

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

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

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

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to 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, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine

surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Relating to Our Intellectual Property

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

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

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

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

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

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

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

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

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

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first nonprovisional effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic medications. In addition, although upon issuance in the United States a patent’s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. The patent term of certain patents can also be extended with respect to a specific product to recapture time lost in clinical trials and regulatory review by the FDA. A patent’s life also can be shortened by a terminal disclaimer over an earlier filed patent or patent application. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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

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

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

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

If we or our partners are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving that a patent is invalid is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If one or more claims of any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the

relevant product candidate until the relevant patent expired. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. If we are unable to obtain a necessary license on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

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

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

We have in-licensed a 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 preissuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property of others. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. An unfavorable outcome in any of these proceedings could require us or our partners to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can.

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

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

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

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

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

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

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

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

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

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

Risks Related to 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, 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, 2020, we cannot assure you that we will not identify other material weaknesses in the future.

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

General Risk Factors

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

Pursuant to Section 404, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with 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 an “accelerated filer” or a “large accelerated filer,” our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures, and hire additional accounting and finance staff.

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

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

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 COVID-19 on our business and on global economic conditions;
- the level of expenses related to any of our research programs or clinical development programs;
- actual or anticipated changes in our estimates as to our financial results or development timelines;
- whether our financial results, forecasts and development timelines meet the expectations of securities analysts or investors;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or other stockholders and the expiration of market standoff or lock-up agreements;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- market conditions in the healthcare sector;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In recent years, stock markets in general, and the market for healthcare companies in particular, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating

performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

If securities 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.

Sales of a substantial number of shares of our common stock in the public market could occur at any time following the expiration of the market standoff and lock-up agreements relating to our IPO, or the early release of these agreements or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, and could reduce the market price of our common stock. As of September 30, 2021, we have 239,789,419 shares of common stock outstanding. Of these shares, the 25,000,000 shares were sold in our IPO and may be resold in the public market immediately, unless purchased by our affiliates. Substantially all of the remaining shares of our common stock is outstanding is currently prohibited or otherwise restricted under securities laws, market standoff agreements entered into by our stockholders with us, or lock-up agreements entered into by our stockholders with the underwriters of our IPO; however, subject to applicable securities law restrictions and excluding shares of restricted stock that will remain unvested, these shares will be able to be sold in the public market beginning 180 days after the date of the Prospectus. The representatives of the underwriters may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, any applicable market standoff and lock-up agreements, and Rule 144 and Rule 701 under the Securities Act.

Moreover, holders of an aggregate of approximately 194.5 million shares of our common stock will have rights, subject to conditions, to require us to file registration statements with the SEC covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described in the Prospectus. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. We, and indirectly, our stockholders, will bear the cost of issuing and servicing securities issued in any such transactions. Because our decision to issue debt or equity securities in any future offering will depend on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any future offerings. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell, or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Additionally, any future collaborations we enter into with third parties may provide capital in the near term but limit our potential cash flow and revenue in the future. If we raise additional funds through strategic partnerships, alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to

our technologies or our products, or grant licenses on terms unfavorable to us. Certain of the foregoing transactions may require us to obtain stockholder approval, which we may not be able to obtain.

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

We are an "emerging growth company" as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC-registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404, not being required to comply with the auditor requirements to communicate critical audit matters in the auditor's report on the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. We 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.

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

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

The requirements of being a public company require our management to devote substantial time to new 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 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 may make it more difficult and 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.

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

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

As of December 31, 2020, we had federal and state net operating loss (NOLs) carryforwards of approximately $116.1 million and $61.2 million, respectively. Under the Tax Cuts and Jobs Act of 2017 (the Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act), our NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of our IPO and/or subsequent shifts in our stock ownership (some of which may be outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset post-change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOLs and tax credits to offset California taxable income in tax years beginning after December 31, 2019 and before January 1, 2023. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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

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

While we have not experienced any material system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of our product candidates could be delayed. In addition, the loss of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data.

Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

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

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

On June 16, 2021, our Registration Statement on Form S-1 (File No. 333-256470) relating to our IPO of common stock was declared effective. The Registration Statement registered the issuance of up to 28,750,000 shares, at a public offering price of $17.00 per share, with an aggregate offering price of $488,750,000. On June 21, 2021, we issued and sold 25,000,000 million shares of common stock under the Registration Statement at a public offering price of $17.00 per share, for aggregate gross proceeds of $425.0 million, resulting in net proceeds to us of $391.8 million, after deducting underwriting discounts and commissions of $29.8 million and other offering expenses of $3.4 million. Upon completion of the sale of the shares of our common stock referenced in the preceding sentence, our IPO terminated. Goldman Sachs & Co. LLC, BofA Securities, Inc., J.P. Morgan Securities, LLC and Morgan Stanley & Co. LLC acted as joint bookrunning managers of the initial public offering and as representatives of the underwriters.

The net proceeds from our IPO have been invested according to our approved investment policy in a mix of money market funds and high-quality, fixed income securities with a maturity date of two years or less. There has been no material change in the planned use of proceeds from our IPO from that described in the Prospectus.

No payments were made from our net proceeds or as offering expenses directly or indirectly to any of our directors or officers (or their associates) or persons owning 10.0% or more of any class of our equity securities or to any other affiliates, other than payments from our net proceeds in the ordinary course of business to officers for salaries and to non-employee directors as compensation for service on the board of directors or committees of the board of directors.

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
3.1	Amended and Restated Certificate of Incorporation (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-8 (File No. 333-257249), filed with the SEC on June 21, 2021).
3.2	Amended and Restated Bylaws (incorporated herein by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-8 (File No. 333-257249), filed with the SEC on June 21, 2021).
4.1	Form of Common Stock Certificate (incorporated herein by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-1/A (File No. 333-256470), filed with the SEC on June 9, 2021).
31.1*	Certification of Principal Executive Officer 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.
31.2*	Certification of Principal Financial Officer 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.
32.1*+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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.

SIGNATURES

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

Lyell Immunopharma, Inc.

Date: November 12, 2021

By: /s/ CHARLES NEWTON

Charles Newton
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, 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 12, 2021

By: /s/ ELIZABETH HOMANS

Elizabeth Homans
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Charles Newton, certify that:

1. I have reviewed this 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 12, 2021

By: /s/ CHARLES NEWTON

Charles Newton
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Lyell Immunopharma, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021 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 result of operations of the Company.

Date: November 12, 2021

By: /s/ ELIZABETH HOMANS

Elizabeth Homans
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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, 2021 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 result of operations of the Company.

Date: November 12, 2021

By: /s/ CHARLES NEWTON

Charles Newton
Chief Financial Officer
(Principal Financial and Accounting Officer)