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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41859

CARGO Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**84-4080422**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
835 Industrial Road, Suite 400 San Carlos, California	**94070**
(Address of principal executive offices)	**(Zip Code)**

(650) 499-8950

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	CRGX	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 August 8, 2024, the registrant had 45,904,634 shares of common stock, $0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements in this Quarterly Report on Form 10-Q, other than statements of historical fact, including, without limitation, statements regarding our strategy, future operations, future operating expenses, future financial position, future revenue, projected costs, prospects, plans, intentions, expectations, goals and objectives may be forward-looking statements. The words "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "should," "would" or "will," and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The forward-looking statements in this report include, but are not limited to, statements about:

- the potential for adverse events, undesirable side effects or unexpected characteristics associated with any of our product candidates;
- the timing of achieving our scientific, clinical, manufacturing, regulatory and/or other product development objectives;
- the timing of our planned Investigational New Drug (IND) application submissions to the United States Food and Drug Administration (FDA) for our product candidates, including firicabtagene autoleucel (firi-cel) (previously CRG-022);
- our expectations regarding the potential market size and size of the potential patient populations for our product candidates and any future product candidates, if approved for commercial use;
- our clinical and regulatory development plans;
- our expectations with regard to the results of our clinical studies, preclinical studies and research and development programs, including the timing and availability of data from such studies;
- the number, size and design of our planned clinical trials, and what regulatory authorities may require to obtain full marketing approval;
- our plans to research, develop and, if approved, commercialize our product candidates, including firi-cel and CRG-023;
- the timing of commencement of future preclinical studies and clinical trials and research and development programs;
- our ability to acquire, discover, develop and advance product candidates into, and successfully complete, clinical trials;
- our ability to obtain certain designations, such as a Breakthrough Therapy or Regenerative Medicine Advance Therapy, for one or more of our product candidates;
- a requirement to obtain approval of a companion diagnostic in connection with the approval of any of our product candidates;
- our intentions and our ability to establish collaborations and/or partnerships;
- the discovery of previously unknown or unexpected problems with our product candidates or any future product candidates or with the facilities where such product candidates are or will be manufactured;
- the timing or likelihood of regulatory submissions and potential approvals for our product candidates, including the potential requirement to adopt a Risk Evaluation and Mitigation Strategy;
- our commercialization, marketing and manufacturing strategies, including the buildout of our own manufacturing facility, capabilities and expectations;
- the rate and degree of market acceptance of our product candidates, if approved;
- the success of competing products or platform technologies that are or may become available;

- impact from future regulatory, judicial, and legislative changes or developments in the United States and foreign countries;
- our intentions with respect to the commercialization of our product candidates;
- the size and growth potential of the markets for our product candidates, if approved for commercial use, and our ability to serve those markets;
- the pricing and reimbursement of our product candidates, if approved;
- future agreements with third parties in connection with the potential commercialization of our product candidates;
- the potential effects of health epidemics, pandemics, other widespread outbreaks of contagious disease, such as COVID-19 and the post-COVID-19 environment, on our preclinical and clinical programs and business;
- the implementation of our business model and strategic plans for our business and product candidates, including additional indications for which we may pursue;
- our ability to effectively manage our growth, including our ability to attract and retain key scientific and management personnel, and maintain our culture;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates, including the projected terms of patent protection;
- potential claims relating to our intellectual property and third-party intellectual property;
- estimates of our expenses, future revenue, capital requirements, our needs for additional financing and our ability to obtain additional capital;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our future financial performance;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act and a smaller reporting company as defined in Rule 12b-2 of the Securities and Exchange Act of 1934, as amended (the Exchange Act);
- developments and projections relating to our competitors and our industry, including competing products;
- our expectations regarding the use of proceeds from our initial public offering and our existing cash and cash equivalents; and
- other risks and uncertainties, including those listed under the caption “Risk Factors” in this Quarterly Report on Form 10-Q.

We have based these forward-looking statements largely on our current expectations, estimates, forecasts and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward- looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Quarterly Report on Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. You should refer to the section titled “Risk factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, if our forward- looking statements prove to be inaccurate, the inaccuracy may be material. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, 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.

Investors and others should note that we may announce material business and financial information to our investors using our investor relations website, Securities and Exchange Commission filings, webcasts, press releases and conference calls. We use these mediums, including our website, to communicate with the public about our company, our business and other issues. It is possible that the information that we make available may be deemed to be material information. We, therefore, encourage investors and others interested in our company to review the information that we make available on our website.

RISK FACTORS SUMMARY

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in the section titled "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, among others, the following:

- We are a clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.
- Our limited operating history may make it difficult to evaluate our prospects and likelihood of success.
- The substantial obligations from our license agreements may result in dilution to our stockholders, may be a drain on our cash resources or may cause us to incur debt obligations to satisfy the payment obligations.
- If we are unable to successfully identify, develop, obtain regulatory approval and ultimately commercialize any of our current or future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.
- We have experienced rapid operational growth since our inception in December 2019 and expect to continue to grow in the future as our clinical and preclinical trials progress, we begin to advance the development of new and current product candidates and our headcount increases. If we fail to effectively manage our growth, we may not be able to execute on our business objectives.
- Our ability to develop our product candidates and our platform technologies, as well as our future growth, depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.
- We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.
- We rely on third parties to conduct our clinical trials, manufacturing and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.
- We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

CARGO THERAPEUTICS, INC.
Condensed Balance Sheets
(in thousands, except share and per share data)

	June 30, 2024 (Unaudited)	December 31, 2023 (Note 2)
Assets		
Current assets:		
Cash and cash equivalents	$ 153,582	$ 405,732
Marketable securities	289,896	—
Prepaid expenses and other current assets	4,618	3,745
Total current assets	448,096	409,477
Operating lease right-of-use assets	25,136	28,222
Restricted cash	567	567
Property and equipment, net	11,837	10,379
Other non-current assets	4,378	4,391
Total assets	$ 490,014	$ 453,036
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,007	$ 5,013
Accrued clinical and research and development expenses	13,133	7,242
Accrued expenses and other current liabilities	5,635	6,629
Operating lease liabilities, current	649	2,278
Total current liabilities	26,424	21,162
Operating lease liabilities, non-current	27,489	26,263
Other non-current liabilities	—	225
Total liabilities	53,913	47,650
Stockholders' equity:		
Common stock	46	41
Additional paid-in capital	661,683	550,491
Accumulated other comprehensive loss	(323)	—
Accumulated deficit	(225,305)	(145,146)
Total stockholders' equity	436,101	405,386
Total liabilities and stockholders' equity	$ 490,014	$ 453,036

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

CARGO THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(unaudited, in thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 37,458	$ 13,929	$ 67,961	$ 26,491
General and administrative	11,860	3,867	22,163	6,552
Total operating expenses	49,318	17,796	90,124	33,043
Loss from operations	(49,318)	(17,796)	(90,124)	(33,043)
Interest income	4,987	578	9,992	683
Interest expense	—	—	—	(1,604)
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	(634)	—	(692)
Change in fair value of derivative liabilities	—	—	—	6,453
Loss on extinguishment of convertible notes	—	—	—	(2,316)
Other expense, net	(17)	—	(27)	(80)
Net loss	$ (44,348)	$ (17,852)	$ (80,159)	$ (30,599)
Other comprehensive loss:				
Unrealized loss on marketable securities	(44)	—	(323)	—
Comprehensive loss	$ (44,392)	$ (17,852)	$ (80,482)	$ (30,599)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.02)	$ (26.56)	$ (1.90)	$ (48.21)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	43,344,345	672,253	42,170,123	634,704

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

CARGO THERAPEUTICS, INC.
Condensed Statements of Stockholders' Equity
(unaudited, in thousands, except share data)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2023	41,205,551	$ 41	$ 550,491	$ —	$ (145,146)	$ 405,386
Exchange of common stock for pre-funded warrants	(1,842,499)	(2)	(23)	—	—	(25)
Exercise of stock options	5,595	—	26	—	—	26
Vesting of restricted stock	—	—	11	—	—	11
Stock-based compensation	—	—	3,904	—	—	3,904
Net loss	—	—	—	—	(35,811)	(35,811)
Other comprehensive loss	—	—	—	(279)	—	(279)
Balances at March 31, 2024	39,368,647	39	554,409	(279)	(180,957)	373,212
Issuance of common stock in private placement, net of issuance costs of $7,119	6,471,000	7	102,881	—	—	102,888
Exercise of stock options	22,744	—	80	—	—	80
Vesting of restricted stock	—	—	11	—	—	11
Stock-based compensation	—	—	4,302	—	—	4,302
Net loss	—	—	—	—	(44,348)	(44,348)
Other comprehensive loss	—	—	—	(44)	—	(44)
Balances at June 30, 2024	45,862,391	$ 46	$ 661,683	$ (323)	$ (225,305)	$ 436,101

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

CARGO THERAPEUTICS, INC.
Condensed Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(unaudited, in thousands, except share data)

	Redeemable Convertible Preferred Stock		Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2022	—	$ —	810,700	$ 1	1,091,800	$ 1	$ 11,761	$ (46,999)	$ (35,236)
Reclassification of Series Seed redeemable convertible preferred stock	810,700	9,830	(810,700)	(1)	—	—	(9,829)	—	(9,830)
Issuance of Series A-1 redeemable convertible preferred stock, net of issuance costs of $755 and convertible preferred stock tranche asset and liability of $7,317 on issuance	5,072,919	60,760	—	—	—	—	—	—	—
Issuance of Series A-2 redeemable convertible preferred stock upon conversion of convertible notes	3,229,851	35,576	—	—	—	—	—	—	—
Issuance of restricted stock	—	—	—	—	1,874	—	—	—	—
Vesting of restricted stock	—	—	—	—	—	—	18	—	18
Repurchase of restricted stock	—	—	—	—	(4,698)	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	31	—	31
Net loss	—	—	—	—	—	—	—	(12,747)	(12,747)
Balances at March 31, 2023	9,113,470	106,166	—	—	1,088,976	1	1,981	(59,746)	(57,764)
Exercise of stock options	—	—	—	—	1,695	—	2	—	2
Vesting of restricted stock	—	—	—	—	—	—	43	—	43
Repurchase of restricted stock	—	—	—	—	(4,686)	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	592	—	592
Net loss	—	—	—	—	—	—	—	(17,852)	(17,852)
Balances at June 30, 2023	9,113,470	$ 106,166	—	$ —	1,085,985	$ 1	$ 2,618	$ (77,598)	$ (74,979)

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

CARGO THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(unaudited, in thousands)

	Six months ended June 30,	
	2024	2023
OPERATING ACTIVITIES		
Net loss	$ (80,159)	$ (30,599)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,206	623
Amortization of operating lease right-of-use assets	2,762	1,043
Depreciation	1,165	499
Acquired in-process research and development	150	466
Accretion on investments in marketable securities	(3,636)	—
Change in fair value of derivative liabilities	—	(6,453)
Loss on extinguishment of convertible notes	—	2,316
Noncash interest expense	—	1,604
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	692
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(973)	(296)
Other non-current assets	13	(3,836)
Accounts payable	2,323	1,384
Accrued clinical and research and development expenses	6,130	5,031
Accrued expenses and other current liabilities	(1,132)	(523)
Operating lease liabilities	(79)	(916)
Net cash used in operating activities	(65,230)	(28,965)
INVESTING ACTIVITIES		
Purchases of marketable securities	(360,382)	—
Proceeds from sales and maturities of marketable securities	73,799	—
Purchase of property and equipment	(2,752)	(2,054)
Purchase of in-process research and development	(830)	(59)
Net cash used in investing activities	(290,165)	(2,113)
FINANCING ACTIVITIES		
Proceeds from issuance of common stock in private placement, net of issuance costs	103,269	—
Proceeds from issuance of convertible notes, net of issuance costs - related party	—	2,212
Proceeds from issuance of convertible notes, net of issuance costs	—	1,286
Proceeds from issuance of redeemable convertible preferred stock and tranche obligations, net of issuance costs	—	68,077
Proceeds from exercise of stock options	106	2
Payment of deferred initial public offering costs	(105)	—
Payment of transaction costs for exchange of common stock for warrants	(25)	—
Net cash provided by financing activities	103,245	71,577
Net (decrease) increase in cash, cash equivalents and restricted cash	(252,150)	40,499
Cash, cash equivalents, and restricted cash at beginning of period	406,299	1,872
Cash, cash equivalents, and restricted cash at end of period	$ 154,149	$ 42,371
COMPONENTS OF CASH, CASH EQUIVALENTS, AND RESTRICTED CASH		
Cash and cash equivalents	$ 153,582	$ 42,371
Restricted cash	567	—
Total cash, cash equivalents, and restricted cash	$ 154,149	$ 42,371

CARGO THERAPEUTICS, INC.
Condensed Statements of Cash Flows
(unaudited, in thousands)

	Six months ended June 30,	
	2024	2023
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES		
Exchange of common stock for pre-funded warrants	$ 37,600	$ —
Conversion of convertible notes to shares of Series A-2 redeemable convertible preferred stock	$ —	$ 35,576
Reclassification of shares of Series Seed redeemable convertible preferred stock to mezzanine equity	$ —	$ 9,830
Purchase of property and equipment in accounts payable and accrued expenses and other current liabilities	$ 754	$ 1,612
In-process research and development costs in accounts payable, accrued expenses and other current liabilities, and other non-current liabilities	$ 493	$ 790
Deferred offering costs related to initial public offering included in accounts payable, accrued expenses and other current liabilities	$ —	$ 218
Deferred issuance costs for the second tranche of Series A-1 redeemable convertible preferred stock in accounts payable, accrued expenses and other current liabilities	$ —	$ 33
Deferred issuance costs related to the private placement, included in accounts payable, accrued expenses and other current liabilities	$ 381	$ —

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

CARGO THERAPEUTICS, INC.

Notes to Unaudited Condensed Financial Statements

1. Organization

Description of the business

CARGO Therapeutics, Inc. (the "Company") was incorporated in the state of Delaware in December 2019 as Syncopation Life Sciences, Inc. and changed its name to CARGO Therapeutics, Inc. in September 2022. It is a clinical-stage biotechnology company positioned to advance next generation, potentially curative cell therapies for cancer patients. The Company's programs, platform technologies, and manufacturing strategy are designed to directly address the key limitations of approved cell therapies, including limited durability of effect, suboptimal safety and unreliable supply. The Company's lead program, firicabtagene autoleucel (firi-cel) (previously CRG-022), an investigational autologous CD22 chimeric antigen receptor ("CAR") T-cell therapy, has demonstrated robust safety, activity and manufacturability in clinical trials and is currently being studied in a potentially pivotal Phase 2 clinical trial for the treatment of large B-cell lymphoma ("LBCL"). The Company is also leveraging its proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multi-functional genetic "cargo" designed to enhance CAR T-cell persistence, as well as help safeguard against tumor resistance and T-cell exhaustion. The Company's most advanced preclinical program, CRG-023, is a tri-specific CAR T product candidate that incorporates three distinct CARs to address either tumor antigen loss (e.g., CD19) or low-density antigen expression, loss of co-stimulation (e.g., CD2/CD58) and lack of T-cell persistence.

Since its founding, the Company has devoted substantially all of its resources to organizing and staffing the Company, business planning, raising capital, establishing licensing arrangements, building its proprietary platform technologies, discovering its product candidates, establishing its intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of its product candidates and related raw materials, and providing general and administrative support for these operations.

Reverse Stock Split

On November 1, 2023, the Company's board of directors approved an amended and restated certificate of incorporation to effect a reverse split of shares of the Company's common stock and redeemable convertible preferred stock on a 13.5685-for-1 basis (the "Reverse Stock Split") which was effected on November 3, 2023. The par value and authorized number of shares of common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All share data and per share data amounts for all periods presented in the condensed financial statements and notes thereto have been retrospectively adjusted to reflect the effect of the Reverse Stock Split.

Initial Public Offering

On November 14, 2023, the Company closed its initial public offering ("IPO"), pursuant to which it issued and sold an aggregate of 18,750,000 shares of its common stock at a public offering price of $15.00 per share and on November 21, 2023, the Company issued and sold 2,512,181 additional shares of its common stock to the underwriters of the IPO pursuant to the partial exercise of their option to purchase additional shares, resulting in net proceeds of $291.0 million, after deducting underwriting discounts, commissions and other offering expenses. Upon the closing of the IPO, the Company's 18,836,561 outstanding shares of redeemable convertible preferred stock then outstanding automatically converted into 18,836,561 shares of common stock. Following the closing of the IPO, no shares of redeemable convertible preferred stock were authorized or outstanding.

In connection with the closing of its IPO, on November 14, 2023, the Company's certificate of incorporation was amended and restated to authorize 500,000,000 shares of common stock, par value $0.001 per share and 50,000,000 shares of preferred stock, par value of $0.001 per share.

CARGO THERAPEUTICS, INC.

Notes to Unaudited Condensed Financial Statements

Liquidity

Since inception, the Company has incurred significant operating losses and negative cash flows, and it expects that it will continue to incur losses and negative cash flows for the foreseeable future as it continues its research and development efforts, advances its product candidates through preclinical and clinical development, enhances its platforms and programs, expands its product pipeline, seeks regulatory approval, prepares for commercialization, hires additional personnel, protects its intellectual property and grows its business. As of and for the six months ended June 30, 2024, the Company had an accumulated deficit of $225.3 million, cash and cash equivalents and marketable securities of $443.5 million and negative cash flows from operations of $65.2 million. The Company believes its existing cash and cash equivalents and marketable securities will be sufficient to support operations for at least 12 months from the issuance of these unaudited condensed financial statements.

2. Summary of Significant Accounting Policies

Basis of presentation

The Company has prepared the accompanying condensed financial statements in accordance with U.S. generally accepted accounting principles ("GAAP") and the requirements of the Securities and Exchange Commission ("SEC") for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP can be condensed or omitted. The financial statements are presented in U.S. dollars.

Reclassifications

Certain reclassifications of previously reported amounts have been made to conform to the current period presentation. Specifically, interest income was previously presented within other income (expense), net for the six months ended June 30, 2023 in the Registration Statement on Form S-1 filed with the SEC on November 13, 2023. Interest income is presented separately in the unaudited condensed statement of operations and comprehensive loss within these financial statements.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. The Company bases its estimates on historical experience and on various other assumptions believed to be reasonable. Actual results could differ from those estimates and such differences could be material to the financial position and results of operations.

Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses, the fair value of derivative liabilities, the initial fair value of the financial commitment liabilities related to the convertible notes, valuation of the redeemable convertible preferred stock tranche asset and liability, valuation of deferred tax assets, the fair value of equity instruments, equity-based instruments, stock-based compensation, and the determination of the incremental borrowing rate.

Unaudited interim condensed financial statements

The condensed balance sheet as of June 30, 2024 and the condensed statements of operations and comprehensive loss, condensed statement of stockholders' equity (deficit), and condensed statement of redeemable convertible preferred stock and stockholders' deficit for the three and six months ended June 30, 2024, and 2023 and condensed statements of cash flows for the six months ended June 30, 2024, and 2023 are unaudited. These unaudited condensed financial statements have been prepared on the same basis as the Company's annual financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for the fair statement of the Company's financial position, results of operations and cash flows for the interim periods presented. The condensed results of operations for the three and six months ended June 30, 2024 are not necessarily

indicative of the results to be expected for the full year or for any other future annual or interim period. The condensed balance sheet as of December 31, 2023 included herein was derived from the audited financial statements as of that date. These condensed financial statements should be read in conjunction with the Company's audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 21, 2024.

Marketable securities

The Company invests in marketable securities, primarily securities issued by the U.S. government and its agencies. All marketable securities have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable debt securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company evaluates securities for impairment at the end of each reporting period. Factors considered in the evaluation include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospect of the issuer, and the Company's intent and ability to hold the investment to allow for anticipated recovery in fair value. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit-related is reported as a component of other comprehensive loss. Realized gains and losses are included in other income (expense), net. The cost of securities sold is based on the specific-identification method. Interest earned on marketable securities is included in interest income. Accrued interest on marketable securities is included in prepaid expenses and other current assets on the balance sheets.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in Accounting Standards Codification ("ASC") 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"). This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period while the warrants are outstanding. The Company's pre-funded warrants met all the criteria for equity classification and were recorded as a component of additional paid-in capital at their fair value on issuance.

Net loss per share attributable to common stockholders

The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed using the weighted-average number of shares of common stock outstanding during the period excluding unvested restricted stock subject to repurchase. Basic net loss per share includes pre-funded warrants issued in January 2024 because the pre-funded warrants have a nominal exercise price of $0.001 per share and they were fully vested and exercisable upon their issuance. Diluted net loss per share attributable to common stockholders is computed using the sum of the weighted-average number of shares of common stock outstanding during the period and the effect of dilutive securities.

For periods when the Company's redeemable convertible preferred stock was outstanding, the holders of such shares were contractually entitled to participate in dividends but not contractually required to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. As the Company was in a net loss position for the periods presented, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders because the effects of potentially dilutive securities are antidilutive.

Recently adopted accounting pronouncements

The Company has implemented all new accounting pronouncements, which are expected to have a material impact on its condensed financial statements and does not believe that there are any other new pronouncements that have been issued that might have a material impact on its financial statements.

Recently issued accounting pronouncements not yet adopted

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting—Improvements to Reportable Segment Disclosures*. ASU 2023-07 requires disclosure of incremental segment information on an interim and annual basis and provides new segment disclosure requirements for entities with a single reportable segment. ASU 2023-07 is effective for all public companies for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The Company adopted annual requirements under ASU 2023-07 on January 1, 2024 and plans to adopt interim requirements under ASU 2023-07 on January 1, 2025. The Company will begin including financial statement disclosures in accordance with ASU 2023-07 in its Annual Report on Form 10-K for the year ending December 31, 2024.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes—Improvements to Income Tax Disclosures*. ASU 2023-09 requires consistent categories and greater disaggregation of information in the rate reconciliation, income taxes paid disaggregated by jurisdiction and certain other amendments to improve the effectiveness of income tax disclosures. ASU 2023-09 is effective for the Company beginning on January 1, 2025, with early adoption permitted. The Company is assessing the impact of the adoption of this standard on its financial statements.

