UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2023

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: 001-40384

TALARIS THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**83-2377352**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
93 Worcester St. Wellesley, MA	**02481**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (502) 398-9250

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 $0.0001 per share	TALS	The Nasdaq Global 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 May 1, 2023, the registrant had 42,166,025 shares of common stock, $0.0001 par value per share, outstanding.

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SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties, including those described in Part II, Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q (this “Quarterly Report”). The principal risks and uncertainties affecting our business include the following:

- We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future could have negative consequences.
- Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, an acquisition, merger, a business combination and/or divestiture, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.
- If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.
- If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.
- Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
- We may become involved in litigation, including securities class action litigation, that could divert management’s attention and harm the company’s business, and insurance coverage may not be sufficient to cover all costs and damages.
- Should we resume development of our product candidates, our business will substantially depend upon the successful development and regulatory approval of FCR001, our lead product candidate. If we are unable to obtain regulatory approval for FCR001, our business may be materially harmed.
- We are a biotechnology company and we have incurred net losses since our inception. We anticipate that we will continue to incur significant net losses for the foreseeable future, and may never achieve or maintain profitability.
- We have not yet completed any registrational trials and have no history of commercializing products, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- Our product candidates represent a novel therapeutic approach that could result in heightened regulatory scrutiny. The regulatory landscape that applies to our Facilitated Allo-HSCT Therapy is rigorous, complex, uncertain and subject to change.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Should we resume development of our product candidates, the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.
- Should we resume development of our product candidates, delays or difficulties in the enrollment of patients in clinical trials, would have a material adverse effect on our business.
- The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Should we resume development of our product candidates, any product candidate we advance into clinical trials, may not have favorable efficacy or safety in later clinical trials or receive regulatory approval.
- Should we resume development of our product candidates, interim, “top line” or preliminary data from our clinical trials that we may announce or share with regulatory authorities 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.
- Should we resume production of our product candidates, or associated conditioning regimens or treatment protocols, they may cause undesirable side effects such as infection or graft vs. host disease, or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.
- Even if we resume development of our product candidates and receive regulatory approval, we will still face extensive ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense, and our products may still face future development and regulatory difficulties.
- We currently operate our own manufacturing facility. Should we resume development of our product candidates, we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.
- Our product candidates are uniquely manufactured for each patient, and should we resume development of our product candidates, we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities.
- If our manufacturing facility is damaged or destroyed or production at our manufacturing facility is otherwise interrupted, our business would be negatively affected.
- We have historically been dependent on a limited number of suppliers and, in some cases sole suppliers, for some of our components and materials used in our product candidates.
- We have historically relied, and may in the future rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet

expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

- We depend on intellectual property licensed from the ULRF, and termination of this license could result in the loss of significant rights, which would materially harm our business.
- Should we resume development of our product candidates, we expect such product candidates to be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.
- Should we resume development of our product candidates, we may be unable to obtain and maintain sufficient intellectual property protection for our product candidates and manufacturing process. If the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.
- Our recent reductions in force may negatively impact employee morale and productivity. Further, uncertainties surrounding the future of our clinical programs may increase retention risk.
- While positions have been eliminated, certain functions necessary to our reduced operations remain, and we may be unsuccessful in re-distributing duties and obligations to our remaining employees and consultants.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

TALARIS THERAPEUTICS, INC.

BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,224	$ 13,670
Marketable securities	141,589	167,612
Prepaid and other current assets	3,047	4,331
Total current assets	168,860	185,613
Property and equipment, net	2,584	5,348
Right-of-use assets	1,052	2,643
Other assets	111	111
Total assets	$ 172,607	$ 193,715
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,384	$ 3,887
Accrued expenses	6,044	6,665
Lease liability, current	751	910
Total current liabilities	10,179	11,462
Share repurchase liability	162	208
Other liabilities	14	16
Lease liability, net of current	521	1,974
Total liabilities	10,876	13,660
Stockholders' equity		
Common stock, $0.0001 par value, 140,000,000 shares authorized and 41,910,130 issued and outstanding and 10,000,000 non-voting shares authorized as of March 31, 2023 and 140,000,000 shares authorized and 41,629,426 issued and outstanding and 10,000,000 non-voting shares authorized as of December 31, 2022	4	4
Additional paid-in-capital	349,264	345,513
Accumulated deficit	(187,238)	(164,741)
Accumulated other comprehensive loss	(299)	(721)
Total stockholders' equity	161,731	180,055
Total liabilities and stockholders' equity	$ 172,607	$ 193,715