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on the accompanying financial statements and disclosures.

3. Fair Value Measurement

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Carrying amounts of certain of the Company's financial instruments including, cash and cash equivalents, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities approximate fair value due to the short-term nature of these instruments.

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Notes to Unaudited Condensed Financial Statements

The following table presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of June 30, 2024:

	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)			
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 152,495	$ —	$ —	$ 152,495
Total		$ 152,495	$ —	$ —	$ 152,495
Marketable securities:					
U.S. government and agencies securities	Level 2	$ 201,494	$ —	$ (277)	$ 201,217
U.S. Treasury securities	Level 2	88,725	—	(46)	88,679
Total		$ 290,219	$ —	$ (323)	$ 289,896
Total assets		$ 442,714	$ —	$ (323)	$ 442,391

The Company's marketable securities as of June 30, 2024 mature within a year.

The following table presents the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy as of December 31, 2023:

	Valuation Hierarchy	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
		(in thousands)			
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 398,017	$ —	$ —	$ 398,017
Total		$ 398,017	$ —	$ —	$ 398,017

The valuation techniques used to measure the fair values of the Company's Level 2 financial instruments, which generally have counterparties with high credit ratings, are based on quoted market prices when available. If quoted market prices are not available, the fair value for the security is estimated under the market or income approach using pricing models with market observable inputs.

During the three and six months ended June 30, 2024, and 2023, the Company did not recognize an allowance for credit-related losses or an other-than-temporary impairment charge for any of its investments.

4. Balance Sheet Components

Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of the following:

	June 30, 2024	December 31, 2023
	(in thousands)	
Interest receivable	$ 1,343	$ 316
Other receivables	1,172	1,423
Prepaid research and development	926	825
Prepaid other	1,177	1,181
Total prepaid expenses and other current assets	$ 4,618	$ 3,745

CARGO THERAPEUTICS, INC.

Notes to Unaudited Condensed Financial Statements

Property and equipment, net

Property and equipment, net consisted of the following:

	June 30, 2024	December 31, 2023
	(in thousands)	
Laboratory equipment	$ 10,123	$ 9,644
Furniture and fixtures	180	87
Computer equipment	782	593
Leasehold improvements	679	134
Construction in progress	3,149	1,833
Property and equipment at cost	14,913	12,291
Less: accumulated depreciation	(3,076)	(1,912)
Property and equipment, net	$ 11,837	$ 10,379

Depreciation expense for the three months ended June 30, 2024, and 2023 was $0.6 million and $0.3 million, respectively, and for six months ended June 30, 2024, and 2023 was $1.2 million and $0.5 million, respectively,

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

	June 30, 2024	December 31, 2023
	(in thousands)	
Accrued compensation and related expenses	$ 3,473	$ 5,391
Accrued purchases of property and equipment	366	112
Accrued deferred offering costs	381	95
Other	1,415	1,031
Total accrued expenses and other current liabilities	$ 5,635	$ 6,629

5. Leases

In December 2023, the Company entered into a 7-year lease for 99,557 square feet of lab and office space in San Carlos, California. The agreement provides for two options to renew for three years each, which the Company is not reasonably certain to exercise. The Company is required to maintain a letter of credit for $0.6 million which has been classified as non-current restricted cash on the unaudited condensed balance sheets.

The Company also leases 31,117 square feet of lab and office space in San Mateo, California which expires in November 2024. The Company was a sublessor in two agreements for a combined 2,300 square feet of the Company's leased premises which expired in May 2023 and October 2023. In the second quarter of 2024, the Company approved the plan to cease use of the San Mateo leased premises with a planned abandonment date of August 15, 2024. In June 2024, the Company executed an amendment to terminate one of the two leases in San Mateo effective August 15, 2024. As a result, the Company reduced the operating lease liability and right-of-use asset of the modified lease by $0.3 million. The Company also accelerated the amortization of the right-of-use asset for the remaining leased premises and related leasehold improvements to recognize amortization on a straight-line basis between the approval date and the planned abandonment date.

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Notes to Unaudited Condensed Financial Statements

The future payments associated with the Company's operating lease liabilities as of June 30, 2024 were as follows:

	Amount (in thousands)
2024 (remaining six months)	$ 660
2025	4,676
2026	7,224
2027	7,441
Thereafter	25,784
Total undiscounted lease payments	45,785
Less: imputed interest	(17,647)
Total operating lease liabilities	$ 28,138

A summary of total lease costs and other information for the periods relating to the Company's operating leases was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
Operating lease cost	$ 2,418	$ 683	$ 4,667	$ 1,246
Variable lease cost	1,451	179	1,678	308
Sublease income	—	(140)	—	(220)
Total lease cost	$ 3,869	$ 722	$ 6,345	$ 1,334

	June 30, 2024	December 31, 2023
Other information:		
Weighted-average remaining lease term (in years)	6.6	6.7
Weighted-average discount rate	13.7%	13.6%

Supplemental cash flow and noncash information related to the Company's operating leases was as follows:

	Six months ended June 30,	
	2024	2023
	(in thousands)	
Cash paid for amounts included in the measurement of lease liabilities	$ 1,985	$ 1,127
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 2,291
Decrease in right-of-use assets and liabilities from lease modifications	$ 324	$ —

6. Common stock

Common stock issued and outstanding on the unaudited condensed balance sheets and statements of stockholders' equity includes shares related to restricted stock that are subject to repurchase and therefore are excluded from the reserved common stock in the table below.

CARGO THERAPEUTICS, INC.

Notes to Unaudited Condensed Financial Statements

The Company's reserved common stock, on an as-converted basis for issuance was as follows:

	June 30, 2024	December 31, 2023
Common stock options issued and outstanding under the Plan	5,973,422	3,720,455
Common stock issuable upon exercise of pre-funded warrants	1,842,499	—
Remaining shares available for issuance under the Plan	3,672,829	3,893,858
Remaining shares available for issuance under the ESPP	798,780	386,725
Total reserved common stock	12,287,530	8,001,038

Pre-funded Warrants – Exchange Agreement

In January 2024, the Company entered into an exchange agreement (the "Exchange Agreement"), with certain stockholders (the "Exchanging Stockholders"), pursuant to which the Company exchanged an aggregate of 1,842,499 shares of the Company's common stock owned by the Exchanging Stockholders for pre-funded warrants to purchase an aggregate of 1,842,499 common stock. The warrants have an exercise price of $0.001 per share and no expiration date. The pre-funded warrants are exercisable immediately and no additional consideration was rendered in the exchange. Holders of the pre-funded warrants (together with their affiliates and other attribution parties) may not exercise any portion of a pre-funded warrant if after giving effect to such exercise the holder, together with its affiliates, would beneficially own more than 9.99% (the "Exercise Limitation") of the Company's outstanding common stock immediately after exercise. At the holders' election, the Exercise Limitation may be increased or decreased to any other percentage not in excess of 9.99% and will be effective 61 days after notice of such change to the Company.

The Company determined the fair value of the pre-funded warrants issued was $37.6 million which was equal to the fair value of the shares of the exchanged common stock.

Private Placement

On May 30, 2024, the Company sold and issued 6,471,000 shares of its common stock to certain healthcare-focused institutional investors in a private placement (the "Private Placement") at $17.00 per share for gross proceeds of approximately $110.0 million. In June 2024, the Company filed a Registration Statement on Form S-1 with the SEC to register the shares of common stock sold in the Private Placement. The Company raised net proceeds of $102.9 million, after deducting placement agent fees and offering expenses of $7.1 million.

7. Stock-Based Compensation

2023 Incentive Award Plan

In November 2023, the Company's board of directors adopted the 2023 Incentive Award Plan (the "2023 Plan"). On January 1, 2024, the shares of common stock authorized for issuance under the 2023 Plan increased by 2,060,277 shares and as of June 30, 2024, a total of 3,672,829 shares of common stock were available for future issuance under the 2023 Plan.

Stock options

Stock option activity for the six months ended June 30, 2024 was as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	3,720,455	$ 7.61	9.49	$ 57,821
Granted	2,513,302	23.50		
Exercised	(28,339)	3.74		
Cancelled and forfeited	(231,996)	13.65		
Outstanding at June 30, 2024	5,973,422	$ 14.08	9.22	$ 31,187
Vested and expected to vest, June 30, 2024	5,973,422	$ 14.08	9.22	$ 31,187
Exercisable at June 30, 2024	656,807	$ 11.11	8.38	$ 5,029

Aggregate intrinsic value in the above table is calculated as the difference between the exercise price of the options and the Company's estimated fair value of its common stock as of June 30, 2024 and December 31, 2023.

The aggregate intrinsic value of options exercised during the three months ended June 30, 2024, and 2023 was $0.4 million and $7,000, respectively, and during six months ended June 30, 2024, and 2023 was $0.5 million and $7,000, respectively. The estimated weighted-average grant-date fair value of options granted during the six months ended June 30, 2024, and 2023 was $18.73 and $3.71 per share, respectively. As of June 30, 2024, there was $56.2 million of unrecognized stock-based compensation related to stock options, which is expected to be recognized over a weighted-average period of 3.3 years.

Restricted stock awards

The following table summarizes the Company's restricted stock activity.

	Number of Awards	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2023	239,699	$ 0.93
Vested	(111,001)	1.01
Unvested as of June 30, 2024	128,698	$ 0.86

The purchase price of the restricted stock awards is the fair value of common stock as determined by the board of directors at the issuance date. The shares generally vest monthly over four years from the grant date.

The Company recorded $0.1 million as a share repurchase liability for restricted stock awards in accrued expenses and other current liabilities on the unaudited condensed balance sheets as of June 30, 2024 and December 31, 2023.

As of June 30, 2024, unrecognized stock-based compensation expense related to outstanding unvested restricted stock awards was $43,000, which is expected to be recognized over a weighted-average period of 1.7 years.

Stock-based compensation expense

Total stock-based compensation expense recorded in the unaudited condensed statements of operations and comprehensive loss was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
General and administrative	$ 2,601	$ 411	$ 4,841	$ 427
Research and development	1,701	181	3,365	196
Total stock-based compensation expense	$ 4,302	$ 592	$ 8,206	$ 623

The estimated grant-date fair value of awards granted was calculated based on the following assumptions:

	Six months ended June 30,	
	2024	2023
Expected term (in years)	5.5 - 6.1	5.7 - 6.3
Expected volatility	85.7% - 104.1%	85.5% - 86.8%
Expected dividend	—	—
Risk-free interest rate	4.2% - 4.7%	3.6%

Employee Stock Purchase Plan

On November 14, 2023, the Company's board of directors adopted the 2023 Employee Stock Purchase Plan (the "ESPP") which became effective immediately. On January 1, 2024, the number of shares of common stock authorized for issuance under the ESPP increased automatically by 412,055 shares and as of June 30, 2024, a total of 798,780 shares were available for future issuance under the ESPP. There were no shares issued under the ESPP during the three and six months ended June 30, 2024.

8. License and Research and Development Agreements

Stanford license agreement

In August 2022, the Company entered into a license agreement with the Board of Trustees of the Leland Stanford Junior University ("Stanford University") relating to the Company's platform technologies relating to CAR T-cell therapies (the "Stanford License"). Pursuant to the Stanford License, Stanford University granted the Company a worldwide, exclusive license under certain patent rights, and a worldwide non-exclusive license under certain technology, in each case, owned or controlled by Stanford University, to make, use and sell products, methods or services in the field of human therapeutic and diagnostic products. The licensed patent rights cover platform technology relating to the use of CD2/CD58 co-stimulatory signaling in cell therapy.

As consideration for the licenses granted under the Stanford License, the Company made an upfront payment of $50,000 and issued 67,605 shares of its common stock with a fair value of $0.1 million, of which 22,317 shares were issued to Stanford University, 27,100 shares were issued to two non-profit organizations that supported the research, and 18,188 shares were issued to various Stanford University inventors. The Company determined that the purchase of the licenses under the Stanford License represented an asset acquisition as it did not meet the definition of a business. As the acquired licenses represented in-process research and development ("IPR&D") assets with no alternative future use, the Company recorded the upfront consideration of $0.2 million as research and development expense in August 2022, upon entering into the Stanford License.

No research and development expense pursuant to the Stanford License was recorded during both the three and six months ended June 30, 2024, and 2023.

In addition to annual license maintenance fees of up to $0.1 million per year, the Company may be required to pay up to $7.5 million upon achievement of sales milestones, up to $4.0 million upon achievement of development milestone events for each product covered by licensed patent rights, including upon initiation of specific clinical trials or receipt of regulatory approvals, up to $50,000 in a milestone payment upon achievement of a certain commercial milestone event, up to $0.5 million in a milestone payment upon achievement of certain additional development milestone events, and a double-digit percentage of development and sales milestone payments on the first two licensed non-patent products and, subject to certain royalty reductions, as applicable, low single-digit percentage royalties on net sales of products that are covered by the licensed patent rights or licensed technology. Subject to the terms of the Stanford License, the Company also agreed to pay Stanford University a certain percentage of non-royalty sublicense-related revenue that the Company receives from third-party sublicenses.

Oxford license and supply agreement

In June 2022, the Company entered into a License and Supply Agreement (the "Oxford Agreement"), with Oxford Biomedica (UK) Limited ("Oxford") for the manufacture and supply of lentiviral vectors for clinical and potentially commercial purposes by the Company. Pursuant to the Oxford Agreement, Oxford granted to the Company a non-exclusive worldwide, sub-licensable, royalty-bearing license under certain intellectual property rights for the purposes of research, development, manufacturing and commercialization of products transduced with the vectors manufactured by Oxford or by the Company following a technology transfer by Oxford, which products are directed against certain initial targets, and upon payment of certain fees, additional targets as agreed by Oxford and the Company.

As consideration for the license granted under the Oxford Agreement, the Company paid an upfront license fee of $0.2 million. The Company determined that the purchase of the license under the Oxford Agreement represented an asset acquisition as it did not meet the definition of a business. As the acquired license represented IPR&D assets with no alternative future use, the Company recorded the upfront payment of $0.2 million as research and development expense in June 2022.

In March 2024, the Company entered into an amendment to the Oxford Agreement pursuant to which Oxford and the Company agreed to an amended royalty payment structure for certain lentiviral vectors manufactured by Oxford. Under the firi-cel program the Company may be obligated to pay up to an aggregate amount of $4.8 million in regulatory and commercial milestones. This includes reduced regulatory and commercial milestones for the firi-cel program, as part of the amendment. In addition, the Company is no longer obligated to pay earned royalties on net sales of licensed products manufactured by Oxford under its firi-cel program and remains obligated to pay an earned royalty at low single-digit percentages of net sales of licensed products under its firi-cel program that are manufactured by an affiliate or a third party. Under its CRG-023 program, the Company may be obligated to pay up to an aggregate amount of $9.5 million in additional target fees, regulatory and commercial milestones and pay an earned royalty at low single-digit percentages of net sales.

No research and development expense related to the license was recorded during both the three and six months ended June 30, 2024, and 2023.

Unless terminated earlier, the Oxford Agreement will expire when no further payments are due to Oxford. The Company can terminate the agreement at will upon advance written notice and may be subject to certain manufacturing slot cancellation fees.

National Cancer Institute

In March 2022, the Company entered into an exclusive license agreement (the "2022 NCI License") with the U.S. Department of Health and Human Services, as represented by The National Cancer Institute ("NCI"), pursuant to which the Company obtained a worldwide, royalty-bearing, exclusive license under certain patent rights to make, use, sell, offer for sale, and import certain autologous products covered by such licensed patents in the field of CAR-T immunotherapies for the treatment of B-cell malignancies that express CD22, and a non-sublicensable exclusive

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license for evaluation purposes only to make, use, and import, but not sell, certain allogenic products and to practice processes in the field of certain CAR-T immunotherapies for the treatment of B-cell malignancies that express CD22 for evaluation purposes, with an exclusive option to negotiate a non-exclusive or exclusive commercialization license. In March 2024, Company exercised its right to extend the exclusive option one time for an additional year and paid an extension royalty of $50,000.

As consideration for the licenses granted under the 2022 NCI License, the Company is required to pay the NCI a non-refundable license fee of $0.6 million, of which $0.2 million was paid in 2022, $0.1 million was paid in 2023 and $0.2 million was paid in March 2024, and the remaining balance of $0.1 million is payable on the third anniversary of the effective date of the agreement. The Company accrued the non-refundable upfront fees of $0.4 million upon entering into the 2022 NCI License. Non-refundable upfront fees of $0.1 million were accrued in accrued expenses and other current liabilities as of both June 30, 2024, and December 31, 2023, and as of December 31, 2023, $0.2 million, is classified as other non-current liabilities on the unaudited condensed balance sheet. The Company determined that the purchase of the license under the 2022 NCI License represented an asset acquisition as it did not meet the definition of a business. As the acquired license represented IPR&D assets with no alternative future use, the Company recorded the initial consideration of $0.6 million under the 2022 NCI License as research and development expense in March 2022, upon entering into the 2022 NCI License. The Company recorded research and development expense of $0.1 million related to the minimum annual royalty, the option extension fee and the achievement of certain development milestones for each of the six months ended June 30, 2024, and 2023. No research and development expense related to the license was recorded during the three months ended June 30, 2024, and 2023.

The Company agreed to pay up to $0.2 million in regulatory milestone payments upon achieving specific regulatory filings, up to $1.8 million in development milestone payments upon achieving specific clinical trials or registration trials, and up to $16.0 million in sales milestones upon achievement of specific commercial milestone events for up to three distinct licensed products, and an earned royalty on net sales of autologous cell therapy products covered by the licensed patent rights and, if the Company chooses to exercise the exclusive option mentioned above, on net sales of allogenic products, at a low single-digit percentage, depending on the amount of annual net sales and subject to the terms of the 2022 NCI License. The Company is also required to make minimum annual royalty payments of $50,000 per year, which will be creditable against royalties due for sales in that year. In addition, the Company is obligated to pay the NCI a percentage of non-royalty revenue received by the Company from its right to sublicense. Additionally, in the event the Company is granted a priority review voucher (“PRV”), the Company would be obligated to pay the NCI a minimum of $5.0 million upon the sale, transfer or lease of the PRV or $0.5 million upon submission of the PRV for use by the U.S. FDA. The Company is also obligated to pay the NCI a royalty based on a percentage of the fair market value of the consideration the Company receives for any assignment of the 2022 NCI License to a non-affiliate (upon the NCI’s prior written consent) or on an allocated portion of the fair value of consideration received in connection with a change in control (including an IPO). On the closing of the Company's IPO in November 2023, the change in control milestone was met, and the Company and the NCI are in discussions regarding the amount of such payment.

The NCI may terminate or modify the 2022 NCI License in the event of an uncured material breach, including, but not limited to, if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NCI.

In February 2023, the Company entered into an exclusive license agreement (the “2023 NCI License”) with the NCI, pursuant to which the Company obtained a worldwide, royalty-bearing, exclusive license under certain patent rights owned by the NCI to make, use, sell and import products and to practice processes in the field of certain CAR-T immunotherapies for the treatment of B-cell malignancies, wherein the T cells are engineered to express CD22 in combination with binders, CARs or other receptors targeting CD19, CD20, and/or CD79b; and at least one of the following: manufacturing the product with the STASH platform technology and/or a technology to activate CD2 signaling in the CAR T cell.

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As consideration for the licenses granted under the 2023 NCI License, the Company agreed to pay the NCI a non-refundable license fee of $0.3 million in three installments whereby the first installment was payable within 60 days of the execution of the agreement and the remaining two payments are due on the first and second anniversaries of the effective date of the agreement. Additionally, the Company agreed to reimburse the NCI for $0.1 million in expenses incurred by the NCI prior to January 1, 2022, related to the preparation, filing, prosecution, and maintenance of all patent applications and patents included in the license under the 2023 NCI License. The Company determined that the purchase of the license under the 2023 NCI License represented an asset acquisition as it did not meet the definition of a business. As the acquired license represented IPR&D assets with no alternative future use, upon entering the 2023 NCI License in February 2023, the Company recorded the initial consideration of $0.4 million under the 2023 NCI License, consisting of the non-refundable upfront fees, as research and development expense. The Company accrued these amounts upon entering into the 2023 NCI License, of which $0.1 million was classified as accrued expenses and other current liabilities on the unaudited condensed balance sheet as of June 30, 2024, and the remaining $0.3 million was paid as of June 30, 2024.

The Company recorded research and development expense of $50,000 and $0.4 million related to the minimum annual royalty, the license issue royalty, the reimbursement of past patent application expenses during the six months ended June 30, 2024, and 2023, respectively. No research and development expense related to the license was recorded during the three months ended June 30, 2024, and 2023.

The Company agreed to pay up to $0.1 million in milestone payments upon achievement of certain regulatory milestone events, up to $1.7 million in milestone payments upon achievement of certain development milestone events including initiation of specific clinical trials or registration trials, and up to $16.0 million in milestone payments upon achievement of specific commercial milestone events. Subject to the terms of the 2023 NCI License, the Company also agreed to pay a low single-digit percentage on earned royalties on net sales of products covered by the licensed patent rights. The Company also agreed to make minimum annual royalty payments of $50,000 per year, which will be creditable against royalties due for sales in that year. In addition, the Company is obligated to pay the NCI a percentage of non-royalty revenue received by the Company from its right to sublicense at defined percentages. Additionally, if the Company is granted a PRV, the Company would be obligated to pay the NCI a minimum of $5.0 million upon the sale, transfer or lease of the PRV or $0.5 million upon submission of the PRV for use by the FDA. The Company is also obligated to pay the NCI a royalty based on a percentage of the fair market value of the consideration the Company receives for any assignment of the 2023 NCI License to a non-affiliate (upon the NCI's prior written consent) or on an allocated portion of the fair value of consideration received in connection with a change in control (including an IPO). On the closing of the Company's IPO in November 2023, the change in control milestone was met, and the Company and the NCI are in discussions regarding the amount of such payment.