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

TALARIS THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended March 31,	
	2023	**2022**
Operating expenses		
Research and development	$ 13,415	$ 14,196
General and administrative	6,182	4,218
Restructuring costs	4,481	—
Total operating expenses	24,078	18,414
Loss from operations	(24,078)	(18,414)
Interest and other income, net	1,581	155
Net loss	$ (22,497)	$ (18,259)
Unrealized gain (loss) on marketable securities	422	(848)
Total other comprehensive loss	422	(848)
Total comprehensive loss	$ (22,075)	$ (19,107)
Net loss	$ (22,497)	$ (18,259)
Net loss per common share, basic and diluted	(0.54)	(0.45)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	41,796,830	40,980,213

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

TALARIS THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share amounts)
(unaudited)

	Common Stock		Additional		Accumulated Other	Total
	Outstanding Shares	Amount	Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Equity
Balance at December 31, 2021	40,913,049	$ 4	$ 333,730	$ (90,847)	$ (78)	242,809
Issuance of common stock upon exercise of stock options	110,819	—	131	—	—	131
Stock-based compensation expense	—	—	2,197	—	—	2,197
Net loss	—	—	—	(18,259)	—	(18,259)
Unrealized loss on marketable securities	—	—	—	—	(848)	(848)
Balance at March 31, 2022	41,023,868	$ 4	$ 336,058	$ (109,106)	$ (926)	$ 226,030
Balance at December 31, 2022	41,629,426	$ 4	$ 345,513	$ (164,741)	$ (721)	$ 180,055
Issuance of common stock upon exercise of stock options	87,781	—	92	—	—	92
Vesting of restricted stock units	192,832	—	—	—	—	—
Stock-based compensation expense	—	—	3,659	—	—	3,659
Net loss	—	—	—	(22,497)	—	(22,497)
Unrealized gain on marketable securities	—	—	—	—	422	422
Balance at March 31, 2023	41,910,039	$ 4	$ 349,264	$ (187,238)	$ (299)	$ 161,731

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

TALARIS THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Three months ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (22,497)	$ (18,259)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	436	297
Accretion and amortization of marketable securities, net	(1,285)	3
Amortization of right-of-use assets	203	191
Stock-based compensation expense	3,659	2,197
Asset impairment	2,712	—
Loss on disposal of assets	19	—
Changes in operating assets and liabilities:		
Prepaid and other current assets	1,284	(346)
Other assets	—	(7)
Accounts payable	(414)	755
Accrued expenses	(793)	(1,054)
Operating lease liability	(224)	(129)
Other liabilities	(2)	72
Net cash used in operating activities	(16,902)	(16,280)
Cash flows from investing activities:		
Purchases of property and equipment	(320)	(1,341)
Purchases of marketable securities	(25,270)	(39,982)
Maturities of marketable securities	53,000	61,750
Net cash provided by investing activities	27,410	20,427
Cash flows from financing activities:		
Proceeds from exercise of stock options	46	30
Net cash provided by financing activities	46	30
Net increase in cash and cash equivalents	10,554	4,177
Cash and cash equivalents at beginning of period	13,670	18,614
Cash and cash equivalents at end of period	$ 24,224	$ 22,791
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment additions included in accounts payable and accrued expenses	$ 230	$ 667

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

1. Nature of Business and Liquidity

Talaris Therapeutics, Inc. (“Talaris” or the “Company”) is a cell therapy company developing an innovative method of allogeneic hematopoietic stem cell transplantation (“allo-HSCT”), called Facilitated Allo-HSCT Therapy. The Company maintains corporate offices in Boston, Massachusetts, a laboratory in Houston, Texas and its cell processing facility in Louisville, Kentucky.