Unless earlier terminated, the 2023 NCI License will expire upon the expiration of the last to expire licensed patent right. The NCI may terminate or modify the 2023 NCI License in the event of an uncured material breach, including, but not limited to, if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NCI.

In connection with the closing of the Company's IPO in November 2023, the Company accrued a total of $0.3 million of research and development expense within accrued clinical and research and development expenses on the balance sheet related to the change in control royalty for both the 2022 NCI License and the 2023 NCI License.

CARGO THERAPEUTICS, INC.

Notes to Unaudited Condensed Financial Statements

9. Net Loss Per Share

A reconciliation of net loss attributable to common stockholders and the number of shares in the calculation of basic and diluted loss per share was as follows:

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
	(in thousands, except share and per share amounts)			
Numerator:				
Net loss attributable to common stockholders	$ (44,348)	$ (17,852)	$ (80,159)	$ (30,599)
Denominator:				
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	43,344,345	672,253	42,170,123	634,704
Net loss per share attributable to common stockholders, basic and diluted	$ (1.02)	$ (26.56)	$ (1.90)	$ (48.21)

The following potentially dilutive shares were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis):

	June 30,	
	2024	2023
Redeemable convertible preferred stock, as converted	—	9,113,470
Outstanding stock options	5,973,422	2,147,565
Restricted stock awards subject to repurchase	128,698	372,686
Total	6,102,120	11,633,721

10. Subsequent events

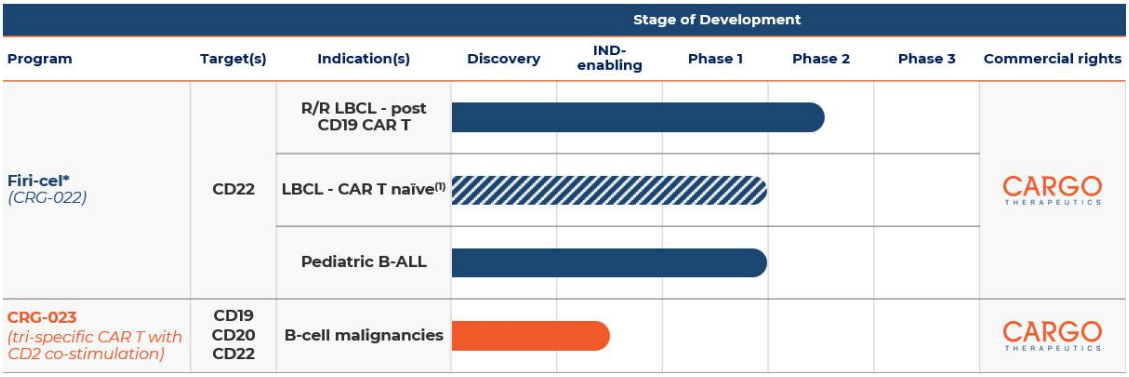
In July 2024, the Company entered into a sublease agreement (the "Sublease") with Vaxcyte, Inc. ("Vaxcyte") to sublease a portion of the Company's headquarters located at 835 Industrial Road, San Carlos, California 94070. The portion of the premises subject to the Sublease is approximately 38,200 square feet. The Sublease term will end on the day that is the last day of the 24th month from the commencement date, with Vaxcyte having the right to extend the term of the Sublease for one additional 12-month period unless the Company intends to reoccupy the space, unless sooner terminated or cancelled in accordance with the terms and conditions of the Sublease. The Sublease did not relieve the Company of its obligations under the primary lease. The total undiscounted lease payments due from the sublessee related to the initial term of the lease are $4.8 million.

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

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto for the year ended December 31, 2023, included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission, or the SEC, on March 21, 2024. This discussion and analysis contains forward-looking statements based upon current beliefs, plans, and expectations related to future events and our future performance that involves 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 discussed in the forward-looking statements as a result of several factors including those set forth in the section titled "Risk Factors." See also the section titled "Special Note Regarding Forward-Looking Statements".

Overview

We are a clinical-stage biotechnology company uniquely positioned to advance next generation, potentially curative cell therapies for cancer patients. Our programs, platform technologies, and manufacturing strategy are designed to directly address the limitations of approved chimeric antigen receptor (CAR) T-cell therapies. A CAR is an engineered protein that is delivered into T cells, enabling recognition and destruction of cancer cells. We believe the limitations of approved autologous CAR T- cell therapies include limited durability of effect, safety concerns and unreliable supply. Our lead program, firicabtagene autoleucel (firi-cel) (previously CRG-022), is an investigational autologous (derived from a patient's cells) T-cell product candidate expressing a CD22 CAR that is designed to enable the detection of B-cell lymphoma tumor cells. The underlying CAR, which we exclusively licensed from the National Cancer Institute (NCI) in the field of CAR-T immunotherapies for the treatment of B-cell malignancies that express CD22, was studied by Stanford University (Stanford) in a Phase 1 clinical trial in patients with large B-cell lymphoma (LBCL) whose disease relapsed or was refractory (R/R) to CD19 CAR T-cell therapy. On the basis of the results from the clinical trial, we are evaluating firi-cel in a potentially pivotal Phase 2 clinical trial in patients with LBCL whose disease is R/R to CD19 CAR T-cell therapy. We also plan to evaluate firi-cel in patients at earlier stages of disease, including LBCL and other hematologic malignancies. Beyond our lead program, we are leveraging our proprietary cell engineering platform technologies to develop a pipeline of programs that incorporate multiple transgene therapeutic "cargo" designed to enhance CAR T-cell persistence, as well as to help safeguard against tumor resistance and T-cell exhaustion. Our most advanced preclinical program, CRG-023, is a tri-specific CAR T product candidate that incorporates three distinct CARs to address either tumor antigen loss (e.g., CD19) or low-density antigen expression, loss of co-stimulation (e.g., CD2/CD58) and lack of T-cell persistence. Our founders are pioneers and world-class experts in CAR T-cell therapy, and our team has significant experience and success developing, manufacturing, launching and commercializing oncology and cell therapy products. We aim to become a fully integrated, leading cell therapy company. Together, we are united in our mission to outsmart cancer and deliver more cures for patients.



(1) Based on data from the Phase 1 clinical trial conducted by Stanford and pending data from our ongoing Phase 2 clinical trial in R/R LBCL – post CD19 CAR T, we are in discussions with the FDA on the initiation of a Phase 2 program in LBCL – CAR T naïve without completing earlier clinical trials in LBCL – CAR T-naïve patients.

* firicabtagene autoleucel

We have incurred significant operating losses and negative cash flows since our inception. Since our founding, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, establishing licensing arrangements, building our proprietary platform technologies, discovering our product candidates, establishing our intellectual property portfolio, conducting research, preclinical studies, and clinical trials, establishing arrangements with third parties for the manufacture of our product candidates and related raw materials, and providing general and administrative support for these operations.

Our net losses were $44.3 million and $17.9 million for the three months ended June 30, 2024, and 2023, respectively, and $80.2 million and $30.6 million for the six months ended June 30, 2024, and 2023 respectively. As of June 30, 2024, we had an accumulated deficit of $225.3 million and cash and cash equivalents and marketable securities of $443.5 million. Based on our current operating plans, we estimate that our existing cash and cash equivalents and marketable securities as of June 30, 2024 will be sufficient to meet our working capital and capital expenditures through 2026. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

We expect to continue to incur significant and increasing net operating losses for the foreseeable future as we:

- advance our product candidates through clinical and preclinical development;
- seek regulatory approval, prepare for and, if approved, proceed to commercialization of our product candidates;
- continue our research and development efforts and expand our pipeline of product candidates;
- attract, hire and retain additional personnel;
- maintain, expand and protect our intellectual property portfolio;
- operate as a public company;
- implement operational, financial and management information systems;
- make royalty, milestone or other payments under current, and any future, license or collaboration agreements;
- potentially seek to identify, acquire or in-license new technologies or product candidates;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain marketing approval;
- potentially experience any delays, challenges, or other issues associated with the clinical development of our product candidates, including with respect to our regulatory strategies; and
- develop manufacturing processes and methods and establish manufacturing capacity to supply for clinical trials in our pipeline and eventually for commercialization, if approved.

Our net losses may fluctuate significantly from period to period, depending upon the timing of our expenditures on other research and development activities. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued research and development and other current liabilities.

To date, we have funded our operations primarily with the proceeds from the sale and issuance of our convertible preferred stock and convertible notes as well as the sale and issuance of our common stock. We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with therapeutic product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise substantial additional capital. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to fund our operations through public or private equity offerings or debt financings, credit or loan facilities, potentially other capital sources, such as

collaboration or licensing arrangements with third parties or other strategic transactions, or a combination of one or more of these funding sources. If we are unable to obtain adequate funding as and when needed, or on attractive terms, we could be required to significantly delay, reduce or eliminate some or all of our research and development activities, product portfolio expansion or commercialization efforts, out-license intellectual property rights to our product candidates, sell unsecured assets, or scale back or terminate our pursuit of new strategic arrangements and transactions, or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all. See the subsection titled "Management's Discussion and Analysis of Financial Condition and Results of Operations – *Liquidity and capital resources*" below.

We utilize third-party contract development and manufacturing organizations (CDMOs), to manufacture and supply our preclinical and clinical materials during the development of our product candidates, as well as third-party contract research organizations (CROs) to conduct our clinical trials and preclinical studies. We expect to use similar contract resources for the commercialization of our products, at least until our resources and operations are at a scale that justifies investment in internal manufacturing capabilities. The terms and conditions for each of the CDMOs are defined in the respective manufacturing and supply agreements.

Components of operating results

Operating expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and development expenses

Our research and development expenses consist of direct costs, including manufacturing and technical operations, preclinical and clinical fees paid to CROs, supplies, health authority filings, technology licenses and in-process research and development (IPR&D) assets as well as indirect costs consisting of employee-related costs and allocated facilities and other operating costs.

We expense all research and development costs in the periods in which such costs are incurred. Since we are engaged in multiple research and development programs at any one time, we track our direct costs by the stage of program, clinical or preclinical. Our indirect costs are not directly tied to any one program and are deployed across multiple programs, and as such, we do not track indirect costs on a specific program basis.

We cannot reasonably determine the nature, timing, and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. Product candidates in later stages of development generally have higher development costs than those in earlier stages. We expect that our research and development expenses will increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates as our product candidates advance into later stages of development, as we begin to conduct clinical trials, as we seek regulatory approvals for any product candidates that successfully complete clinical trials, as we expand our product pipeline, as we maintain, expand, protect and enforce our intellectual property portfolio, and as we incur expenses associated with hiring additional personnel to support our research and development efforts.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. Our research and development expenses may vary significantly based on factors such as:

- the number and scope of preclinical and IND-enabling studies;
- the phases of development of our product candidates;
- the progress and results of our research and development activities;
- per subject trial costs;
- the number of trials required for regulatory approval;

- the number of sites included in the trials;
- the countries in which the trials are conducted;
- length of time required to enroll eligible subjects and initiate clinical trials;
- the number of subjects that participate in the trials;
- the drop-out and discontinuation rate of subjects;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of subject participation in the trials and follow-up;
- the cost and timing of manufacturing of our product candidates;
- the timing of licensing milestone payments related to development, regulatory, manufacturing and commercial events;
- manufacturing success with patient materials;
- the receipt of regulatory approvals from applicable regulatory authorities;
- mitigation/responses to potential health authority questions, and/or inspections;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the outcome of interactions with the FDA and other non-U.S. health authorities that may require extension or modification of our potentially pivotal Phase 2 clinical trial;
- the hiring and retention of research and development personnel;
- the degree to which we obtain, maintain, defend and enforce our intellectual property rights; and
- the extent to which we establish collaboration, licensing or similar arrangements and the performance of any related third parties.

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.

General and administrative expenses

Our general and administrative expenses consist primarily of employee-related costs and expenses for outside services, including legal, human resources, audit, and accounting services, as well as facilities and other operating costs not included in research and development expenses. We expect that our general and administrative expenses will increase for the foreseeable future to support our expanding headcount and operations, and as we advance our product candidates through clinical development. We also expect to continue to incur additional costs associated with operating as a public company, including increased expenses related to legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, investor and public relations costs, and other administrative and professional services.

Interest income

Interest income includes interest income earned on our cash, cash equivalents, marketable securities, and restricted cash and non-cash interest income related to accretion of the discount on marketable securities.

Interest expense

Interest expense primarily consisted of accrued interest, amortization of debt discounts and issuance costs related to our convertible notes that were settled in February 2023.

Net change in fair value of redeemable convertible preferred stock tranche obligations

The net change in fair value of redeemable convertible preferred stock tranche obligations consists of measurement gains or losses recorded on subsequent remeasurement of the redeemable convertible preferred stock tranche asset and liability related to our Series A-1 redeemable convertible preferred stock. We remeasured the fair value of the redeemable convertible preferred stock tranche asset and liability until their settlement in July and October 2023, respectively, upon issuance of the second and third tranche of Series A-1 redeemable convertible preferred stock.

Change in fair value of derivative liabilities

The change in fair value of derivative liabilities consists of measurement losses recorded on subsequent remeasurement of derivative liabilities related to our convertible notes. We remeasured the fair value of the derivative liabilities until the underlying convertible notes were settled through conversion in February 2023.

Loss on extinguishment of convertible notes

The loss on extinguishment of convertible notes consists of the loss realized upon conversion of our convertible notes into Series A-2 redeemable convertible preferred stock in February 2023.

Other expense, net

Other expense, net consists primarily of costs allocated to the redeemable preferred stock tranche obligations issued in connection with Series A-1 redeemable convertible preferred stock issued in February 2023 and foreign currency gains and losses.

Results of operations

Comparison of the three months ended June 30, 2024, and 2023

Our results of operations for each of the periods indicated are summarized in the table below (in thousands):

	Three months ended June 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 37,458	$ 13,929	$ 23,529
General and administrative	11,860	3,867	7,993
Total operating expenses	49,318	17,796	31,522
Loss from operations	(49,318)	(17,796)	(31,522)
Interest income	4,987	578	4,409
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	(634)	634
Other expense, net	(17)	—	(17)
Net loss	$ (44,348)	$ (17,852)	$ (26,496)

Research and development expenses

	Three months ended June 30,		
	2024	2023	Change
	(in thousands)		
Direct costs:			
Manufacturing and technical operations	$ 17,084	$ 5,838	$ 11,246
Preclinical and clinical	5,312	1,322	3,990
Consultants and other outside services	798	728	70
License fees	—	—	—
Indirect costs:			
Employee-related costs	9,336	4,176	5,160
Facilities and other operating costs	4,928	1,865	3,063
Total research and development expenses	$ 37,458	$ 13,929	$ 23,529

Research and development expenses were $37.5 million and $13.9 million for the three months ended June 30, 2024, and 2023, respectively. The $23.5 million increase in research and development expenses during this period was primarily due to:

- $11.2 million increase in manufacturing and technical operations costs and $4.0 million increase in preclinical and clinical costs, of which $3.9 million related to the clinical costs for the continued development of firi-cel through our Phase 2 clinical trial which was initiated in the third quarter of 2023;
- $5.2 million increase in employee-related costs due to increased headcount on our research and development teams to support our development efforts, including a $1.5 million increase in stock-based compensation expense for research and development employees; and
- $3.1 million increase in facilities and other operating costs primarily related to our new facility lease that was entered into in December 2023, depreciation expense related to more lab equipment in use in 2024 and increased allocated overhead as a result of our continued growth.

General and administrative expenses

	Three months ended June 30,		
	2024	2023	Change
	(in thousands)		
Employee-related costs	$ 6,270	$ 1,225	$ 5,045
Outside services	3,751	2,378	1,373
Facilities and other operating costs	1,839	264	1,575
Total general and administrative expenses	$ 11,860	$ 3,867	$ 7,993

General and administrative expenses were $11.9 million and $3.9 million for the three months ended June 30, 2024, and 2023, respectively. The $8.0 million increase in general and administrative expenses during this period was primarily due to:

- $5.0 million increase in employee-related costs due to higher headcount in our finance and administrative personnel, including a $2.2 million increase in stock-based compensation expense for general and administrative employees;
- $1.4 million increase in outside services costs related to legal, accounting, audit, and insurance costs; and
- $1.6 million increase in facilities and other operating costs primarily related to our facility lease that was entered into in December 2023 and software license fees incurred in 2024.

Interest Income

Interest income was $5.0 million and $0.6 million in the three months ended June 30, 2024, and 2023, respectively. The $4.4 million increase was primarily due to higher interest income from our cash, cash equivalents,

restricted cash and marketable securities as a result of higher balances during the three months ended June 30, 2024 as a result of our IPO in November 2023 and private placement in May 2024.

Net change in fair value of redeemable convertible preferred stock tranche obligations

The net change in fair value of redeemable convertible preferred stock tranche obligations related to our Series A Agreement executed in February 2023 was a net loss of $0.6 million in the three months ended June 30, 2023 primarily from the increase in the fair value of the tranche obligation liability that was settled in October 2023 due to the change in the fair value of the underlying shares of our Series A-1 redeemable convertible preferred stock. The fair value of the tranche obligation asset that was settled in July 2023 did not materially change in the period.

Comparison of the six months ended June 30, 2024, and 2023

Our results of operations for each of the periods indicated are summarized in the table below (in thousands):

	Six months ended June 30,		
	2024	2023	Change
Operating expenses:			
Research and development	$ 67,961	$ 26,491	$ 41,470
General and administrative	22,163	6,552	15,611
Total operating expenses	90,124	33,043	57,081
Loss from operations	(90,124)	(33,043)	(57,081)
Interest income	9,992	683	9,309
Interest expense	—	(1,604)	1,604
Net change in fair value of redeemable convertible preferred stock tranche obligations	—	(692)	692
Change in fair value of derivative liabilities	—	6,453	(6,453)
Loss on extinguishment of convertible notes	—	(2,316)	2,316
Other expense, net	(27)	(80)	53
Net loss	$ (80,159)	$ (30,599)	$ (49,560)

Research and development expenses

	Six months ended June 30,		
	2024	2023	Change
Direct costs:			
Manufacturing and technical operations	$ 30,795	$ 11,835	$ 18,960
Preclinical and clinical	8,335	2,098	6,237
Consultants and other outside services	2,021	1,161	860
License fees	150	465	(315)
Indirect costs:			
Employee-related costs	17,731	7,698	10,033
Facilities and other operating costs	8,929	3,234	5,695
Total research and development expenses	$ 67,961	$ 26,491	$ 41,470

Research and development expenses were $68.0 million and $26.5 million for the six months ended June 30, 2024, and 2023, respectively. The $41.5 million increase in research and development expenses during this period was primarily due to:

- $19.0 million increase in manufacturing and technical operations costs, as well as increases in preclinical and clinical costs of $6.2 million and consultants and other outside services costs of $0.9 million, primarily related to the clinical costs for the continued development of firi-cel through our Phase 2 clinical trial which was initiated in the third quarter of 2023;

- $10.0 million increase in employee-related costs due to increased headcount on our research and development teams to support our development efforts, including a $3.2 million increase in stock-based compensation expense for research and development employees; and
- $5.7 million increase in facilities and other operating costs primarily related to our new facility lease that was entered into in December 2023, depreciation expense related to more lab equipment in use in 2024 and increased allocated overhead as a result of our continued growth.

The above increases in research and development expenses were partially offset by a $0.3 million decrease in license fees primarily related to accrual of upfront fees in the six months ended June 30, 2023 upon entering into the 2023 NCI License, with no comparable new licenses entered in the six months ended June 30, 2024.

General and administrative expenses

	Six months ended June 30,		
	2024	2023	Change
	(in thousands)		
Employee-related costs	$ 11,744	$ 2,549	$ 9,195
Outside services	7,348	3,557	3,791
Facilities and other operating costs	3,071	446	2,625
Total general and administrative expenses	$ 22,163	$ 6,552	$ 15,611

General and administrative expenses were $22.2 million and $6.6 million for the six months ended June 30, 2024, and 2023, respectively. The $15.6 million increase in general and administrative expenses during this period was primarily due to:

- $9.2 million increase in employee-related costs due to higher headcount in our finance and administrative personnel, including a $4.4 million increase in stock-based compensation expense for general and administrative employees;
- $3.8 million increase in outside services costs related to legal, accounting and audit costs, as well as an increase in outsourced human resource services; and
- $2.6 million increase in facilities and other operating costs primarily related to our facility lease that was entered into in December 2023 and software license fees incurred in 2024.

Interest Income

Interest income was $10.0 million and $0.7 million in the six months ended June 30, 2024, and 2023, respectively. The $9.3 million increase was primarily due to higher interest income from our cash, cash equivalents, restricted cash and marketable securities as a result of higher balances during the six months ended June 30, 2024 as a result of proceeds from our IPO in November 2023 and private placement in May 2024.

Interest expense

Interest expense was $1.6 million in the six months ended June 30, 2023 related to our convertible notes that were settled through conversion in February 2023.

Net change in fair value of redeemable convertible preferred stock tranche obligations

The net change in fair value of redeemable convertible preferred stock tranche obligations related to our Series A Agreement executed in February 2023 was a net loss of $0.7 million in the six months ended June 30, 2023 primarily from the increase in the fair value of the tranche obligation liability that was settled in October 2023 due to the change in the fair value of the underlying shares of our Series A-1 redeemable convertible preferred stock. The fair value of the tranche obligation asset that was settled in July 2023 did not materially change in the period.

Change in fair value of derivative liabilities

The change in fair value of derivative liabilities associated with our convertible notes was a gain of $6.5 million in the six months ended June 30, 2023. This change was primarily due to the conversion of our convertible notes into shares of Series A-2 redeemable convertible preferred stock in February 2023.

Loss on extinguishment of convertible notes

The loss on extinguishment of convertible notes was $2.3 million in the six months ended June 30, 2023. In February 2023, the convertible notes were converted into shares of our Series A-2 redeemable convertible preferred stock at a conversion price of $10.18 per share, which exceeded the carrying value of the convertible notes and embedded derivative liabilities at the time, and resulted in a loss upon extinguishment.

Other expense, net

Other expense, net was $27,000 and $80,000 in the six months ended June 30, 2024, and 2023, respectively. The decrease of $53,000 is primarily due to costs incurred and allocated to the redeemable preferred stock tranche obligations issued in connection with Series A-1 redeemable preferred stock issued in February 2023.

Liquidity and capital resources

Since our inception, we have funded our operations primarily with the proceeds from the sale and issuance of common stock from our IPO in November 2023 and private placement in May 2024, as well as from the sale and issuances of our convertible preferred stock and convertible notes. On May 30, 2024, we sold and issued 6,471,000 shares of our common stock for net proceeds of approximately $102.9 million in a private placement, after deducting placement agent fees and offering expenses of $7.1 million.

To date, we have incurred significant losses and negative cash flows from operations. As of June 30, 2024, we had available cash and cash equivalents and marketable securities of $443.5 million, which were available to fund operations, and an accumulated deficit of $225.3 million.

We expect to continue to incur significant operating losses in the foreseeable future to support our planned continued development of one or more of our product candidates. Based on our current operating plans, we estimate that our existing cash and cash equivalents and marketable securities as of June 30, 2024 will be sufficient to meet our working capital and capital expenditure needs through 2026. We have based this estimate on our current assumptions, which may prove to be wrong, and we may exhaust our available capital resources sooner than we expect.

Future funding requirements

Because of the numerous risks and uncertainties associated with research, development, manufacturing, supply and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our product candidates or any future product candidates, and conducting preclinical and clinical studies;
- manufacturing success;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the cost of our product candidates, any future product candidates and any products we successfully commercialize;

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the expenses needed to attract and retain skilled personnel;
- the costs of operating as a public company;
- the effect of macroeconomic trends including inflation and rising interest rates;
- addressing any potential supply chain interruptions or delays; and
- the timing, receipt and amount of sales of any future approved or cleared products, if any.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise substantial additional capital. Based upon our current operating plans, we believe that our existing cash and cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the next 12 months following the issuance of our condensed financial statements. However, until such time as we can generate significant product revenue, if ever, we expect to fund our operations through public or private equity offerings or debt financings, creditor loan facilities, potentially other capital sources, such as collaborations or licensing arrangements with third parties or other strategic transactions, or a combination of one or more of these funding sources. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect to continue to expend significant resources for the foreseeable future.

If we raise additional capital through the sale of equity or convertible debt securities, ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. If we raise additional capital through debt or preferred equity financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments, or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, license agreements, strategic transactions or other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. If we are unable to obtain adequate funding as and when needed, or on attractive terms, we could be required to significantly delay, reduce or eliminate some or all of our research and development activities, product portfolio expansion or commercialization efforts, out-license intellectual property rights to our product candidates, sell unsecured assets, or scale back or terminate our pursuit of new strategic arrangements and transactions, or a combination of the above, any of which may have a material adverse effect on our business, results of operations, financial condition and/or our ability to fund our scheduled obligations on a timely basis or at all. Our ability to continue as a going concern is dependent upon our ability to successfully accomplish these plans and secure sources of financing and ultimately attain profitable operations.

Cash flows

Our cash flows for each of the periods indicated are summarized in the table below (in thousands):

	For the six months ended June 30,	
	2024	2023
Cash used in operating activities	$ (65,230)	$ (28,965)
Cash used in investing activities	(290,165)	(2,113)
Cash provided by financing activities	103,245	71,577
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (252,150)	$ 40,499

Operating activities

Cash used in operating activities of $65.2 million for the six months ended June 30, 2024 was primarily attributable to our net loss of $80.2 million, partially offset by $8.6 million in non-cash adjustments and a $6.2 million decrease in our working capital. Non-cash adjustments consisted primarily of $8.2 million in stock-based compensation, $2.8 million in amortization of right-of-use assets and $1.2 million in depreciation, partially offset by $3.6 million in accretion on marketable securities. The $6.2 million decrease in working capital is primarily due to a $6.1 million increase in accrued clinical, research and development expense, and a $2.3 million increase in accounts payable driven by increased research and development expenses mainly related to manufacturing and technical operations, preclinical and clinical, and employee-related expenses, partially offset by a $1.1 million decrease in accrued expenses and other current liabilities primarily due to payment of the accrued annual bonus and a $1.0 million increase in prepaid expenses and other current assets.

Cash used in operating activities of $29.0 million for the six months ended June 30, 2023 was primarily attributable to our net loss of $30.6 million, a $0.9 million decrease in our working capital and a $0.7 million in non-cash adjustments. The $0.9 million decrease in working capital is primarily due to a $5.0 million increase in accrued clinical and research and development expense driven by increased research and development expenses mainly related to manufacturing and technical operations, preclinical and clinical, and employee-related expenses and $1.4 million increase in accounts payable driven by the timing of payments, partially offset by a $3.8 million increase in other assets primarily related to a deposit paid for clinical trial services, a $0.9 million decrease in operating lease liabilities, a $0.5 million decrease in accrued expenses and other current liabilities primarily due to payment of the accrued annual bonus and a $0.3 million increase in prepaid expenses and other current assets. Non-cash adjustments consisted primarily of a $6.5 million gain from the change in fair value of derivative liabilities related to our convertible notes, partially offset by a $2.3 million loss on extinguishment related to an amendment and conversion of our outstanding convertible notes into shares of our Series A-2 redeemable preferred stock in February 2023, $1.6 million in noncash interest expense primarily related to additional issuances of our convertible notes, $1.0 million in amortization of right-of-use assets, $0.7 million from the net change in fair value of tranche obligations related to our Series A-1 redeemable convertible preferred stock, $0.6 million in stock-based compensation, $0.5 million in acquisition of in-process research and development primarily related to upfront fees accrued upon entering into the 2023 NCI License and fees incurred related to achievement of certain development milestones and $0.5 million in depreciation.

Investing activities

Cash used in investing activities of $290.2 million for the six months ended June 30, 2024 consisted of $360.4 million in purchases of marketable securities, $2.8 million in purchases of equipment for our research and development activities, leasehold improvements and purchase of furniture for our new offices, and $0.8 million from the purchase of in-process research and development comprised of fees paid related to our license agreements, partially offset by $73.8 million of proceeds from sales and maturities of marketable securities.

Cash used in investing activities of $2.1 million for the six months ended June 30, 2023 consisted of $2.0 million in purchases of equipment for our research and development activities and $0.1 million from the purchase of in-process research and development comprised of fees paid related to our license agreements.

Financing activities

Cash provided by financing activities of $103.2 million for the six months ended June 30, 2024 consisted of $103.3 million in net proceeds from issuance of common stock in the private placement and $0.1 million in proceeds from exercise of stock options, partially offset by $0.1 million in payments of deferred initial public offering costs and transaction costs for exchange of common stock for warrants.

Cash provided by financing activities of $71.6 million for the six months ended June 30, 2023 primarily consisted of $68.1 million in net proceeds from issuance of Series A-1 redeemable convertible preferred stock and $3.5 million in net proceeds from issuance of convertible notes payable, of which $2.2 million was from related parties.

Off-balance sheet arrangements

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Contractual obligations and commitments

Leases

We have entered into lease arrangements for facilities, which comprise of office and laboratory space, through March 31, 2031. As of June 30, 2024, our total fixed lease payment obligations outstanding are $45.8 million, of which $1.8 million is payable within 12 months.

License agreements

Our contractual obligations are expected to affect our liquidity and cash flows in future periods. Under our license agreements with our research institution partners, we are required to make payments upon successful completion and achievement of certain milestones as well as royalty payments upon sales of products covered by such licenses. The payment obligations under the license fees are recorded in accrued liabilities as such payments are not contingent on future events. The remaining payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, clinical, regulatory, and commercial milestones. To the extent that the timing of these future milestone payments is not known, we have not included these fees in our condensed balance sheet as of June 30, 2024.

Critical accounting policies and significant judgments and estimates

Management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these 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 financial statements, as well as the reported 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 and any such differences may be material.

There have been no material changes to our critical accounting estimates from those described under our "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Estimates" included in our Annual Report on Form 10-K for the year ended December 31, 2023.

Emerging growth company and smaller reporting company status

We are an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). 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 this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recent accounting pronouncements

See Note 2 to our condensed financial statements included in Item 1 of this Quarterly Report on Form 10-Q for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities and Exchange Act of 1934, as amended (the Exchange Act) and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

As of June 30, 2024, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, solely as a result of the material weakness in our internal control over financial reporting described below, as of June 30, 2024, our disclosure controls and procedures were not 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.

Changes in Internal Control over Financial Reporting

There are no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control financial reporting.

In preparing the financial statements as of and for the year ended December 31, 2022, we identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses, which remain unremediated as of June 30, 2024. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

The material weaknesses identified in our internal control over financial reporting related to: (i) an insufficient complement of personnel with an appropriate level of technical knowledge to create the proper environment for effective internal control over financial reporting, (ii) the lack of an effective risk assessment process, (iii) the lack of formalized processes and control activities to support the appropriate segregation of duties over the review of account reconciliations and journal entries and (iv) the lack of monitoring and communication of control processes and relevant accounting policies and procedures.

To remediate these material weaknesses, we are in the process of implementing measures designed to review and document financial processes and controls, formalizing policies and procedures to improve our internal controls over financial reporting, as well as hiring of qualified resources to the finance department, including supervisory roles.

While we believe that these efforts will improve our internal control over financial reporting, the design and implementation of our remediation is ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently a party to any material legal proceedings. From time to time, we may, however, in the ordinary course of business become involved in legal proceedings. Regardless of outcome, litigation could have a material adverse effect on us due to defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 1A. Risk Factors.

Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, as well as the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, before making investment decisions regarding our common stock. The risks described below are not the only ones facing us. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, reputation or results of operations. In such case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment.

Risks related to our limited operating history, financial condition and need for additional capital

We are a clinical-stage biotechnology company and have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability.

We are a clinical-stage biotechnology company with a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant losses since our inception in December 2019, have no products approved for commercial sale, have not generated any revenue from product sales, have financed our operations principally through private placements of convertible preferred stock, convertible promissory notes and our initial public offering of our common stock and expect to incur significant losses for the foreseeable future. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Our net loss was $44.3 million and $17.9 million for the three months ended June 30, 2024, and 2023, respectively, and $80.2 million and $30.6 million for the six months ended June 30, 2024, and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of $225.3 million. Our losses have resulted principally from expenses incurred in connection with our research and development activities, including our clinical and preclinical development activities, as well as the buildout of our platform technologies such as our CD2 platform, and from general and administrative costs associated with our operations.

We have devoted a significant portion of our financial resources and efforts to building our organization, conducting research and development, identifying and developing potential product candidates, executing preclinical studies and clinical trials, building and enhancing our platform technologies, organizing and staffing our company, business planning, establishing, maintaining and protecting our intellectual property portfolio, raising capital and providing general and administrative support for these operations. We are in the early stages of clinical development and have not completed development and commercialization of any of our product candidates.

We expect our expenses and operating losses will continue to increase substantially for the foreseeable future as we expand our research and development efforts, expand the capabilities of our platform technologies, conduct clinical trials and preclinical studies, seek regulatory approval and commercialization of our product candidates and operate as a public company. We anticipate that our expenses will continue to increase substantially as we:

- continue clinical and preclinical development of our current and future product candidates and initiate additional clinical trials and preclinical studies;
- continue to build out and enhance our platform technologies;
- seek regulatory approval of our current and future product candidates;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical and preclinical development, manufacturing and commercialization efforts;
- acquire or in-license additional product candidates, technologies and other assets for our business;
- continue to develop, perfect, maintain and protect 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.

To become and remain profitable, we must succeed in identifying, developing, conducting successful clinical trials, obtaining regulatory approval for and eventually commercializing, manufacturing and supplying products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical studies of our product candidates, continuing to discover and develop additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, developing manufacturing processes and methods, devising and implementing processes for transferring technology and manufacturing processes to a network of third-party manufacturing sites, establishing necessary quality control, ensuring current Good Manufacturing Practice (cGMP) readiness, establishing marketing capabilities, commercializing and ultimately selling any products. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If we are unable to achieve or sustain profitability or to meet outside expectations for our profitability, the price of our common stock could be materially adversely affected.

Because of the numerous risks and uncertainties associated with pharmaceutical and biotechnology products and drug development, including the development of cell therapy product candidates, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration (FDA) or comparable foreign regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any of our product candidates, our expenses could increase and any potential commercial revenue could be further delayed and become more uncertain, which will have a material adverse impact on our business.

Our limited operating history may make it difficult to evaluate our prospects and likelihood of success.

We are a clinical-stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. Since our inception in December 2019, we have devoted substantially all of our resources and efforts to building our organization, in-licensing technologies, building our platform technologies, identifying and developing potential product candidates, preparing for, and as the case may be, initiating clinical trials and preclinical studies, developing manufacturing processes and methods, devising and implementing processes for transferring technology and manufacturing processes to a network of third-party manufacturing sites, ensuring supply of critical reagents and final products to support the clinical trials and eventually commercialization, organizing and staffing our company, business planning, establishing, maintaining and protecting our intellectual property portfolio, raising capital and providing general and administrative support for these operations. All of our product candidates are in either clinical development or in preclinical stages of development, and we have not yet demonstrated our ability to successfully complete any late-stage or registrational 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. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, any predictions you may make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, it could have a material adverse effect on our business.

We will require additional funding in order to finance operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs, commercialization efforts or other operations.

Developing biotechnology products, including conducting clinical trials and preclinical studies, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and our expenses will continue to increase in connection with our ongoing activities,

particularly as we conduct our ongoing and planned preclinical studies and clinical trials of, and seek regulatory approval for, our current product candidates and future product candidates we may develop or otherwise acquire. In addition, as our product candidates progress through development and toward commercialization, we will need to make milestone payments to the licensors and other third parties from whom we have in-licensed our product candidates or certain proprietary products used in the manufacturing of our clinical products, including The Board of Trustees of the Leland Stanford Junior University (Stanford University), The National Cancer Institute (the NCI) and Oxford Biomedica. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate, including manufacturing and supply costs, as well as costs associated with establishing a sales and end-to-end supply chain management infrastructure. To date, we have funded our operations principally through private financings and our recently completed initial public offering. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue the clinical and preclinical development and manufacturing of our product candidates, continuing to develop and enhance our platform technologies, commence additional clinical trials and preclinical studies and continue to identify and develop additional product candidates.

In addition, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and end-to-end supply chain management between the treatment sites and manufacturing sites. Furthermore, following the completion of our initial public offering, we have incurred, and expect to continue to incur, additional costs as we operate as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future regulatory approval or commercialization efforts.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other capital sources, including potential collaborations, licenses and other similar arrangements. We may also raise additional financing on an opportunistic basis in the future. We expect to continue to expend significant resources for the foreseeable future. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including but not limited to:

- the scope, timing, progress, costs and results of discovery, preclinical development and clinical trials for our current or future product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- the costs, timing and outcome of regulatory review of any of our current or future product candidates;
- the costs associated with developing and enhancing our platform technologies, including our current CD2 platform;
- the costs associated with acquiring or licensing additional product candidates, technologies or assets, including the timing and amount of any future milestone, royalty or other payments due in connection with such acquisition or license;
- the cost of manufacturing clinical and commercial supplies of our current or future product candidates, including the costs associated with end-to-end supply chain management between the treatment sites and manufacturing sites;
- 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, including any claims by third parties that we are infringing upon their intellectual property rights;
- our ability to maintain existing, and establish new, strategic collaborations or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;

- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and end-to-end supply chain management, for any of our product candidates for which we receive regulatory approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive regulatory approval;
- expenses to attract, hire and retain skilled personnel;
- the costs of operating as a public company;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- addressing any potential interruptions or delays resulting from factors related to health epidemics, pandemics, other widespread outbreaks of contagious disease, and adverse political events such as government shutdowns;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in business, products and technologies.

Our ability to raise additional funds will depend on financial, economic, political and market conditions and other factors, over which we may have no or limited control. 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. Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, it could force us to delay, limit, reduce or terminate our product development programs, future commercialization efforts or other operations. Because of the numerous risks and uncertainties associated with research, product development and commercialization of product candidates, we are unable to predict the timing or amount of our working capital requirements or when or if we will be able to achieve or maintain profitability.

Accordingly, we will need to continue to rely on additional financing to achieve our business objectives and adequate additional financing may not be available to us on acceptable terms, or at all.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash and cash equivalents, any future equity or debt financings and upfront and milestone and royalty payments, if any, received under any future licenses or collaborations. We do not have any committed external source of funds. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. In addition, the possibility of such issuance may cause the trading price of our common stock to decline. Debt financing and preferred equity financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring, selling or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, supply or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of common stock. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

The substantial obligations from our license agreements may result in dilution to our stockholders, may be a drain on our cash resources or may cause us to incur debt obligations to satisfy the payment obligations.

In connection with our license agreements, we entered into arrangements whereby the counterparties to such agreements are entitled to substantial contingent consideration payments upon the occurrence of certain events. For example, under the terms of our license agreement with Stanford University, in addition to the annual license maintenance fees of up to $0.1 million per year, we may also be required to pay up to $12.0 million in milestone payments upon achievement of specific intellectual property, clinical, regulatory and commercial milestone events. In addition, under this license agreement we will be obligated to pay low single-digit percentage royalties on net sales. We are also obligated to pay Stanford University a percentage of non-royalty revenue received by us from our right to sublicense at defined percentages.

In addition, under the terms of our license agreement with Oxford Biomedica for the manufacture and supply of lentiviral vectors for clinical and potentially commercial purposes, we may also be required to pay up to $14.3 million if certain development, regulatory and commercial milestones, in the aggregate, are achieved under our firi-cel and CRG-023 programs. Additionally, we are obligated to pay low single-digit percentage royalties on net sales of certain products generated under the Oxford Agreement. Further, under the terms of our license agreements we entered into with the NCI in 2022 and 2023, pursuant to which we obtained exclusive worldwide, royalty-bearing licenses under certain patent rights to research, develop, manufacture and commercialize products covered by such licensed patents, we may be required to pay up to $18.0 million and up to $17.8 million in milestone payments upon achievement of specific intellectual property, clinical and commercial milestone events, respectively, and low single-digit percentage royalties on net sales of products incorporating the licensed patent rights from the NCI. Additionally, under the terms of each license agreement with the NCI, in the event we are granted a priority review voucher (PRV), we would be obligated to pay the NCI a minimum of $5.0 million upon the sale, transfer or lease of the PRV or $0.5 million upon submission of the PRV for use by the FDA.

In order to satisfy our obligations to make these payments, if and when they are triggered, we may need to issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash and cash equivalents or incur debt obligations to satisfy the payment obligations in cash, which may adversely affect our financial position. In addition, these obligations 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.

See the section titled “Business — License agreements” in our Annual Form 10-K for the year ended December 31, 2023 for additional information regarding these agreements.

Risks related to our business

If we are unable to successfully identify, develop, obtain regulatory approval and ultimately commercialize any of our current or future product candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

Our ability to generate revenue from sales of any of our approved product candidates, which we do not expect will occur for at least the next several years, if ever, depends heavily on the successful identification, development, regulatory approval and eventual commercialization of any product candidates, which may never occur. We have invested substantially all of our efforts and financial resources in acquiring or in-licensing our current product candidates and conducting clinical trials and preclinical studies. We have never generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for or commercialize, a marketable product. All of our product candidates will require significant clinical development, regulatory approval, establishment of sufficient manufacturing supply, including commercial manufacturing supply, and may require us to build a commercial organization and make substantial investment and significant marketing efforts before we generate any revenue from product sales. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

The successful development of our product candidates will depend on several factors, including, but not limited to, the following:

- successful and timely completion of clinical trials and preclinical studies for which the FDA, or any comparable foreign regulatory authority, agree with the design, endpoints or implementation;
- sufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies;
- receiving regulatory allowances or authorizations for conducting future clinical trials;
- initiation and successful patient enrollment in, and successful and timely completion of, clinical trials on a timely basis;
- if we are required to supplement our clinical development plans to include additional clinical trials or studies, such as the addition of a double-blind, placebo-controlled, randomized study of firi-cel;
- the frequency and severity of adverse events in clinical trials;
- maintaining and establishing relationships with contract development and manufacturing organizations (CDMOs), contract research organizations (CROs) and clinical sites for the clinical development of our product candidates both in the United States and internationally;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate is safe, pure and potent, or effective for its intended uses;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- timely receipt of regulatory approvals for our product candidates from applicable regulatory authorities;
- addressing any potential interruptions or delays resulting from factors related to health epidemics, pandemics, other widespread outbreaks of contagious disease, and adverse political events such as government shutdowns;
- the extent of any post-marketing commitments or requirements agreed to with applicable regulatory authorities;
- establishing, scaling up and scaling out, either alone or with third-party manufacturers, manufacturing capabilities of clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved, including ability to produce final product using our intended commercial manufacturing process when applied to using patient cells as starting material;
- the protection of our rights in our intellectual property portfolio; and
- our ability to compete with other therapies.

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 would materially adversely affect our business, financial condition and results of operations.

Additionally, clinical or regulatory setbacks to other companies developing similar products or within adjacent fields, including those in gene editing and gene therapy and allogenic cell-based therapies, may impact the clinical development of and regulatory pathway for our current or future product candidates, or may negatively impact the perceptions of value or risk of our technologies.

We have experienced rapid operational growth since our inception in December 2019, and expect to continue to grow in the future as our clinical trials progress, we begin to advance the development of new product candidates and as our headcount increases. If we fail to effectively manage our growth, we may not be able to execute on our business objectives.

We have experienced rapid growth since our inception in December 2019 and expect to continue to grow in the future. For example, as of December 31, 2019, we had no full-time employees and, as of June 30, 2024, we had grown to approximately 150 full-time employees. In addition, we have developed a broad portfolio of product candidates and discovery programs that includes one product candidate in a potentially pivotal Phase 2 clinical trial. We expect continued growth in the number of our employees and the scope of our operations, particularly as we continue our current and future clinical trials and preclinical studies, initiate and conduct IND-enabling studies and build out our clinical operations, as well as our platform technologies.