In February 2023, the Company announced the discontinuation of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001’s ability to induce durable tolerance in living donor kidney transplant recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. In February 2023, the Company also announced a comprehensive review of strategic alternatives focused on maximizing shareholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of the Company's cell therapy chemistry, manufacturing and controls ("CMC") capabilities. In March 2023, pending the outcome of the Company's review of strategic alternatives, the Company voluntarily paused enrollment in the FREEDOM-3 Phase 2 clinical trial evaluating FCR001's ability to induce tolerance in diffuse systemic scleroderma, a severe autoimmune disease, while continuing to evaluate patients for potential future enrollment.

In April 2023, the Company’s Board of Directors approved, and the Company announced a further reduction in force (the “April Reduction in Force”) that is expected to result in the termination of approximately 80 additional employees, or approximately 95% of the Company’s remaining workforce. The Company estimates that the April Reduction in Force will be substantially completed by May 26, 2023.

Initial Public Offering

The Company completed an initial public offering (“IPO”) on May 11, 2021 in which the Company issued and sold 8,825,000 shares of its common stock at a public offering price of $17.00 per share. The Company’s aggregate gross proceeds from the sale of shares in the IPO was $150.0 million before underwriting discounts and commissions and other expenses of approximately $12.9 million. Upon completion of the offering, the Company’s outstanding convertible preferred stock was automatically converted into shares of common stock and non-voting common stock. Following the IPO, there were no shares of preferred stock outstanding. Prior to the IPO, on April 30, 2021, the Company’s board of directors and shareholders approved a one-for-5.35 reverse share split of issued and outstanding common shares and incentive shares and a proportional adjustment to the existing conversion ratios for the Company’s convertible preferred stock.

Liquidity and Going Concern

The accompanying interim financial statements have been prepared assuming that the Company will continue as a going concern. Management has evaluated whether there are conditions and events that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the financial statements are issued. Since its inception, the Company has incurred net losses and negative cash flows from operations. During the three months ended March 31, 2023 and the year ended December 31, 2022, the Company incurred a net loss of $22.5 million and $73.9 million, respectively, and used $16.9 million and $60.9 million in cash for operations, respectively. In addition, as of March 31, 2023, the Company had an accumulated deficit of $187.2 million. The Company expects to continue to generate operating losses and negative cash flows for the foreseeable future.

The Company currently expects the cash and cash equivalents of $24.2 million and marketable securities of $141.6 million as of March 31, 2023, will be sufficient to fund its operating expenses and capital requirements for more than twelve months from the date the financial statements are available to be issued. However, due to consideration of certain qualitative factors, including the discontinuation or pause of all clinical trials, CMC operations and research activities, as well as workforce reduction of all but a few custodial employees, the Company has concluded there is substantial doubt regarding the ability to continue as a going concern for more than twelve months from the date that the financial statements are available to be issued. These financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company does not currently expect to progress any product candidate through clinical trials or commercial approval and it does not currently expect to generate any revenue from product sales. The Company does expect to devote substantial time and resources to exploring strategic alternatives that the board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The Company has not set a timetable for completion of this strategic review process, and the board of directors has not approved a

definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that the Company will make any additional cash distributions to stockholders.

2. Summary of Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("U.S. GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make judgments, assumptions, and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of financial statements, and the reported amounts of income and expense during the reporting period. The most significant estimates relate to the determination of the fair value of stock option grants and estimates related to the amount of prepaid and accrued research and development expenses as of the balance sheet date. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when the facts and circumstances dictate. These estimates are based on information available as of the date of the financial statements; therefore, actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of March 31, 2023 and December 31, 2022, cash and cash equivalents consisted primarily of checking and savings deposits, money market fund holdings, and commercial paper.