To manage our anticipated future growth, we will continue to implement and improve our managerial, operational and financial systems, expand our facilities and recruit and train additional qualified personnel. Due to the complexity in managing a company that has scaled very quickly and anticipates continued growth, we may not be able to scale our headcount and operations effectively to manage the expansion of our product pipeline or recruit and train the necessary additional personnel. As our operations expand, we also expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

In addition, future growth imposes significant added responsibilities on members of management, including: identifying, recruiting, integrating, maintaining and motivating additional employees; managing our internal development efforts effectively, including the clinical development and FDA review processes for our product candidates, while complying with our contractual obligations to contractors and other third parties; and improving our operational, financial and management controls, reporting systems and procedures.

We currently rely on certain independent organizations, advisors and consultants to provide certain services, including strategic, financial, business development and research and development services, as well as certain aspects of regulatory approval and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants or contract manufacturing organizations is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on reasonable terms, or at all.

If our product candidates do not achieve projected development milestones or commercialization in the announced or expected timeframes, the further development or commercialization of such product candidates may be delayed, and our business will be harmed.

We have estimated and may in the future estimate, the timing of the accomplishment of various scientific, clinical, manufacturing, regulatory and other product development objectives. These milestones have and may in the future include our expectations regarding the commencement or completion of clinical trials and preclinical studies, data readouts, the submission of regulatory applications, the receipt of regulatory approval or the realization of other commercialization objectives. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions, including assumptions regarding capital resources, constraints and priorities, progress of and results from development activities and the receipt of key regulatory approvals or actions, any of which may cause the timing of achievement of the milestones to vary considerably from our estimates. If we fail to achieve announced milestones in the expected timeframes, the commercialization of our product candidates may be delayed, our credibility may be undermined, our business and results of operations may be harmed and the trading price of our common stock may decline.

Our ability to develop our product candidates and our platform technologies, as well as our future growth, depends on attracting, hiring and retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and clinical personnel, many of whom have been instrumental for us and have substantial experience with our product candidates and platform technologies. Given the specialized nature of our product candidates and our platform technologies there is an inherent scarcity of experienced personnel in these fields. As we continue developing our product candidates in our pipeline, we will require personnel with medical, scientific or technical qualifications specific to each program. The loss of key personnel, in particular our senior leadership team, would delay our research and development activities. Despite our efforts to retain valuable employees, members of our team may terminate their employment with us on short notice. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which would have a material adverse effect on our business.

In addition, our research and development programs, as well as the development and enhancement of our platform technologies depend on our ability to attract and retain highly skilled scientists, particularly in California. There is powerful competition for skilled personnel in these geographical markets, and we have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining employees with appropriate qualifications on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel have greater resources than we do, and any of our employees may terminate their employment with us at any time. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, resulting in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, it may harm our ability to recruit and retain highly skilled employees. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business and future growth prospects would be harmed.

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain regulatory approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of organizations, including large pharmaceutical and biotechnology companies, academic institutions, government agencies and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

With the proliferation of new drugs and therapies for our target indications, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer or have fewer or less severe side effects;

- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive or marketed and sold more effectively than any products we may develop. Competitive products approaches may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing such products.

In addition, any collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition and results of operations.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

Because we have limited financial and managerial resources, we focus on product candidates, research programs and platform technologies that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other platform technologies or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future product candidates, research programs and platform technologies for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Our product candidates and platform technologies are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval.

We have concentrated our research and development efforts on our engineered T cell therapy, including related product candidates and platform technologies, and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our pipeline and platforms and there can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

In addition, the clinical study requirements of the FDA, EMA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EMA and FDA for existing CAR T therapies may not be indicative of what these regulators may require for approval of our product candidates. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory

agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from other CAR T therapies that have previously been approved. Unexpected clinical outcomes would significantly impact our business.

Any product candidates that we may develop will be novel and may be complex and difficult to manufacture, and if we experience manufacturing problems, it could result in delays in development and commercialization of such product candidates or otherwise harm our business.

Our product candidates involve or will involve novel technology and will require processing steps that are more complex than those required for most small molecule drugs, resulting in a relatively higher manufacturing cost. Moreover, unlike small molecules, the physical and chemical properties of biologics generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that such product will perform in the intended manner. Although we intend to employ multiple steps to control the manufacturing processes for our product candidates, we may experience manufacturing issues with any of our product candidates, critical reagents or raw materials that could cause production interruptions, including contamination, equipment or reagent failure, improper installation or operation of equipment, facility contamination, raw material shortages or contamination, natural disasters, disruption in utility services, human error, disruptions in the operations of our suppliers, inconsistency in cell growth and variability in product characteristics. We may encounter problems achieving adequate quantities and quality of clinical-grade materials that meet FDA or other comparable applicable standards or specifications with consistent and acceptable production yields and costs. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which such product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Our manufacturing process for any CAR T-cell therapy product candidate that we develop will be susceptible to product loss or failure due to the quality of the raw materials, failure of the products to meet specifications, logistical issues associated shipping such material to the manufacturing site, freezing the manufactured product, shipping the final product globally, thawing and infusing patients with such product. Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, delays in initiating or completing clinical trials, product recalls, product liability claims or insufficient inventory.

As product candidates are developed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is possible that various aspects of the development program, such as manufacturing process and methods, may be altered along the way in an effort to help optimize processes and results. Such changes carry the risk that they will not achieve the intended objectives, and any of these changes could cause our product candidates to perform differently from the previous Phase 1 clinical trials and affect the results of future clinical trials or our reliance on results of trials that have previously been conducted using the product candidate in its previous form. If the manufacturing process is changed during the course of product development, we may be required to repeat some or all of the previously conducted trials or conduct additional bridging trials or alternatively, we may need to re-develop the manufacturing process and methods, which could increase our costs and delay or impede our ability to obtain regulatory approval.

In addition, the facilities used by us and our contract manufacturers to manufacture our product candidates must be evaluated for the manufacture of our product candidates by the FDA or foreign regulatory authorities pursuant to inspections that will be conducted after we submit a Biologics License Application (BLA) to the FDA, or similar foreign applications to foreign regulatory authorities. We do not control the manufacturing process of our contract manufacturers and are dependent on their compliance with cGMP or similar foreign requirements for their manufacture of our product candidates.

The FDA and other foreign regulatory authorities may require us to submit samples of any lot of any product that may receive approval together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA or other foreign regulatory authorities may require that we not distribute a lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in the product that could result in lot failures or product

recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business.

Certain license agreement counterparties currently conduct clinical trials under their own INDs, which could generate unknown or unexpected clinical results outside of our control.

Certain of our license agreement counterparties continue to conduct clinical trials with an investigative candidate with the same CAR sequence as firi-cel. In addition, the Phase 1 trial of firi-cel is ongoing, with the investigators on such trial continuing to release cuts of clinical data at different time points. If either of these activities generate unforeseen or unexpected efficacy or safety data, we may need to refer to such data in our regulatory filings, or otherwise disclose this information, which could harm our business or regulatory strategy if the data are negative. In addition, we do not anticipate being able to incorporate any prior firi-cel data from studies conducted under third-party INDs in future regulatory filings. As a result, we may need to conduct additional clinical trials and could be limited in the scope of the labels we pursue, among other adverse consequences. The consequences of any of the foregoing could be costly to us and otherwise harm our business.

The estimates of market opportunity and forecasts of market growth included in our SEC filings or press releases may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all.

We intend to initially focus our product candidate development on treatments for various lymphomas. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts we may provide to the market are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. For example, the observed persistence of CD22 expression following patients becoming relapsed or refractory to CD19 CAR T-cell therapy may not be as high as we expect. Similarly, the percentage of the population with CD22 expression could be lower than we anticipate. In both instances, the pool of potential patients that our CD22 product candidates could address could be substantially smaller than we anticipate. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market with such patients, for example, being too sick to receive treatment. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

Our business is subject to risks arising from health epidemics, pandemics, other widespread outbreaks of contagious disease, including COVID-19.

Significant outbreaks of contagious diseases and other adverse public health developments pose the risk that we or our employees, contractors, including our CROs, CDMOs, suppliers and other partners may be prevented from conducting business activities for an indefinite period of time, including due to spread of the disease within these groups or due to shutdowns that may be requested or mandated by governmental authorities. For example, COVID-19 and the post-COVID environment, including supply chain, labor market and other disruptions, as well as volatility in the global financial markets, in each case driven by the pandemic, have affected segments of the global economy and our operations. The continued spread of disease and the measures taken by the governments of countries affected could, in addition to disrupting our clinical trials, adversely impact other aspects of our business and operations. In addition, health pandemics and epidemics, such as COVID-19, could continue to produce significant and prolonged disruption of or volatility in global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. The extent to which health epidemics, pandemics, other widespread outbreaks of contagious disease impacts our results will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact. Furthermore, the COVID-19 pandemic, the post-COVID environment or any future pandemic or other outbreak of contagious disease could exacerbate the other risks described in this section.

Even if approved, our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition and results of operations.

Even if the FDA or any comparable foreign regulatory authority approves any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Additionally, the product candidates that we are developing are based on our proprietary platforms, which are new technologies. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our product candidates will depend on a variety of factors, including:

- the timing of market introduction of the product candidate, as well as competitive products;
- the clinical indications for which a product candidate is approved;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- the terms of any approvals and the countries in which approvals are obtained;
- the number and clinical profile of competing products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- the effectiveness of sales and marketing efforts;
- approval of other new therapies for the same indications;
- marketing, manufacturing and supply support;
- adverse publicity about our product candidates;
- potential product liability claims;
- availability of coverage, adequate reimbursement and sufficient payment from health maintenance organizations and other insurers, both public and private, for our product candidates, or the procedures utilizing our product candidates, if approved;
- the willingness of patients to pay out-of-pocket in the absence of coverage by third-party payors and government authorities; and
- other potential advantages over alternative treatment methods.

If our product candidates are approved but fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

We currently have a limited marketing, sales or supply chain infrastructure and we intend to either build out a sales and marketing infrastructure or outsource this function to a third-party. Either of these commercialization strategies carries substantial risks to us.

Given our stage of development, we currently have limited marketing, sales and end-to-end supply chain management capabilities. If any of our product candidates complete clinical development and are approved, we intend to either build out a sales and marketing organization with technical expertise and supporting end-to-end supply chain management 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 build out our own sales and marketing capabilities or enter into arrangements with third parties to perform these services. We have no prior experience as a company in the marketing, sale and end-to-end supply chain management of biopharmaceutical products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products.

To the extent that we enter into collaboration agreements with respect to marketing, sales or end-to-end supply chain management, 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, that our collaborator may not comply with legal and regulatory requirements, or that our collaborator may not have a 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.

We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. While we currently have no products that have been approved for commercial sale, the future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

Even successful defense against product liability claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: decreased demand for our product candidates; injury to our reputation; withdrawal of clinical trial participants; initiation of investigations by regulators; costs to defend the related litigation; a diversion of management's time and our resources; substantial monetary awards to trial participants or patients; product recalls, withdrawals or labeling, marketing or promotional restrictions; loss of revenue; exhaustion of any available insurance and our capital resources; the inability to commercialize any product candidate; and a decline in our share price.

Although we maintain adequate product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain regulatory approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired.

We may not realize the benefits of technologies that we have acquired, or will acquire in the future, or other strategic transactions that we have or will consummate.

Our platform represents an aggregation of innovation and technology from multiple companies and academic institutions, including the NCI, Oxford and Stanford University. Further, a key component of our strategy is to acquire and in-license technologies to support the growth of our product pipeline, as well as to build upon and enhance our platform technologies. As such, we actively evaluate various strategic transactions on an ongoing basis. We may acquire other assets, businesses, products or technologies, as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions and any future strategic transactions depends on the risks and uncertainties involved including:

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of acquisition and integration efforts, strategic alliances or joint ventures challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in our relationships with collaborators or suppliers;
- possible write-offs or impairment charges relating to acquired businesses or joint ventures; and
- challenges resulting from health epidemics, pandemics, other widespread outbreaks of contagious disease, including the COVID-19 pandemic and the post-COVID-19 environment, making it more difficult to integrate acquisitions into our business.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political and regulatory risks associated with specific countries.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses, impairments or write-offs of goodwill or impairments and write-offs of in-process research and development assets, any of which could harm our financial condition.

Our information technology systems, or those used by our third-party contract research organizations or other contractors or consultants, may fail or suffer security breaches.

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information, preclinical and clinical trial data, and personal information of our employees and contractors) (Confidential Information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such Confidential Information. We also have outsourced elements of our operations to third parties, and as a result we rely on the information technology systems of and manage a number of third-party contractors who have access to our Confidential Information.

Despite the implementation of security measures, our information technology systems and those of our CROs, CDMOs and other contractors and consultants are vulnerable to attack and damage or interruption from a variety of threats, including computer viruses and malware (e.g., ransomware), malicious code, natural disasters, terrorism, war, telecommunications and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated national-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization.

We and certain of our service providers are from time to time subject to cyberattacks and security incidents. Although to our knowledge we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and negatively affect our operations, it could result in a material disruption of our development programs and our business operations. Further, there can be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures or our other data protection efforts and our investment in information technology, or those of third parties on which we rely, will be fully implemented, complied with or effective to 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. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence.

For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also have a material adverse effect on our business. To the extent that any disruption or security incident were to result in an actual or perceived loss of, or damage to, our data or applications, or inappropriate disclosure of Confidential Information, the further development and commercialization of our product candidates could be delayed.

Any such security compromise or other event that leads to actual or suspected, or is alleged to lead to, unauthorized access, use, or disclosure of Confidential Information, including personal information regarding our clinical trial subjects or employees, could also harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and fines or mandatory corrective action, and otherwise subject us to liability and proceedings (such as class actions), including under laws and regulations that protect the privacy and security of personal information, and/or significant incident response, system restoration or remediation and future compliance costs, which could adversely affect our results of operations, business or financial condition.

Further, we rely on third-party service providers and technologies to operate critical business systems to process Confidential Information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised. We have and will enter into collaboration, license, contract research and/or manufacturing relationships with organizations that operate in certain countries that are at heightened risk of theft of technology, data and intellectual property through

direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. Accordingly, our efforts to protect and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroy the proprietary nature of our intellectual property.

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

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

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, processing) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements and other obligations relating to data privacy and security.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) and other similar laws. For example, the federal Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (collectively, HIPAA), imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information, such as information we may obtain from research institutions from which we obtain clinical trial data. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. The California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, (collectively, CCPA) requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Other states have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these laws, like the CCPA, may also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation (EU GDPR), the United Kingdom's GDPR (UK GDPR), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais (LGPD)) (Law No. 13,709/2018) and China's Personal Information Protection Law (PIPL) impose strict requirements for processing personal data. For example, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20.0 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of the annual global revenue of a non-compliant undertaking, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the

United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws.

Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, the EU-U.S. Data Privacy Framework (DPF), and the UK Extension to the DPF (which allows for transfers from the EEA or UK to U.S.-based organizations who self-certify compliance under the DPF), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States.

If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups.

Our employees and personnel may use generative artificial intelligence (AI) technologies to perform their work, and the use of such generative AI in connection with our Confidential Information may result in leaks, disclosure, or otherwise unauthorized or unintended access to such information, including if such information is used to further refine and train the underlying generative AI models. The disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations and governments have passed and are likely to pass additional laws regulating generative AI. Further, our ability to continue to develop or use such technologies may depend on access to specific third-party software and infrastructure, such as processing hardware or third-party AI models, and we cannot control the availability or pricing of such third-party software and infrastructure, especially in a highly competitive environment. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

Negative public opinion and increased regulatory scrutiny of research and therapies involving gene editing may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.

The gene-editing technologies that we use are novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates. In addition, given the novel nature of gene engineering technologies, governments may place import, export or other restrictions in order to retain control or limit the use of the technologies. Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

Risks related to the regulatory environment for the development and commercialization of our product candidates

The regulatory landscape that will apply to development of our product candidates is rigorous, complex, uncertain and subject to change, which could result in delays or termination of development of such product candidates or unexpected costs in obtaining regulatory approvals.

All of our product candidates are based on cell therapy technology, and our future success depends on the successful development of product candidates utilizing our novel approach. We cannot assure you that any development problems we or other cell therapy companies experience in the future related to such technology will not

cause significant delays or unanticipated costs in the development of our product candidates, or that such development problems can be solved. In addition, the clinical study requirements of the FDA, and other regulatory agencies, as well as the criteria these regulators use to determine the safety, purity, potency or efficacy of a product candidate, vary substantially according to the type, complexity, novelty and intended use and market of the product candidate. The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied therapeutic modalities. Further, as we are developing novel treatments for diseases in which there may be limited clinical experience, there is heightened risk that the FDA or comparable foreign regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. To date, relatively few cell therapy products have been approved by the FDA or comparable foreign regulatory authorities, which makes it difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in the United States or other jurisdictions. Further, approvals by one regulatory agency may not be indicative of what other regulatory agencies may require for approval in their respective jurisdictions.

Regulatory requirements governing cell therapy products have evolved and may continue to change in the future. For example, the FDA has established the Office of Therapeutic Products within its Center for Biologics Evaluation and Research (CBER), to consolidate the review of cell therapy and comparable products, as well as the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. These and other regulatory review agencies, committees and advisory groups and the requirements and guidelines they promulgate may lengthen the regulatory review process, require us to perform additional preclinical studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

For example, the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) require supervision of human gene transfer trials, including evaluation and assessment 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 the public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

We are subject to significant regulatory oversight by the FDA in connection with our clinical trials, and in addition, the applicable IBC and Institutional Review Board (IRB) of each institution at which we conduct clinical trials of our product candidates, or a central IRB if appropriate, may need to review and approve the proposed clinical trial prior to initiation.

Changes in applicable regulatory guidelines for product candidates such as ours may lengthen the regulatory review process, require us to perform additional studies or trials beyond those we contemplate, increase our development costs, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory and advisory groups and comply with evolving regulations and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we may anticipate. Delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete clinical trials and commercialize our current and future product candidates in a timely manner, if at all, and could seriously harm our business.

Clinical and preclinical development involves a lengthy and expensive process with an uncertain outcome. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects.

Preclinical and clinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the preclinical study or clinical trial process, including due to factors that are beyond our control. The historical failure rate for product candidates in our industry is high. It is not

uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. For example, although we believe the results from Stanford University's Phase 1 clinical trial of its CD22 CAR T-cell therapy under its own IND support further development of this product candidate, there is no guarantee we will observe similar results in our ongoing Phase 2 clinical trial of firi-cel being conducted under our own IND due to a variety of factors which we do not have control over. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and regulatory authorities may not agree with the conclusions we draw from our clinical trials and preclinical studies. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety purity, potency or efficacy of the product candidate in humans. We have limited experience in conducting clinical trials, and as an organization, have not yet completed a clinical for any of our product candidates.

Prior to initiating clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical or non-clinical studies, or complete additional activities relating to chemistry, manufacturing and controls (CMC) for any product candidate before such authorities allow us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs. In particular, the manufacturing of autologous CAR T-cell therapies remains an emerging and evolving field. Accordingly, we expect CMC-related topics, including product specifications, will remain a focus for such regulatory authorities during their reviews of our applications. Moreover, even as we continue our current Phase 2 clinical trial and commence new clinical trials, issues may arise that could cause regulatory authorities to suspend or terminate such clinical trials. Any such delays in the commencement or completion of our ongoing and planned clinical trials for our product candidates could significantly affect our product development timelines and product development costs and harm our financial position.

We do not know whether our planned clinical trials will begin on time or be completed on schedule, if at all. The timing for commencement, data readouts and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtaining allowance or approval from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- if we are required to supplement our clinical development plans to include additional clinical trials or studies, such as the addition of a double-blind, placebo-controlled, randomized study of firi-cel as part of the potentially pivotal Phase 2 clinical trial;
- any failure or delay in reaching an agreement with CROs, CDMOs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CDMOs and trial sites;
- the level of CD22 expression in the patient population in the trial not aligning with our expectations;
- delays in identifying, recruiting and training suitable clinical investigators;
- obtaining approval from one or more IRBs or ethics committees at clinical trial sites;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;

- changes or amendments to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs or CDMOs to perform in accordance with Good Clinical Practice (GCP) requirements or applicable regulatory rules and guidelines in other countries;
- manufacturing sufficient quantities of necessary critical reagents such as viral vectors, and of our product candidates for use in our clinical trials;
- subjects failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up, including subjects failing to remain in our trials;
- patients choosing an alternative product for the indications for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue a clinical trial, or costs being greater than we anticipate;
- subjects experiencing severe or serious unexpected treatment-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by a CDMO delays or failure by our CDMOs or us to make any necessary changes to such manufacturing process, or failure of our CDMOs to produce clinical trial materials in accordance with cGMP regulations or other applicable requirements; and
- third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations and guidelines, and remain subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where such clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or applicable clinical trial protocols, adverse findings from inspections of clinical trial sites by the FDA or comparable foreign regulatory authorities, 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. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to regulators or to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our future product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled subjects in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes and political and economic risks, including war, relevant to such foreign countries.

Moreover, 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 or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority 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 or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

In addition, many of the factors that cause, or lead to, the termination suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any resulting delays to our clinical trials could shorten any period during which we may have the exclusive right to commercialize our product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials will depend, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable regulatory authorities. The conditions for which we currently plan to evaluate our product candidates are orphan or rare diseases with limited patient pools from which to draw for clinical trials. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment in clinical trials may be affected by other factors, including:

- size and nature of the targeted patient population;
- severity of the disease or condition under investigation;
- availability and efficacy of approved therapies for the disease or condition under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any products that may be approved for, or any product candidates under investigation for, the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- difficulty identifying and enrolling patients for clinical trials to expand into earlier lines of LBCL;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of such trials before completion.

Additionally, other pharmaceutical companies targeting these same diseases are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll any clinical trials. We also rely on, and will continue to rely on, CROs, CDMOs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we will have limited influence over their actual performance.