Marketable Securities

The Company classifies its marketable securities as available-for-sale securities, which are carried at their fair value based on the quoted market prices of the securities. Unrealized gains and losses are reported as accumulated other comprehensive loss, a separate component of stockholders' deficit. Realized gains and losses on available-for-sale securities are included in net loss in the period earned or incurred.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset. Equipment and furniture and fixtures are depreciated over five or seven year lives. Leasehold improvements are amortized over the shorter of the lease term or the five-year estimated useful life of the asset. Computer equipment and computer software are depreciated over three years. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

The Company evaluates its long-lived assets, which consist primarily of property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. The Company determined a triggering event had occurred as of March 31, 2023 indicating the carrying amount of certain assets may not be recoverable. For additional disclosures regarding the $2.7 million non-cash impairment charge and accompanying analysis, refer to Note 6. During the year ended December 31, 2022, the Company recorded a $0.2 million non-cash impairment charge (see Note 6).

Concentration of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash and cash equivalents. The Company's investment policy includes guidelines regarding the quality of the financial institutions and financial

instruments and defines allowable investments that it believes minimizes the exposure to concentration of credit risk. The Company may invest in money market funds (minimum of $1 billion in assets), U.S. Treasury securities, corporate debt, bank debt, U.S. government-related agency securities, other sovereign debt, municipal debt and commercial paper. These deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts and believes that it is not exposed to significant credit risk as its deposits are held at financial institutions that management believes to be of high credit quality.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("FDIC") was appointed as receiver. On March 27, 2023, SVB was acquired by First-Citizen BancShares, Inc ("First-Citizen"). Similarly, on May 1, 2023, First Republic Bank ("FRB") was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. JPMorgan Chase Bank, National Association (N.A.) acquired all of FRB's deposit accounts and substantially all of its assets. The Company historically did not and currently does not have banking relationships with SVB or FRB.

Fair Value of Financial Instruments

Fair value is defined as the price that the Company would receive to sell an investment in a timely transaction or pay to transfer a liability in a timely transaction with an independent buyer in the principal market, or in the absence of a principal market, the most advantageous market for the investment or liability. A framework is used for measuring fair value utilizing a three-tier hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 investments) and the lowest priority to unobservable inputs (Level 3 investments).

The three levels of the fair value hierarchy are as follows:

- ***Level 1 inputs:*** Unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities;
- ***Level 2 inputs:*** Quoted prices in markets that are not considered to be active or financial instrument valuations for which all significant inputs are observable, either directly or indirectly; and
- ***Level 3 inputs:*** Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

Financial instruments are categorized in their entirety based on the lowest level of input that is significant to the fair value measurement. The assessment of the significance of a particular input to the fair value measurement requires judgment and considers factors specific to the investment.

The Company's money market funds and marketable securities are carried at fair value determined according to the fair value hierarchy described above (Level 1 and Level 2, respectively).

Research and Development Expenses

Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research organization agreements, investigational sites, and consultants; (iii) the cost of acquiring, developing, and manufacturing clinical study materials; (iv) costs associated with preclinical and clinical activities and regulatory operations; (v) costs incurred in development of intellectual property; and (vi) an allocated portion of facilities and other infrastructure costs associated with our research and development activities. Costs incurred in connection with research and development activities are expensed as incurred.

The Company enters into consulting, research, and other agreements with commercial entities, researchers, universities, and others for the provision of goods and services. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the respective vendors, including the Company's clinical sites. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, nonemployees, and directors based on the fair value on the date of the grant and recognizes stock-based compensation expense of those awards over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock option, restricted stock unit, and stock appreciation right awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company's policy is to account for forfeitures when they occur.