Furthermore, given the nature of the diseases we are targeting, there is a significant risk of patient dropout due to disease progression, potential infections or illnesses (including COVID-19), or death during the course of our clinical trials. These factors could lead to increased rates of patient withdrawal from our trials, potentially impacting

the integrity of our trial data and increasing the duration and cost of our clinical development programs. If a substantial number of patients drop out or miss critical follow-up assessments, we may be required to enroll additional patients, extending the timeline and increasing the cost of our clinical trials. This could delay our development programs and adversely affect our ability to demonstrate the efficacy and safety of our product candidates.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, may lead us to abandon one or more clinical trials altogether, or may lead the FDA and other regulatory authorities to require us to conduct additional clinical trials before we are able to seek regulatory approvals for our product candidates, if ever. Any enrollment issues in our clinical trials may therefore result in increased development costs for our product candidates and jeopardize our ability to obtain regulatory approval for the sale of our product candidates, which would adversely affect our business and financial condition.

Use of our product candidates could be associated with adverse side effects, adverse events or other properties or safety risks, which could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved product or result in other significant negative consequences that could severely harm our business, prospects, operating results and financial condition.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates, whether used alone on in combination with other therapies, could cause us or regulatory authorities to interrupt, delay or halt clinical trials or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities, or, if such product candidates are approved, result in a more restrictive label and other post-approval requirements. Any treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials, when used alone or in combination with other approved product, we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Patients in our ongoing and planned clinical trials may suffer significant adverse events or other side effects, including adverse events not observed in our preclinical studies or in previous clinical trials evaluating our product candidates. Patients treated with our product candidates may also be undergoing surgical, radiation or chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If such significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Moreover, adverse developments in clinical trials conducted by others of cell therapy products or product candidates, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing our technologies, either of which could materially harm our business. For example, on November 28, 2023, the FDA announced that it was investigating reports of reports of T-cell malignancies, including chimeric antigen receptor CAR-positive lymphoma, in patients who received treatment with BCMA-or CD19-directed autologous CAR T cell immunotherapies, and in January 2024, the FDA required the manufacturers of certain CAR-T therapies to add boxed warnings to product labeling cautioning against

the risk of T-cell malignancies, and has continued to update applicable warnings for these products. If we are able to successfully develop and obtain approval of any of our product candidates, the FDA may require such products to carry similar warnings or adopt other precautions that could adversely affect such products' commercial prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or end-to-end supply chain management systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop. Other potentially significant negative consequences associated with adverse events include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

Interim, "topline" and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient data become available 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 clinical trials and preclinical studies, 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. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are further 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 interim, topline or preliminary data and final data could significantly harm our business prospects. Further, disclosure of such 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 or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. 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, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

We have not successfully completed the testing of our product candidates in clinical trials and any favorable data from trials conducted by Stanford University or the NCI may not be replicated in our clinical trials.

In December 2023, we announced the dosing of the first seven patients in our Phase 2 clinical trial of our lead product candidate, firi-cel, in patients with R/R LBCL whose disease has progressed after CD19-directed CAR T-cell therapy. We have only recently initiated our first clinical trial of firi-cel and have not successfully completed the test of our product candidates in clinical trials, including our lead program firi-cel. Specifically, while the firi-cel CAR has been included in CD22 CAR T-cell products dosed in more than 120 patients in separate clinical trials conducted by Stanford University and the NCI, these trials were designed and conducted by third parties. Further, we also did not control the preclinical development of firi-cel, which was conducted by Stanford University and NCI. As a result of the foregoing, there are certain aspects of these clinical trials which could lead to our Phase 2 clinical trial producing different results. For example, it is possible that patients dosed in the Phase 1 clinical trial conducted by Stanford are different than those dosed in our Phase 2 clinical trial. If that were to occur, the results we receive in our Phase 2 clinical trial may be different, such as a lower complete response rate and overall response rate as well as a shorter median survival, than what was observed in the Phase 1 clinical trial conducted by Stanford University. Different results may require us to augment our clinical development plans, which could be costly, or could result in us abandoning the development of firi-cel. The occurrence of either event would harm our business.

In addition, we have changed the manufacturing process of firi-cel in an effort to improve manufacturing yields and efficiency. These improvements are reflected in the firi-cel being used in our potentially pivotal Phase 2 clinical trial and in December 2023, we successfully manufactured firi-cel and dosed our first seven patients. While we have conducted comparability analysis of our firi-cel to the CAR T therapy used in the Stanford study and concluded that the two are comparable, we cannot assure you that such comparability will result in the outcome in our Phase 2 clinical trial being consistent with the outcome observed in the Stanford University conducted Phase 1 clinical trial. In such case, additional clinical and/or CMC development work may be required to address the differences in the outcome, which could delay, prevent or impair our development or potential commercialization efforts.

If our Phase 2 clinical trial results are not consistent with the results from the Phase 1 clinical trial conducted by Stanford University, the development of firi-cel may be adversely impacted, which could harm our business, operating results, prospects or financial condition.

Further, while we received allowance to proceed from the FDA in connection with our IND for firi-cel, which included our comprehensive package to establish the comparability of our intended commercial process to the process used for the Stanford clinical trial, we cannot assure you going forward that the FDA will agree with our claim of comparability and the sufficiency of the data to support it, or agree with our ability to reference the preclinical, manufacturing or clinical data generated by the Stanford clinical trial even if we receive a right of reference from Stanford. If so, the FDA may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate further clinical trials and/or obtain any regulatory approvals. Any of these occurrences may harm our business, financial condition and prospects.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and end-to-end supply chain management of our product candidates are subject to extensive regulation by the FDA in the U.S. and by comparable foreign regulatory authorities in foreign markets. In the U.S., we are not permitted to market our product candidates in the U.S. until we receive regulatory approval of a BLA from the FDA. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable regulatory have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval of a product candidate is never guaranteed. Of the large number of biologics in development, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized.

Prior to obtaining approval to commercialize a product candidate in the U.S. or abroad, we must demonstrate with substantial evidence from adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe, pure and potent or efficacious for their intended uses and that we can consistently and reliably manufacture the product candidate.. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe available preclinical or clinical data support the safety, purity, potency or efficacy of our product candidates, such data may not be sufficient to obtain approval from the FDA and comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities, as the case may be, may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or may object to elements of our clinical development program.

The FDA or comparable foreign regulatory authorities can delay, limit or deny approval of a product candidate for many reasons, including:

- such authorities may disagree with the design or execution of our clinical trials;
- negative or ambiguous results from our clinical trials or results may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected treatment-related side effects may be experienced by participants in our clinical trials or by individuals using therapies similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- such authorities may not accept clinical data from trials that are conducted at clinical facilities or in countries where the standard of care is potentially different from that of their own country;
- we may be unable to demonstrate that a product candidate’s clinical and other benefits outweigh its safety risks;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the U.S. or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on end-to-end supply chain management and use;

- such authorities may find deficiencies in the manufacturing processes or facilities of the third-party manufacturers with which we contract for clinical and commercial supplies;
- such authorities may not accept a submission due to, among other reasons, the content or formatting of the submission; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

With respect to foreign markets, approval procedures vary among countries and, in addition to the foregoing risks, may involve additional product testing, administrative review periods and agreements with pricing authorities.

Even if we eventually complete clinical trials and receive approval of a BLA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS, which may be required because the FDA believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

If we are required by the FDA to obtain approval of a companion diagnostic in connection with approval of any of our product candidates or a companion diagnostic we contemplate developing with collaborators in connection with our CD22 CAR T-cell therapy, and we do not obtain, or face delays in obtaining, FDA approval of such companion diagnostic, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If the FDA believes that the safe and effective use of any of our product candidates depends on an in vitro diagnostic (IVD), then it may require approval or clearance of that diagnostic as a companion diagnostic at the same time that the FDA approves our product candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. Depending on the data from our clinical trials, we may decide to collaborate with diagnostic companies during our clinical trial enrollment process to help identify patients with characteristics that we believe will be most likely to respond to our product candidates. If a satisfactory companion diagnostic is not commercially available in this situation, we may be required to develop or obtain such test, which would be subject regulatory approval requirements. The process of obtaining or creating such diagnostic is time-consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable foreign regulatory authorities, and the FDA has generally required premarket approval of companion diagnostics for cancer therapies. The approval or clearance of a companion diagnostic as part of the therapeutic product's further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect. In addition, in January 2024, the FDA announced its intention to initiate the process to reclassify into Class II most IVDs that are currently regulated as Class III medical devices, including certain companion diagnostic IVDs. If such reclassification efforts occur, any companion diagnostics that are the subject of the down-classification may no longer require premarket approval, but rather may be marketed pursuant to the generally less burdensome 510(k) clearance process. However, there is no assurance that any companion diagnostic required for our development programs will benefit from the reclassification, or that the reclassification, even if it does occur, will result in a shorter timeline to development or marketing of the companion diagnostic.

If the FDA or a comparable foreign regulatory authority requires approval or clearance of a companion diagnostic for any of our product candidates, whether before or after the product candidate obtains regulatory approval, we and/or third-party collaborators may encounter difficulties in developing and obtaining approval or clearance for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval or clearance of a companion diagnostic could delay or prevent approval or continued marketing of the relevant product. We or our collaborators may also experience delays in developing a sustainable, reproducible and

scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidates, if approved, on a timely or profitable basis, if at all.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained.

We may in the future seek accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit.

The accelerated approval pathway may be used in cases in which the advantage of a new biologic over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional confirmatory studies to verify and describe the biologic's clinical benefit. If such post-approval studies fail to confirm the biologic's clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the biologic on an expedited basis. Under the Food and Drug Omnibus Reform Act of 2022, the FDA was provided new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under these provisions, the FDA may require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. Specifically, FDA guidance relating to accelerated approval of oncology therapeutics indicates that a confirmatory trial for a particular oncology product candidate should be underway when the related BLA is submitted to the FDA and also states that the FDA may require that a confirmatory trial for a particular oncology product candidate be well underway, if not fully enrolled, by the time of the accelerated approval action. For example, in March 2024, the FDA issued complete response letters concerning Regeneron Pharmaceuticals, Inc.'s BLA for odronextamab for the treatment of lymphoma due to the enrollment status of confirmatory Phase 3 trials. Application of this guidance and related rules to one or more of our product candidates may result in a delay of the FDA review and approval process despite any earlier beneficial regulatory designation such product candidates may have received.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA seeking accelerated approval or any other form of expedited development, review or approval. Furthermore, if we decide to submit an application for accelerated approval for our product candidates, there can be no assurance that such application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

A designation from the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive FDA approval.

The FDA and comparable foreign regulatory authorities offer certain designations for product candidates that are designed to encourage the research and development of product candidates that are intended to address conditions with significant unmet medical need. These designations may confer benefits, but there can be no assurance that we will successfully obtain any such designations for any product candidates. In addition, while such designations could expedite the development or approval process, they generally do not change the standards for approval. Even if we obtain such designations for one or more of our current or future product candidates, there can be no assurance that we will realize their intended benefits.

For example, we seek Breakthrough Therapy designations for firi-cel and any other product candidates where we believe the clinical data support such designation. A "Breakthrough Therapy" is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition, where preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, increased interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as Breakthrough Therapies also receive the same benefits associated with the FDA's Fast Track designation program, including eligibility for rolling review of a submitted BLA, if the relevant criteria are met.

Although we have not applied for or received Breakthrough Therapy Designation in connection with our IND for firi-cel, Stanford University has received Breakthrough Therapy designation from the FDA for its CD22 CAR T-cell therapy candidate for, following fludarabine and cyclophosphamide, the treatment of adult patients with relapsed or refractory large B cell lymphoma after CD19-directed CAR T-cell therapy. Although Stanford University's CD22 CAR T is an earlier, comparable version of firi-cel, our firi-cel program will not receive the benefits of this designation until and unless we obtain the rights to Stanford University's IND for the program and the FDA agrees to transfer the designation to our IND for firi-cel, or until we otherwise request and obtain such designation from the FDA with respect to our IND for firi-cel. We cannot assure you that the FDA will agree with our claim of comparability and the sufficiency of the data to support it, or agree with our ability to reference the preclinical, manufacturing or clinical data generated by the Stanford clinical trial even if we obtain a right of reference from Stanford. If the FDA disagrees, there may be limitations on the inclusion of Phase 1 data in any potential product label.

In addition, we may seek regenerative medicine advanced therapy (RMAT) designation for firi-cel and any other product candidates where we believe the clinical data support such designation. Our CAR T-cell products may qualify as regenerative medicine therapies under the FDA's RMAT program, which is designed to expedite development and review of therapies intended to treat serious or life-threatening diseases. If granted, RMAT designation could provide benefits such as early interactions with the FDA to discuss potential surrogate or intermediate endpoints for accelerated approval, eligibility for priority review, and the ability to meet post-approval requirements through real-world evidence. However, RMAT designation is discretionary, and the FDA may disagree with our assessment of our CAR T-cell therapies' eligibility. Even if granted, RMAT designation does not guarantee a faster development or review process, nor does it ensure FDA approval. The FDA may later determine that our CAR T-cell product candidates no longer meet RMAT criteria, potentially causing delays and additional costs in our development programs. Furthermore, the benefits of RMAT designation may not materialize as expected; for instance, the use of surrogate endpoints for accelerated approval may not be deemed appropriate for our specific CAR T-cell therapies. The complex nature of CAR T-cell therapies, including challenges in manufacturing, characterization, and long-term follow-up of genetically modified cells, may complicate the application of RMAT benefits. Additionally, as the field of CAR T-cell therapy rapidly evolves, changes in the regulatory landscape could affect our ability to obtain or maintain RMAT designations. For example, if long-term safety concerns arise across CAR T-cell therapies, the FDA may revise its approach to RMAT designation or post-approval requirements for this class of products.

Designations, such as a Breakthrough Therapy and RMAT is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of designation for a product candidate may not result

in a faster development process, review or approval compared to drugs considered for approval under standard FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as Breakthrough Therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification and rescind the designation, or otherwise decide that the time period required for FDA review or approval will not be reduced.

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, prevent new or modified products from being developed, review, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and foreign regulatory authorities 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 or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities 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, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new biologics or modifications to 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 critical FDA employees and stop critical activities. In addition, during the COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has resumed standard inspection operations, any resurgence of COVID-19 or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular 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.

Even if we obtain FDA approval for any of our product candidates in the United States, we may never obtain approval for or commercialize such candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense.

For any regulatory approvals that we may receive for our product candidates, the manufacturing processes, labeling, packaging, end-to-end supply chain management, adverse event reporting, storage, advertising, promotion,

import, export and recordkeeping for our product candidates 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 ongoing compliance with cGMPs for manufacturing, as well as GCPs for any clinical trials that we may conduct. In addition, manufacturers of biological products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and other applicable standards. In addition, any regulatory approvals we may receive will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, and such approvals may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, such regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on end-to-end supply chain management or use of product, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be promulgated or other events could occur that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs and biologics. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe, pure and potent or effective, by FDA. While physicians in the United States may choose, and are generally permitted, to prescribe drugs and biologics for uses that are not described in the product's labeling and for uses that

differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA.

If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion any product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

We believe that any of our future product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing.

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

The availability of coverage and the adequacy of 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, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations. The Centers for Medicare & Medicaid Services (CMS) is also developing new reimbursement models, such as the Cell and Gene Therapy (CGT) Access Model. While currently voluntary, the CGT Access Model is structured as an outcomes-based initiative, meaning reimbursement may be tied to the effectiveness of the therapy, which may differ from clinical trial results. These evolving reimbursement landscapes create substantial uncertainty and may significantly impact our ability to generate revenue from any approved products.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and only offer to reimburse patients for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

In addition, in the event that we develop companion diagnostic tests for use with our products, if approved, such companion diagnostic tests may require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical product. For example, in the outpatient setting, the need for separate reimbursement of companion diagnostic tests could create additional payment complexities for our product candidates, if approved, and may delay or limit their adoption. In the inpatient setting, where companion diagnostic tests are typically not reimbursed separately, hospitals may be reluctant to adopt our therapies if they perceive the associated companion diagnostic tests as an additional unreimbursed expense, in which case we may need to consider subsidizing the costs of companion diagnostic tests, which would adversely affect our profitability. The unavailability of adequate reimbursement for companion diagnostic tests could reduce healthcare providers' willingness to prescribe and patients' willingness to use our products, thereby limiting our revenue. Similar challenges to obtaining coverage and reimbursement applicable to pharmaceutical products will apply to companion diagnostics tests.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products.

Specifically, due to the high cost of CAR T-cell therapies, payors may be reluctant to provide coverage or may impose significant restrictions on reimbursement or require additional rebates to participate in recent payment model initiatives. These challenges could include: implementing high co-payments that patients may find unaffordable, imposing stringent prior authorization requirements, limiting coverage to specific patient populations or conditions potentially narrower than any approved label, requiring additional levels of approval for subsequent CAR T-cell therapies after an initial treatment, and mandating outcomes-based payment models that tie reimbursement to clinical effectiveness. Further, payors may adopt more conservative reimbursement approaches, which could result in more restrictive utilization management tools, potentially delaying or denying coverage for some patients. Delays in obtaining reimbursement approvals may cause healthcare professionals to consider alternative, less expensive, or less logistically complex treatment options, particularly for patients with rapidly progressing disease. Furthermore, Medicare's coverage of CAR T-cell therapies is currently limited to those meeting specific criteria set forth in a national coverage decision. If we are unable to secure favorable coverage and reimbursement terms, healthcare providers may be hesitant to prescribe our therapies, and patients may be unable to afford treatment. This could substantially limit the adoption of our product candidates, if approved, and materially adversely affect our business, financial condition, and results of operations.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each

payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of our product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

Recently enacted legislation, future legislation and healthcare reform measures may increase the difficulty and cost for us to obtain regulatory approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States. The ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered outpatient drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in place in its current form.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's Average Manufacturer Price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs and reform government program reimbursement methodologies for products.

Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update its guidance documents as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, even though this part of the IRA remains subject to ongoing legal challenges. The impact of the IRA on the pharmaceutical industry and our business cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

We expect that these new laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease or order, or arranging for or recommending the purchase, lease or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert

that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services (CMS), information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by such healthcare professionals and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology 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; some state laws that require biotechnology companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, agents, contractors or collaborators that would violate the laws or regulations of the jurisdictions in which we operate,

including, without limitation, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition and patient privacy and other privacy laws and regulations. Misconduct by employees could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. We adopted a code of conduct and an insider trading policy applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy.

Risks related to our dependence on third parties

We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, our development programs and our ability to seek or obtain regulatory approval for or commercialize our product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we rely on, and will continue to rely on, medical institutions, clinical investigators, CROs, CDMOs and consultants to conduct clinical trials and preclinical studies, in each case in accordance with trial protocols and regulatory requirements. These CROs, CDMOs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. Though we expect to carefully manage our relationships with such CROs, CDMOs, investigators and other third parties, 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, while we have and will have agreements governing the activities of our third-party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs, CDMOs and other third parties does not relieve us of our regulatory responsibilities.

In addition, we and our CROs and CDMOs are required to comply with Good Laboratory Practice (GLP) and GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs, CDMOs or trial sites fail to comply with applicable GLP, GCP, cGMP or other requirements, the data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional studies or trials before approving our marketing applications, if ever. Furthermore, our clinical trials must be conducted with materials manufactured in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

There is no guarantee that any of our CROs, CDMOs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required, including in compliance with GCPs and GMPs. Third parties may have staffing difficulties, may undergo changes in priorities or may become financially distressed, adversely affecting their willingness or ability to conduct our trials or studies. If any of these third parties fails to meet expected deadlines, carry out their contractual duties or obligations, adhere to our clinical protocols or meet regulatory requirements or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other activities that could harm our competitive position.

In addition, our CROs and CDMOs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms or at all. Switching or adding additional CROs, CDMOs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO or CDMO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs and CDMOs, investigators and other third parties, 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.

We currently rely on third parties for the manufacture of our product candidates during clinical development, and expect to continue to rely on third parties for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of critical reagents, raw materials and our final product candidates, or such quantities at an acceptable cost, which could delay, prevent or impair our development or potential commercialization efforts.

We do not own or operate manufacturing facilities at this time. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates, lentiviral vector and related raw materials for clinical development, as well as for commercial manufacture if any of our product candidates receives regulatory approval. The facilities used by our third-party manufacturers must be approved for the manufacture of our product candidates by the FDA, or any comparable foreign regulatory authority, pursuant to inspections that will be conducted after we submit a BLA to the FDA, or submit a comparable marketing application to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of our product candidates. If these third-party manufacturers cannot successfully manufacture material or components thereof that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and/or maintain regulatory approval for the use of their manufacturing facilities and will cause supply disruption.

In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture our product candidates, or if such authorities withdraw any such approval in the future, we may be required to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our financial position.

Our or a third party's failure to execute on our manufacturing requirements on commercially reasonable terms and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including:

- an inability to initiate or complete clinical trials of our product candidates in a timely manner;
- delay in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;

- additional inspections by regulatory authorities of third-party manufacturing facilities or our manufacturing facilities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize any product candidate, an inability to meet commercial demands.

In addition, we do not have any noncancellable long-term commitments or supply agreements with any third-party manufacturers. We may be unable to establish any long-term supply agreements with third-party manufacturers or to do so on acceptable terms, which increases the risk of failing to timely obtain sufficient quantities of our product candidates or such quantities at an acceptable cost. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product candidates according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Further, while we do not have any noncancellable long-term commitments or supply agreements with third-party manufacturers, many of our agreements with such parties have liquidated damage provisions in them which require us to pay cancellation fees for any manufacturing work that we cancel but had already been scheduled or otherwise committed to by us, as well as certain out-of-pocket expenses. Such cancellation fees could be significant and if we are required to pay them, our operational results and business may be harmed.

In addition, certain of the third parties we use for our manufacturing processes provide services that would be difficult to replace. As a result, if such parties were to increase the cost of their services, we may be required to either pay higher amounts or alternatively develop and or procure an alternative solution. If either were to occur, our results of operations and business may be harmed.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or regulatory approval, and any related remedial measures may be costly or time-consuming to implement. If our existing or future third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all, which would have a material adverse impact on our financial position. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods.

Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed within a reasonable time frame and at an acceptable cost or at all.

We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our product candidates for our current clinical trials and preclinical studies and intend to continue to rely on these third parties for any future clinical trials that we undertake. There are a limited number of suppliers for raw materials that we use to manufacture our product candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our preclinical

studies, clinical trials and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. 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. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event a new supplier must be used. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

We may not realize the benefits of any licensing arrangement, and if we fail to enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. Therefore, for some of our product candidates we may enter into collaborations with pharmaceutical or biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Moreover, our estimates of the potential revenue we are eligible to receive under any strategic collaborations we may enter into may include potential payments related to therapeutic programs for which our collaborators may discontinue development in the future. If that were to occur, we may have to curtail the development of a particular product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

In instances where we do enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that is required of us to complete our development obligations or that the collaboration partner devotes to the product development or marketing programs;
- the collaboration partner may experience financial difficulties;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may be required to relinquish important rights such as marketing, end-to-end supply chain management and intellectual property rights;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors;
- we and our collaboration partner may disagree regarding the development plan for product candidates on which we are collaborating (for example, we may disagree with a collaboration partner regarding target indications or inclusion or exclusion criteria for a clinical trial); or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

Risks related to intellectual property

We depend on intellectual property licensed from third parties and we are currently party to in-license agreements under which we acquired rights to use, develop, manufacture and/or commercialize certain of our proprietary technologies and product candidates. If we breach our obligations under these agreements or if any of these agreements is terminated, or otherwise experience disruptions to our business relationships with our licensors, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business.

We are dependent on patents, know-how, and proprietary technology, both our own and licensed from others. We are a party to intellectual property license agreements and in the future, we may enter into additional license agreements. For example, with respect to developing our product candidates, we have licensed certain intellectual property from the NCI, Oxford and Stanford University. These license agreements impose, and we expect that future license and acquisition agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under current or future intellectual property license agreements, we may be required to pay damages and the licensor may have the right to terminate the license. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop, manufacture, use and/or commercialize our product candidates or platform technologies. See the section titled "Business—Intellectual property—License agreements" included in our Annual Report on Form 10-K for the year ended December 31, 2023 for additional information regarding these key agreements.

In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop, manufacture, use and/or commercialize the affected product candidates or platform technologies. Our business also would suffer if any current or future licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop, manufacture and commercialize products, we may be unable to achieve or maintain profitability.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant research programs or product candidates and our business, financial condition, results of operations and prospects could suffer.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may also arise between us and our current and future licensors regarding intellectual property subject to a license agreement, including those relating 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 infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the priority of invention of patented technology;
- rights upon termination of the license agreements;
- the scope and duration of exclusivity obligations of each party to the license agreements;
- the amount and timing of payments owed under license agreements; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

The resolution of any contractual interpretation dispute that may arise, if unfavorable to us, could have a material adverse effect on our business, financial condition, results of operations and prospects. Such resolution could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement or decrease the third party's financial or other obligations under the relevant agreement. Furthermore, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer.

We depend, in part, on our licensors to file, prosecute, maintain, defend and enforce certain patents and patent applications that are material to our business.

Certain patents and patent applications relating to our product candidates, platform technologies or certain products used in the manufacturing of our clinical products are owned or controlled by certain of our licensors, including Stanford University, the NCI and Oxford. In some circumstances, we may not have the right to control the preparation, filing, prosecution, maintenance and defense of patent applications or patents covering technology that we license from third parties. In such circumstances, our licensors generally have rights to file, prosecute, maintain and defend the licensed patents in their name, generally with our right to comment on such filing, prosecution, maintenance and defense, with some obligation for the licensor to consider or incorporate our comments. We generally have the first right to enforce our exclusively licensed patent rights against third parties, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, including due to the impact of health epidemics, pandemics, or other widespread outbreaks of contagious disease, including the COVID-19 pandemic and the post-COVID-19 environment, on our licensors' business operations, our ability to develop and commercialize those product candidates

may be adversely affected and we may not be able to prevent competitors from making, using or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even in the circumstances where we have the right to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. This could cause us to lose rights in any applicable intellectual property that we in-license, and as a result our ability to develop and commercialize product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Furthermore, the U.S. government and/or government agencies have provided, and in the future may provide, funding or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. We rely on our licensors to ensure compliance with applicable obligations arising from such funding or assistance, such as timely reporting, an obligation associated with in-licensed patents and patent applications. The failure of our licensors to meet their obligations may lead to a loss of rights or the unenforceability of relevant patents.

We may not be successful in obtaining or maintaining necessary rights for our product pipeline which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business will likely depend in part on our ability to acquire or in-license additional proprietary rights, including to expand our product pipeline. In that event, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may involve additional technologies or product candidates that may require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical companies and academic institutions may also have filed or are planning to file patent applications potentially relevant to our business. Our product candidates may also require specific formulations or other technology to work effectively and efficiently. These formulations or technology may be covered by intellectual property rights held by others. From time to time, in order to avoid infringing these third-party rights, we may be required to license technology from additional third parties to further develop, manufacture or commercialize our product candidates. We may be unable to acquire or in-license any relevant third-party intellectual property rights, including any such intellectual property rights required to manufacture, use or sell our product candidates, that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, and as a result we may be unable to develop, manufacture or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors' access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, 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 larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We may be dependent on intellectual property for which development was funded or otherwise assisted by, the U.S. government and/or government agencies, such as The National Cancer Institute, for development of our technology and product candidates. Failure to meet our own obligations to such government agencies, may result in the loss of our rights to such intellectual property, which could harm our business.

The U.S. government and/or government agencies have provided, and in the future may provide, funding, facilities, personnel or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. The U.S. government and/or government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under certain specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense of these licenses, could result in the loss of significant rights and could harm our ability to commercialize licensed products and harm our competitive position, business, financial condition, results of operations and prospects. For example, the research resulting in certain of our in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. These rights may permit the government to disclose our confidential information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology.

Our proprietary position may depend upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition-of-matter patents on the active pharmaceutical ingredient (API) in prescription drug products are generally considered to be the strongest form of intellectual property protection for drug products because such patents provide protection without regard to any particular method of use or manufacture or formulation of the API used. We currently have claims in our in-licensed issued U.S. patents that cover the composition-of-matter of our product candidates that expire in 2033 without taking into account any possible patent term adjustments or extensions. We are pursuing claims in our pending owned or in-licensed patent applications that cover the manufacturing, formulation or method-of-use of our product candidates. Our proprietary patent position of our product candidates after 2033 may depend upon issuance of patents from such patent applications. The claims in such patents may not prevent a competitor or other third party from using the same product candidate for a noncovered use, from using a noncovered formulation or from making the same product candidate by a noncovered process.

If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. We cannot ensure that patent rights relating to inventions described and claimed in our pending patent applications will issue or that patents based on our patent applications will not be challenged and rendered invalid and/or unenforceable.

We or our licensors have filed, and we anticipate that in the future we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict:

- if and when any patents will issue;
- whether any of our patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage, including the degree and range of protection our patents that may be issued will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether any of our intellectual property will provide any competitive advantage;
- whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose; or

- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner, including as a result of health epidemics, pandemics, or other widespread outbreaks of contagious disease, including the COVID-19 pandemic and the post-COVID-19 environment impacting our or our licensors' operations. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Our ability to enforce patent rights also depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. If we initiate lawsuits to protect or enforce our patents, or litigate against third-party claims, such proceedings would be expensive and would divert the attention of our management and technical personnel.

Composition of matter patents for biological and pharmaceutical products often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO), or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement can be difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical fields can be uncertain, and evaluating the scope of such patents involves complex legal, factual and scientific analyses and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. In addition,

the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. Recent years have witnessed constant changes in policy governing the scope of claims allowable in the field of antibodies and adoptive cell therapy in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction that we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights, and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result the impact of such third-party intellectual property rights upon the patentability of our own patents and patent applications, as well as the impact of such third-party intellectual property upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are confidential for typically a period of 18 months after filing, or may not be published at all, we cannot be certain that we were the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U.S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U.S. patent laws, including new procedures for challenging pending patent applications and issued patents.

Our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or become involved in post-grant review procedures, oppositions, derivations, reexaminations or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- we cannot predict the scope of protection of any patent issuing based on our patent applications, including whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries;
- the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;
- if enforced, a court may not hold that our patents are valid, enforceable and infringed;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may fail to adequately protect and police our trademarks and trade secrets; and
- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patents and patent applications.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to 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 any other elements of our product candidates, technology and product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Trade secrets and confidential information, however, may be difficult to protect. We seek to protect our trade secrets, know-how and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors and collaborators. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our products, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes and software, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

We may be subject to claims that our employees, consultants or independent contractors have 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 used or disclosed confidential information of these third parties or our employees' former employers or our consultants' or

contractors' current or former clients or customers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If we are not successful, we could lose access or exclusive access to valuable intellectual property.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Some of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

Third-party claims of intellectual property infringement against us or our collaborators may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post-grant review and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Furthermore, patent reform and changes to patent laws in the United States and in foreign jurisdictions add uncertainty to the possibility of challenge to our patents in the future, and could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. We cannot assure you that our product candidates and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or supply chain activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;

- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. We cannot provide any assurances that valid third-party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or other intellectual property, or that we are otherwise employing their proprietary technology without authorization and may sue us. There may be third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates. We are aware of certain third-party patents, including by parties such as Juno Therapeutics, Kite Pharma, the United States Department of Health and Human Services, University of Pennsylvania, and Fred Hutchinson Cancer Research Center with claims to compositions and methods that may be relevant to our product candidates. We believe that we have reasonable defenses against possible allegations of infringement, such as noninfringement or invalidity defenses. There can be no assurance that these defenses will succeed. It is also possible that patents owned by third parties of which we are aware or might become aware, but which we believe are not valid, or do not believe are relevant to our product candidates and other proprietary technologies we may develop, could be found to be infringed by our product candidate. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained, or may apply for or obtain patents in the future that may prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates, and may claim that use of our technologies or the manufacture, use or sale of our product candidates infringes upon these patents. As the number of competitors in our market grows and the number of patents issued in this area increases, the possibility of patent infringement claims against us may increase. Moreover, individuals and groups that are non-practicing entities, commonly referred to as “patent trolls,” purchase patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or “invitations to license,” or may be the subject of claims that our product candidates or technologies and business operations infringe, misappropriate or otherwise violate the intellectual property rights of others. If any such third-party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, or if we are found to otherwise infringe a third-party’s intellectual property rights, the holders of any such patents may be able to block, including by court order, our ability to develop, manufacture or commercialize the applicable product candidate unless we obtain a license under the applicable patents or other intellectual property, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or 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 invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings,

which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

Third parties asserting their patent or other intellectual property rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, cause development delays and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible on a cost-effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

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

Patents are of national or regional effect, and filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. In addition, the laws of some foreign countries, particularly certain developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from 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, trade secrets and other intellectual property, particularly those relating to biotechnology products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third-party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Because of the expense and uncertainty of litigation, we may conclude that even if a third-party is infringing our issued patents, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action, which typically last for years before they are concluded, may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our

competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In such cases, we may decide that the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings and that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, in-license needed technology or other product candidates or enter into development partnerships that would help us bring our product candidates to market.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property or the intellectual property of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or other intellectual property or the intellectual property of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. In addition, in an infringement proceeding or a declaratory judgment action, a court may decide that one or more of our patents is not valid or is unenforceable, or 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. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology 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 a license on commercially reasonable terms. Litigation, interference, derivation or other proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim we infringe their patents or that the patent covering our product candidate is invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent, including lack of novelty, obviousness, non-enablement or insufficient written description or that that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, derivation and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement

proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e)(1). With respect to the validity of our patents, 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 invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates and such an outcome may limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Such a loss of patent protection could have a material adverse impact on our business. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Changes in U.S. patent law or the patent laws of other countries could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the Leahy-Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (1) file any patent application related to our product candidates and other proprietary technologies we may develop or (2) invent any of the inventions claimed in our or our licensor's patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in a series of cases, the U.S. Supreme Court held that certain claims,

including those to diagnostic methods and companion diagnostics are not drawn to patent eligible subject matter under the Patent Act (Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012); Assoc. for Molecular Pathology v. Myriad Genetics, Inc. (2013); Alice Corp. v. CLS Bank International (2014)). In addition, the U.S. Supreme Court has held that certain claims covering a genus of antibodies do not satisfy either the enablement or the written description requirement of the Patent Act (Amgen Inc. et al. v. Sanofi et al. (2023)). Although we do not believe that any of the patents owned or licensed by us will be found invalid based on these decisions, we cannot predict how their interpretation and future decisions by Congress, the federal courts or the USPTO may impact the value of our patents and may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

Similarly, changes in patent laws and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, the complexity and uncertainty of European patent laws have increased in recent years. In Europe, a new unitary patent system took effect June 1, 2023, which will significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (the UPC). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC have the option of opting out of the jurisdiction of the UPC over the first seven years of the court's existence and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

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, if all maintenance fees are paid timely, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. 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. The launch of a generic version of one of our products in particular would be likely to result in an immediate and substantial reduction in the demand for that product, which could have a material adverse effect on our business, financial condition, results of operations and prospects. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. 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.

A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each regulatory approval, and any patent can be extended only once, for a single product. Patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product

approval, or 5 years from the expiration date of the patent to be extended. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, if we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed. We may not receive an extension if we fail to exercise due diligence during the testing phase or regulatory review process, apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration and may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch their product earlier than might otherwise be the case, and our revenue could be reduced, possibly materially. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

Our use of open source software could impose limitations on our ability to commercialize our product candidates.

Our use of open source software could impose limitations on our ability to commercialize our product candidates. Our technology may use open source software that contains modules licensed for use from third-party authors under open source licenses. Some of the software may be provided under license arrangements that allow use of the software for research or other non-commercial purposes. As a result, in the future, as we seek to use our platform in connection with commercially available products, we may be required to license that software under different license terms, which may not be possible on commercially reasonable terms, if at all. If we are unable to license software components on terms that permit its use for commercial purposes, we may be required to replace those software components, which could result in delays, additional cost and/or additional regulatory approvals.

Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the software code. Some open source licenses contain requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use. If we combine our proprietary software with open source software in a certain manner, we could, under certain of the open source licenses, be required to release the source code of our proprietary software to the public. This could allow our competitors to create similar products with lower development effort and time, and ultimately could result in a loss of product sales for us. Although we monitor our use of open source software, the terms of many open source licenses have not been interpreted by U.S. courts, and there is a risk that those licenses could be construed in a manner that could impose unanticipated conditions or restrictions on our ability to commercialize our product candidates. We could be required to seek licenses from third parties in order to continue offering our product candidates, to re-engineer our product candidates or to discontinue the sale of our product candidates in the event re-engineering cannot be accomplished on a timely basis, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

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

We may 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. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. 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, valuable 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.

We or our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions.

Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. 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. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Risks related to ownership of our common stock

Our stock price has been, and is likely to continue to be highly volatile or may decline regardless of our operating performance, resulting in substantial losses for investors.

The trading price of our common stock has been, and is likely to continue to be, highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which they paid. The trading price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including the factors listed below and other factors described in this "Risk factors" section:

- the timing, progress, costs, commencement, enrollment or results of current and future clinical trials and preclinical studies we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the issuance by the FDA of a "refusal to file" letter or a request for additional information;
- changes in laws or regulations in the United States or other countries, including, but not limited to, preclinical study or clinical trial requirements for approvals;
- changes in the structure of healthcare payment systems;
- successful or negative clinical outcomes or other adverse events related to product candidates being developed by others in the oncology or cell therapy fields;
- publication of research reports about us or our industry, or cell therapy programs in particular including, but not limited to, any publications Stanford University or the NCI may make regarding the development of their CD22 programs, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- any changes to our relationship with manufacturers, suppliers, collaborators or other strategic partners;
- manufacturing or supply challenges;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- variations in our results of operations or those of companies that are perceived to be similar to us;
- our cash position;
- an inability to obtain additional funding;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- announcements made by us or our competitors of new product and service offerings, acquisitions, strategic relationships, joint ventures or capital commitments;
- our inability to establish collaborations, if needed;
- our ability to effectively manage our growth;
- changes in the market valuations of similar companies;

- press reports, whether or not true, about our business;
- sales or perceived potential sales of our common stock by us or our stockholders in the future;
- overall fluctuations in the equity markets;
- ineffectiveness of our internal controls;
- changes or developments in the global regulatory environment;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement or expectation of additional financing efforts;
- expiration of market stand-off or lock-up agreements;
- general political and economic conditions;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the trading price of our common stock, regardless of our actual operating performance. If the trading price of our common stock does not exceed the initial public offering price, you may not realize any return on, and may lose some or all of, your investment. In addition, 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.

Our operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- timing and variations in the level of expense related to the current or future development of our programs;
- stock-based compensation estimates;
- our ability to enroll patients in clinical trials and timing and status of enrollment for our clinical trials;
- timing and results of clinical trials, or the addition or termination of clinical trials or funding support by us or potential future partners;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;
- competition from products that compete with our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of our product candidates;
- our execution of any collaboration, licensing or similar arrangements and the timing of payments we may make or receive under potential future arrangements or the termination or modification of any such potential future arrangements;
- any intellectual property infringement, misappropriation or violation lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;

- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any product candidates we may develop receive regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidates, which may be difficult to predict;
- the timing and cost to establish a sales, marketing and supply chain infrastructure to commercialize any products for which we may obtain regulatory approval and intend to commercialize on our own or jointly with current or future collaborators;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with any of our product candidates;
- our ability to commercialize our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies;
- regulatory developments affecting current or future product candidates or those of our competitors;
- impact from health epidemics, pandemics, or other widespread outbreaks of contagious disease, including the COVID-19 pandemic and the post-COVID-19 environment, on us or third parties with which we engage; and
- changes in general global market, political and economic conditions.

If our operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We have identified material weaknesses in our internal control over financial reporting. If our remediation of the material weaknesses is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In preparing the financial statements as of and for the year ended December 31, 2022, management identified it had not fully maintained components of the COSO framework, a system for establishing internal controls, which constituted material weaknesses. Specifically, the control deficiencies related to: (i) an insufficient complement of personnel with an appropriate level of technical knowledge to create the proper environment for effective internal control over financial reporting, (ii) the lack of an effective risk assessment process, (iii) the lack of formalized processes and control activities to support the appropriate segregation of duties over the review of account reconciliations and journal entries and (iv) the lack of monitoring and communication of control processes and relevant accounting policies and procedures.

These material weaknesses resulted in adjustments to the financial statements.

To remediate these material weaknesses, we are in the process of implementing measures designed to review and document financial processes and controls, formalizing policies and procedures to improve our internal controls over financial reporting, as well as hiring of qualified resources to the finance department, including supervisory roles. As of June 30, 2024, these material weaknesses have not yet been remediated.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weaknesses in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

If we fail to remediate our existing material weaknesses or identify new material weaknesses in our internal controls over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, if we are unable to conclude that our internal controls over financial reporting are effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and financial condition or divert financial and management resources from our regular business activities.

An active, liquid trading market for our common stock may not be maintained.

We can provide no assurance that we will be able to maintain an active trading market for our common stock. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling our common stock and our ability to acquire other companies, products or technologies by using our common stock as consideration.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates own a significant majority of our outstanding voting stock as of June 30, 2024. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Our common stock price could decline as a result of sales of a large number of shares of common stock in the public market or the perception that these sales could occur. In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our existing equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, future lock-up agreements and Rule 144 under the Securities Act of 1933, as amended, or the Securities Act and Rule 701 under the Securities Act. These sales, or the perception that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

In addition, certain holders of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

In addition, in the future, we may issue additional shares of common stock, or other equity or convertible debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline.

We do not currently intend to pay dividends on our common stock, so any returns will be limited to the value of our common stock.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value of our common stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law 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.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the trading price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a staggered board of directors divided into three classes serving staggered three-year terms, such that not all members of the board of directors will be elected at one time;
- authorize our board of directors to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- eliminate the ability of our stockholders to fill vacancies on our board of directors;
- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings;
- permit our board of directors to establish the number of directors;
- provide that our board of directors is expressly authorized to make, alter or repeal our amended bylaws;
- provide that stockholders can remove directors only for cause and only upon the approval of not less than 66-2/3% of all outstanding shares of our voting stock;
- require the approval of not less than 66-2/3% of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and
- the jurisdictions in which certain stockholder litigation may be brought.

As a Delaware corporation, we will be subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified

in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two-thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company.

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 and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a breach of a fiduciary duty owed by any director, officer or other employee to us or our stockholders, (3) any action asserting a claim against us or any director, officer or other employee arising pursuant to the Delaware General Corporation Law, (4) any action to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or amended and restated bylaws or (5) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court's having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Exchange Act.

Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may result in increased costs to stockholders to bring a claim for any such dispute and may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock shall be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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

We have incurred substantial losses during our history, do not expect to become profitable in the near future, and we may not achieve profitability. As of December 31, 2023, we had U.S. federal and state net operating loss carryforwards (NOLs) of $10.8 million and $2.3 million, respectively. Our federal NOL carryforwards of $10.8 million carry forward indefinitely. The state NOL carryforwards of $2.3 million begin to expire in 2040. In addition, as of December 31, 2023, we have U.S. federal and state research and development tax credits of $2.3 million and $1.9 million, respectively. The federal research and development tax credits of $2.3 million begin to expire in 2042. The state research and development tax credits of $1.9 million carry forward indefinitely.