The Company classifies stock-based compensation expense in its statement of operations in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company recently completed its IPO and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the US Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is zero because the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Prior to the Company's IPO, the Company considered the estimated fair value of the common stock as of the measurement date in determining the exercise price for options granted. The estimated fair value of the common stock was determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred shareholders, and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, forecasted future operations of the Company, an evaluation or benchmark of the Company's competition, and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date. The fair value for options granted since the Company's IPO are based on the closing stock price on grant date.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

The Company provides reserves for potential payments of tax to various tax authorities related to uncertain tax positions. These reserves are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filings or positions is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense. The Company had no significant uncertain tax positions as of March 31, 2023 and December 31, 2022.

Basic and Diluted Net Loss Per Share

The Company calculates basic and diluted net loss per share using the two-class method. The two-class method requires income available to common stock as if all income for the period had been distributed. Accordingly, basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period, without consideration of potential dilutive securities. Diluted net loss per share is computed by dividing the net loss by the sum of the weighted average number of common shares outstanding during the period plus the dilutive effects of potentially dilutive securities outstanding during the period. Potentially dilutive securities include vested and unexercised stock options, restricted stock issued upon early exercise of stock options, convertible preferred shares and contingent stock liabilities. The dilutive effect of stock options and contingent stock liabilities are computed using the treasury stock method and the dilutive effect of convertible preferred shares is calculated using the if-converted method. The Company has generated a net loss for all periods presented, therefore diluted net loss per share is the same as basic net loss per share since the inclusion of potentially dilutive securities would be anti-dilutive.

Segments

Operating segments are defined as components of an entity for which separate financial information is made available and is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company's CODM is the chief executive officer and operations are managed as a single segment for the purposes of assessing performance and making operating decisions.

Comprehensive Loss

Comprehensive loss represents net loss for the period plus the results of certain other changes in stockholders' equity. The Company's comprehensive loss included unrealized gains related to marketable securities for the three months ended March 31, 2023 and 2022.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, and subsequently has issued additional guidance (collectively, "ASC 842"), which requires companies to generally recognize operating and financing lease liabilities and corresponding right-of-use assets on the balance sheet. The Company adopted ASC 842 on January 1, 2022 using the modified retrospective approach, with no restatement of prior periods. Upon adoption, the Company elected the package of transitional practical expedients which allowed the Company to carry forward prior conclusions related to whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for existing leases. In addition, the Company made an accounting policy election to not apply the recognition requirements in the leasing standards to short-term leases, which is a lease that at commencement date has a lease term of 12 months or less and does not contain a purchase option that it is reasonably certain to exercise.

As a result of the adoption of the new leasing standards, on January 1, 2022, the Company recorded right-of-use assets of $3.4 million and operating lease liabilities of $3.5 million. The adoption did not have a material impact on the statement of operations or the statement of cash flows. For additional information on the adoption of the new leasing standard, refer to Note 8.

3. Fair Value of Financial Assets

The following table presents information about the Company's financial instruments that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the inputs the Company utilized to determine such fair value *(in thousands)*:

	March 31, 2023			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 23,811	$ 23,811	$ —	$ —
Marketable securities	141,589	16,932	124,657	—
Total financial assets measured at fair value	$ 165,400	$ 40,743	$ 124,657	$ —

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 12,309	$ 12,309	$ —	$ —
Marketable securities	167,612	31,718	135,894	—
Total financial assets measured at fair value	$ 179,921	$ 44,027	$ 135,894	$ —

4. Marketable Securities

The fair value of the Company's marketable securities as of March 31, 2023 and December 31, 2022 is based on level 1 and level 2 inputs. The Company's investments consist mainly of U.S. government and agency securities, government-sponsored bond obligations and certain other corporate debt securities. Fair value is determined by taking into consideration valuations obtained from third-party pricing services. The third-party pricing services utilize industry standard valuation models, for which all significant inputs are observable, either directly or indirectly, to estimate fair value. These inputs include reported trades of and broker/dealer quotes on the same or similar securities; issuer credit spreads; benchmark securities; and other observable inputs. There were no transfers between levels within the hierarchy during the three months ended March 31, 2023 and the year ended December 31, 2022. The Company has assessed U.S. government treasuries as level 1 and all other marketable securities as level 2 within the fair value hierarchy of ASC 820. The Company classifies its entire investment portfolio as available-for-sale as defined in ASC 320, *Debt Securities*. Securities are carried at fair value with the unrealized gains (losses) reported in other comprehensive loss.