Changes in tax laws or regulations may adversely impact our ability to utilize all, or any, of our NOL carryforwards. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (the TCJA), significantly revised the Internal Revenue Code of 1986 (the Code), as amended. Future guidance from the Internal Revenue Service and other tax authorities with respect to the TCJA may affect us, and certain aspects of the TCJA could be repealed or modified in future legislation. For example, the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act) modified certain provisions of the TCJA. Under the TCJA, as modified by the CARES Act,

unused losses generated in taxable years ending after December 31, 2017 will not expire and may be carried forward indefinitely, but the deductibility of such 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 to the TCJA or the CARES Act.

Under Sections 382 and 383 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards 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 acquisitions of assets and/or subsequent shifts in our stock ownership (some of which are outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits. As of December 31, 2023, we have a valuation allowance for the full amount of our net deferred tax assets as the realization of the net deferred tax assets is not determined to be more likely than not.

General Risk Factors

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the trading price or trading volume of our common stock could decline.

The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more of these analysts initiate research with an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease coverage of us or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the trading price or trading volume of our common stock to decline.

We are an "emerging growth company" as defined in the JOBS Act and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including:

- not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes-Oxley Act;
- reduced disclosure obligations regarding executive compensation in our periodic reports and annual report on Form 10-K; and
- exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We could be an emerging growth company for up to five years following the completion of our initial public offering. Our status as an emerging growth company will end as soon as any of the following takes place:

- the last day of the fiscal year in which we have at least $1.235 billion in annual revenue;
- the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates;
- the date on which we have issued, in any three-year period, more than $1.0 billion in non-convertible debt securities; or
- the last day of the fiscal year ending after the fifth anniversary of the completion of our initial public offering.

Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, if we are a smaller reporting company with less than $100.0 million in annual revenue, we would not be required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (Section 404).

We cannot predict if investors will find our common stock less attractive if we choose to rely on any of the exemptions afforded to emerging growth companies and smaller reporting companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the trading price of our common stock may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for any new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

The requirements of being a public company may strain our resources, result in more litigation and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will continue to increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to continue to comply with these requirements, which will increase our costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time-consuming. These laws, regulations and standards are 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. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this Annual Report on Form 10-K and in future filings required under the Exchange Act, our business and financial condition will become more visible, which we believe may result in threatened or

actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

Failure to comply with governmental laws and regulations could harm our business.

Our business is subject to regulation by various federal, state, local and foreign governments. Noncompliance with applicable regulations or requirements could subject us to investigations, sanctions, enforcement actions, disgorgement of profits, fines, damages, civil and criminal penalties, injunctions or other collateral consequences. If any governmental sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, operating results, and financial condition could be materially adversely affected. In addition, responding to any action will likely result in a significant diversion of management's attention and resources and an increase in professional fees. Enforcement actions and sanctions could harm our business, reputation, operating results and financial condition.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that future deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, political unrest, or continued unpredictable and unstable market or other macroeconomic or geopolitical conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.

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

Pursuant to Section 404 of Sarbanes-Oxley and the related rules of the SEC, our management will be required to report on the effectiveness of our internal control over financial reporting beginning with the annual report for our fiscal year ending December 31, 2024. When we lose our status as an "emerging growth company" and reach an accelerated filer threshold, 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 our 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 may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we

or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be 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 we and/or 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 statements, the trading price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

If our estimates or judgments relating to our critical accounting policies prove to be incorrect or financial reporting standards or interpretations change, our results of operations could be adversely affected.

The preparation of financial statements in conformity with generally accepted accounting principles in the United States (U.S. GAAP), requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, as provided in "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Estimates" included in our Annual Report on Form 10-K for the year ended December 31, 2023. The results of these estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our financial statements include but are not limited to stock-based compensation and evaluation of acquisitions of assets and other similar transactions as well as clinical trial accruals. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock.

Additionally, we regularly monitor our compliance with applicable financial reporting standards and review new pronouncements and drafts thereof that are relevant to us. As a result of new standards, changes to existing standards and changes in their interpretation, we might be required to change our accounting policies, alter our operational policies and implement new or enhance existing systems so that they reflect new or amended financial reporting standards, or we may be required to restate our audited or unaudited financial statements and related notes. Such changes to existing standards or changes in their interpretation may also have an adverse effect on our reputation, business, financial position and profit.

We could be subject to changes in tax rates, the adoption of new tax legislation or could otherwise have exposure to additional tax liabilities, which could harm our business.

Changes to tax laws or regulations in the jurisdictions in which we operate, or in the interpretation of such laws or regulations, could significantly increase our effective tax rate, and otherwise have a material adverse effect on our financial condition. In addition, other factors or events, including business combinations and investment transactions, changes in stock-based compensation, changes in the valuation of our deferred tax assets and liabilities, adjustments to taxes upon finalization of various tax returns or as a result of deficiencies asserted by taxing authorities, increases in expenses not deductible for tax purposes, changes in available tax credits, changes in transfer pricing methodologies, other changes in the apportionment of our income and other activities among tax jurisdictions and changes in tax rates, could also increase our effective tax rate. Our tax filings are subject to review or audit by the U.S. Internal Revenue Service (IRS) and state, local and foreign taxing authorities. We may also be liable for taxes in connection with businesses we acquire. Our determinations are not binding on the IRS or any other taxing authorities, and accordingly the final determination in an audit or other proceeding may be materially different than the treatment reflected in our tax provisions, accruals and returns. An assessment of additional taxes because of an audit could harm our business.

We may be subject to claims that our employees, consultants or independent contractors have 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. Although we try to ensure that individuals working for or collaborating with us do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information proprietary to these third parties or our employees' former employers, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. We may be subject to claims that patents and applications we have filed to protect inventions of our employees, consultants, advisors or other third parties, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the trading price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition. Additionally, the dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements and damages awarded to plaintiffs.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended (FCPA), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act

and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

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

(a) Recent Sales of Unregistered Securities

In July 2023, we issued and sold an aggregate of 3,381,941 shares of our series A-1 redeemable convertible preferred stock, par value $0.001 per share, to the purchasers listed on Exhibit A of the Series A Preferred Stock Purchase Agreement at a purchase price of $13.57 per share, for an aggregate price of approximately $45.9 million.

In October 2023, we issued and sold an aggregate of 6,341,150 shares of our Series A-1 redeemable convertible preferred stock, par value $0.001 per share, to the purchasers listed on Exhibit A of the Series A Preferred Stock Purchase Agreement at a purchase price of $13.57 per share, for net proceeds of approximately $86.0 million.

In January 2024, we issued pre-funded warrants to purchase 1,842,499 shares of common stock at an exercise price of $0.001 per share in exchange for 1,842,499 shares of our common stock. The issuance of such warrants was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) of the Securities Act, involving an exchange of securities exchanged by the issuer with its existing security holders exclusively where no commission or other remuneration is paid or given directly or indirectly for soliciting such exchange. No underwriters were involved in this issuance of shares.

In May 2024, we issued and sold 6,471,000 shares of our common stock for a purchase price of $17.00 per share in a private placement. The issuance of the shares was exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(a)(2) of the Securities Act of 1933, as amended.

(b) Use of Proceeds

On November 9, 2023, our registration statement on Form S-1 (File No. 333-275113) (the Prospectus) relating to our initial public offering (IPO) became effective.

There has been no material change in the planned use of proceeds from the IPO from that described in the Prospectus.

(c) Issuer Repurchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c) Insider Adoption or Termination of Trading Arrangements

No director or officer adopted or terminated a trading arrangement for the purchase of Company securities for the quarterly period ended June 30, 2024 that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c), or a "Rule 10b5-1 trading arrangement", or (2) a "non-Rule" 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation, as amended, currently in effect.	8-K	11/14/2023	3.1	
3.2	Bylaws, as amended, currently in effect.	8-K	11/14/2023	3.2	
4.1	Reference is made to Exhibits 3.1 through 3.2				X
4.2	Form of Common Stock Certificate.	S-1/A	11/6/2023		
4.3	Amended and Restated Investors' Rights Agreement, dated February 9, 2023, by and among the Registrant and the investors listed therein.	S-1/A	11/6/2023	4.3	
4.4	Form of Securities Purchase Agreement, dated May 28, 2024, by and among the Company and the Purchasers	8-K	5/28/2024	10.1	
10.1†	Sublease Agreement, dated July 1, 2024, by and between the Company and Vaxcyte, Inc.	8-K	7/8/2024	10.1	
10.2	Second Amendment to Sublease Agreement, dated June 21, 2024, by and between BigHat Biosciences, Inc. and CARGO Therapeutics, Inc. (f/k/a Syncopation Life Sciences, Inc.)				X
10.3#	Amended and Restated Non-Employee Director Compensation Program				X
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.				X
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.				X
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
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.				X
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				X

+ This certification accompanies the Quarterly Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

# Indicates management contract or compensatory plan.

† Certain portions of this document constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

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.

CARGO Therapeutics, Inc.

Date: August 12, 2024

By: /s/ Gina Chapman

Gina Chapman
Chief Executive Officer

Date: August 12, 2024

By: /s/ Anup Radhakrishnan

Anup Radhakrishnan
Chief Financial Officer

Exhibit 10.2

SECOND AMENDMENT TO SUBLEASE

THIS SECOND AMENDMENT TO SUBLEASE (this "Amendment") is made as of June 21, 2024 by and between BigHat Biosciences, Inc., a Delaware corporation ("Sublessor") and Cargo Therapeutics, Inc. (formerly known as Syncopation Life Sciences, Inc.), a Delaware corporation ("Sublessee"), with reference to the following facts and objectives:

RECITALS

A. Sublessor, as tenant, and BP3-SF6 1900 ADLP LLC, as landlord ("Master Lessor"), are parties to that certain Lease dated as September 3, 2021, as amended by that certain First Amendment to Lease dated August 19, 2022 (as amended, the "Master Lease"), with respect to premises currently consisting of approximately 31,117 rentable square feet located on the third (3rd) floor (the "3rd Floor Premises") and approximately 33,008 rentable square feet located on the fourth (4th) floor of the building located at 1900 Alameda de las Pulgas, San Mateo, California (the "Building").

B. Sublessor and Sublessee are parties to a Sublease dated November 4, 2021 (the "Sublease"), with respect to a portion of the 3rd Floor Premises consisting of approximately 15,400 rentable square feet (the "Original Subleased Premises"), as amended by that certain First Amendment to Sublease dated August 17, 2022 (the "First Amendment") wherein the premises subleased under the Sublease were expanded to include the remainder of the 3rd Floor Premises (the "Expansion Subleased Premises").

C. Sublessor and Sublessee desire to terminate the Sublease with respect to the Expansion Subleased Premises and further modify the Sublease as set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Reduction of Subleased Premises. On the last to occur of (a) August 16, 2024, (b) the date by which both Sublessor and Sublessee has obtained the Required Consent (as defined below) and (c) the date Sublessee delivers possession of the Expansion Subleased Premises to Sublessor in the condition required under Paragraph 14 of the Sublease and Section 15.2 of the Master Lease as incorporated into the Sublease (as applied to such space) (the "Reduction Date"), the Subleased Premises shall be decreased to include only the Original Subleased Premises. Following the Reduction Date, all references in the Sublease to the "Subleased Premises" shall be deemed to mean only the Original Subleased Premises and the Subleased Premises shall be deemed to consist of approximately 15,400 rentable square feet. The Original Subleased Premises shall remain part of the Subleased Premises through the Expiration Date of the Sublease, which the parties acknowledge is November 10, 2024. The terms of Paragraph 3(B) of the Sublease shall be of no further force and effect. Effective as of the Reduction Date, the Sublease shall be deemed terminated with respect to the Expansion Subleased Premises with respect to the portion of the Term arising from and after the Reduction Date; provided, however, that nothing herein shall excuse, waive, delay, abrogate or otherwise effect Sublessee's obligations under the Sublease with respect to the Expansion Subleased Premises prior to the Reduction Date or Sublessor's rights and remedies with respect to any prior and/or continuing defaults of Sublessee under the Sublease, and all of Sublessor's rights and remedies under the Sublease with respect to

any prior and/or continuing defaults are hereby expressly reserved to Sublessor. Sublessee's failure to surrender the Expansion Subleased Premises as required in this Section 1 shall be considered a holdover with respect to such space and be subject to the terms of Paragraph 6 of the Sublease with respect to such space.

2. Base Rent. Sublessee shall no longer pay Base Rent for the Expansion Subleased Premises commencing on the Reduction Date, but shall continue to pay Base Rent for the Original Subleased Premises in the amounts and in the manner described in Paragraph 4(A) of the Sublease.

3. Additional Rent. As of the Reduction Date, Sublessee's Share shall be deemed to be 24.02% of the premises under the Master Lease and 13.59% of the Building, subject to any adjustments of the square footage of the premises under the Master Lease, Subleased Premises or Building. Throughout the Term, Sublessee shall continue to pay all Rent payable under the Sublease, as modified herein, including, without limitation, Operating Expenses, Tax Expenses and Utilities Costs, in accordance with the terms of the Sublease.

4. Required Consents. This Amendment and Sublessor's and Sublessee's obligations hereunder are conditioned upon the written consent hereto of Master Lessor in form and substance reasonably acceptable to both Sublessor and Sublessee (the "Required Consent"). Each party shall use commercially reasonable efforts to obtain the Required Consent. If the Required Consent is not received within fifteen (15) days following the full execution and delivery of this Amendment, this Amendment may be terminated by either party upon delivery of written notice to the other party prior to the receipt of the Required Consent.

5. Parking. Commencing on of the Reduction Date, the number of parking spaces as to which Sublessee has parking rights shall decrease from seventy-eight (78) to thirty-nine (39).

6. Furniture, Fixtures and Equipment. Sublessee shall surrender the "Expansion Furniture" (as defined in Paragraph 9 of the First Amendment) in accordance with Paragraph 26 of the Sublease.

7. Shared Areas. Notwithstanding anything to the contrary contained in Section 10 of the First Amendment, on the Reduction Date, the provisions regarding the Shared Areas in Paragraph 2 of the Sublease shall be deemed reinstated and be of full force and effect.

8. Certified Access Specialist. For purposes of Section 1938 of the California Civil Code, Sublessor hereby discloses to Sublessee, and Sublessee hereby acknowledges, that Sublessor has not had an inspection of the Subleased Premises performed by a Certified Access Specialists (CASp). As required by Section 1938(e) of the California Civil Code, Sublessor hereby states as follows: "A Certified Access Specialist (CASp) can inspect the subject premises and determine whether the subject premises comply with all of the applicable construction-related accessibility standards under state law. Although state law does not require a CASp inspection of the subject premises, the commercial property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the subject premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of the CASp inspection, the payment of the fee for the CASp inspection, and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the premises."

9. Broker. Sublessee and Sublessor each represent that it has dealt with no real estate brokers, finders, agents or salesmen in connection with this Amendment. Each party agrees to hold the other party harmless from and against all claims for brokerage commissions, finder's fees or other compensation made by

any agent, broker, salesman or finder as a consequence of such party's actions or dealings with such agent, broker, salesman, or finder.

10. Miscellaneous. This Amendment shall in all respects be governed by and construed in accordance with the laws of the State of California. If any term of this Amendment is held to be invalid or unenforceable by any court of competent jurisdiction, then the remainder of this Amendment shall remain in full force and effect to the fullest extent possible under the law, and shall not be affected or impaired. If either party brings any action or legal proceeding with respect to this Amendment, the prevailing party shall be entitled to recover reasonable attorneys' fees, experts' fees, and court costs. This Amendment, together with the Sublease, constitutes the entire agreement between Sublessor and Sublessee regarding the Sublease and the subject matter contained herein and supersedes any and all prior and/or contemporaneous oral or written negotiations, agreements or understandings. This Amendment shall be binding upon and inure to the benefit of Sublessor and Sublessee and their respective heirs, successors and assigns. No subsequent change or addition to this Amendment shall be binding unless in writing and duly executed by both Sublessor and Sublessee. Except as specifically amended hereby, all of the terms and conditions of the Sublease are and shall remain in full force and effect and are hereby ratified and confirmed. Any capitalized terms used but not defined herein shall have the meanings ascribed to such terms in the Sublease or the Master Lease, as applicable. Sublessee and Sublessor each represent and warrant to the other that each person executing this Amendment on behalf of such party is duly authorized to execute and deliver this Sublease on behalf of that party. This Amendment may be executed in counterparts. Signature pages may be detached from the counterparts and attached to a single copy of this Amendment to physically form one document. In addition, the parties hereto consent and agree that this Amendment may be signed using electronic signature technology (e.g., via DocuSign or similar electronic signature technology), and that such signed electronic record shall be valid and as effective to bind the party so signing as a paper copy bearing such party's handwritten signature.

[SIGNATURES ARE ON THE FOLLOWING PAGE]

SUBLESSOR: **SUBLESSEE:**

BIGHAT BIOSCIENCES, INC., a Delaware corporation

By: /s/ Mark DePristo

Name: Mark DePristo

Its: CEO

CARGO THERAPEUTICS, INC., a Delaware corporation

By: /s/ Anup Radhakrishnan

Name: Anup Radhakrishnan

Its: Chief Financial Officer

Exhibit 10.3

CARGO THERAPEUTICS, INC.
AMENDED AND RESTATED
NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

This Cargo Therapeutics, Inc. (the "***Company***") Amended and Restated Non-Employee Director Compensation Program (this "***Program***") has been adopted under the Company's 2023 Incentive Award Plan (the "***Plan***") and shall be effective upon the closing of the Company's initial public offering of its common stock (the "***Effective Date***"). Capitalized terms not otherwise defined herein shall have the meaning ascribed in the Plan.

Cash Compensation

Commencing on the Effective Date, annual retainers will be paid in the following amounts to Non-Employee Directors:

Non-Employee Director:	$40,000
Chair:	$30,000
Audit Committee Chair:	$15,000
Research and Development Committee Chair:	$15,000
Compensation Committee Chair:	$10,000
Nominating and Governance Committee Chair:	$9,000
Audit Committee Member (non-Chair):	$7,500
Research and Development Committee Member (non-Chair):	$7,500
Compensation Committee Member (non-Chair):	$5,000
Nominating and Governance Committee Member (non-Chair):	$4,500

All annual retainers are additive and will be paid in cash quarterly in arrears promptly following the end of the applicable calendar quarter, but in no event more than 30 days after the end of such quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described above, for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable. In the event the Effective Date does not occur on the first day of a calendar quarter, the retainer paid to each Non-Employee Director for the calendar quarter during which the Effective Date occurs will be prorated for the portion of such calendar quarter occurring on and after the Effective Date.

Equity Compensation

Initial Stock Option Grant: Each Non-Employee Director who is initially elected or appointed to serve on the Board on or after the Effective Date shall be granted an Option under the Plan or any other applicable Company equity incentive plan then-maintained by the Company to purchase 50,000 shares of Common Stock (the "***Initial Option***"), *provided*, that in the event the grant date fair value of the Initial Option exceeds $800,000, the number of shares subject to the Initial Option automatically shall be reduced to the maximum number of

shares that results in the Initial Option having a grant date fair value of $800,000 or less, in each case, with grant date fair value determined consistently with the Company's financial statements.

The Initial Option will be automatically granted on the date on which such Non-Employee Director commences service on the Board, and will vest as to 1/36th of the shares subject thereto on each monthly anniversary of the applicable date of grant such that the shares subject to the Initial Option are fully vested on the third anniversary of the date of grant, subject to the Non-Employee Director continuing in service on the Board through each such vesting date.

Annual Stock Option Grant: On the date of each annual meeting of the Company's stockholders after the Effective Date (each, an "***Annual Meeting***"), each Non-Employee Director who will continue to serve as a Non-Employee Director immediately following such meeting, shall be granted an Option under the Plan or any other applicable Company equity incentive plan then-maintained by the Company to purchase 25,000 shares of Common Stock (the "***Annual Option***"), *provided*, that in the event the grant date fair value of the Annual Option exceeds $400,000, the number of shares subject to the Annual Option automatically shall be reduced to the maximum number of shares that results in the Annual Option having a grant date fair value of $400,000 or less, in each case, with grant date fair value determined consistently with the Company's financial statements.

The Annual Option will be automatically granted on the date of the applicable Annual Meeting, and will vest in full on the earlier of (i) the first anniversary of the date of grant and (ii) immediately prior to the Annual Meeting following the date of grant, subject to the Non-Employee Director continuing in service on the Board through such vesting date.

The per share exercise price of each Option granted to a Non-Employee Director shall equal the Fair Market Value of a share of Common Stock on the date the Option is granted.

The term of each Option granted to a Non-Employee Director shall be ten years from the date the Option is granted, subject to earlier termination in connection with cessation of Board service.

Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their employment with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Option, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from

employment with the Company and any parent or subsidiary of the Company, Annual Options as described above.

Change in Control

Upon a Change in Control of the Company, all outstanding equity awards granted under the Plan and any other equity incentive plan maintained by the Company that are held by a Non-Employee Director shall become fully vested and/or exercisable, irrespective of any other provisions of the Non-Employee Director's Award Agreement.

Reimbursements

The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures as in effect from time to time.

Miscellaneous

The other provisions of the Plan shall apply to the Options granted automatically pursuant to this Program, except to the extent such other provisions are inconsistent with this Program. All applicable terms of the Plan apply to this Program as if fully set forth herein, and all grants of Options hereby are subject in all respects to the terms of the Plan. The grant of any Option under this Program shall be made solely by and subject to the terms set forth in a written agreement in a form to be approved by the Board and duly executed by an executive officer of the Company.

* * * * *

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Gina Chapman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CARGO Therapeutics, 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;
4. 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;
5. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2024

/s/ Gina Chapman

Gina Chapman

Chief Executive Officer

(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Anup Radhakrishnan, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of CARGO Therapeutics, 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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
    b. 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 12, 2024

/s/Anup Radhakrishnan

Anup Radhakrishnan

Chief Financial Officer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Gina Chapman, Chief Executive Officer of CARGO Therapeutics, Inc. (the "Company"), and Anup Radhakrishnan, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2024, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 12, 2024

By: /s/ Gina Chapman

Gina Chapman

Chief Executive Officer

(Principal Executive Officer)

Date: August 12, 2024

By: /s/ Anup Radhakrishnan

Anup Radhakrishnan

Chief Financial Officer

(Principal Financial Officer)