As of March 31, 2023 and December 31, 2022, none of the Company's investments were determined to be other than temporarily impaired.

The following table summarizes the Company's investments *(in thousands)*:

	March 31, 2023			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$ 111,739	$ 6	$ (181)	$ 111,564
Government and agency securities	30,149	—	(124)	30,025
Total	$ 141,888	$ 6	$ (305)	$ 141,589

	December 31, 2022			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$ 119,313	$ 19	$ (365)	$ 118,967
Government and agency securities	43,016	—	(368)	42,648
Corporate debt securities	6,004	—	(7)	5,997
Total	$ 168,333	$ 19	$ (740)	$ 167,612

The aggregate fair value of available-for-sale securities in an unrealized loss position as of March 31, 2023 was $125.0 million. The Company has reviewed its portfolio of available-for-sale debt securities and determined that the decline in fair value below cost did not result from credit-loss related factors. As such, no allowance for credit losses was recorded as of March 31, 2023.

5. Prepaid and Other Current Assets

Prepaid and other current assets consisted of the following *(in thousands)*:

	March 31, 2023	December 31, 2022
Prepaid insurance	$ 325	$ 1,037
Prepaid research and development expenses	1,809	2,426
Other current assets	913	868
Total prepaid and other current assets	$ 3,047	$ 4,331

6. Property and Equipment, Net

Property and equipment, net consisted of the following *(in thousands)*:

	March 31, 2023	December 31, 2022
Equipment	$ 4,727	$ 6,562
Leasehold improvements	918	1,191
Computer equipment	861	859
Furniture and fixtures	524	674
Construction in progress	63	242
Total property and equipment	7,093	9,528
Less accumulated depreciation	(4,509)	(4,180)
Property and equipment, net	$ 2,584	$ 5,348

Depreciation expense was $0.4 million and $0.3 million for the three months ended March 31, 2023 and 2022, respectively.

As of March 31, 2023, the Company reviewed the cumulative impact of its announcements in February, March and April of 2023 to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials and initiate a reduction in force of 33% of its employees, pause enrollment in its FREEDOM-3 clinical trial and initiat a second reduction in force of 95% of its remaining employees, respectively, on the carrying value of certain of its long-lived assets. The analysis resulted in the Company determining a triggering event had occurred in relation to the long-lived assets used primarily in the Company's CMC operations with a net book value of $4.7 million as of March 31, 2023. The net book value of these assets consisted of $3.9 million of equipment, $0.5 million of leasehold improvements and $0.3 million of furniture and fixtures. The Company obtained third-party quotes to assess the current fair value of these assets and determine if an impairment had occurred. The value determined from these quotes was $2.0 million, resulting in the Company recording a non-cash impairment expense of $2.7 million for the assets. The impairment amount was allocated $2.2 million to equipment, $0.3 million to leasehold improvements and $0.2 million to furniture and fixtures. The $2.7 million impairment has been recorded in restructuring costs in the accompanying statement of operations and comprehensive loss.

In July 2022, the Company received a notice from a third-party vendor indicating the decommissioning of its software platform. As a result, the Company recorded a $0.2 million non-cash impairment expense in research and development operating expense in the statement of operations and comprehensive loss for the year ended December 31, 2022.

7. Accrued Expenses

Accrued expenses consisted of the following *(in thousands)*:

	March 31, 2023	December 31, 2022
Compensation and benefit costs	$ 3,200	$ 3,566
Research and development expenses	1,768	1,978
Professional fees, consulting and other	1,076	1,121
Total accrued expenses	$ 6,044	$ 6,665

As a result of the Company's initial reduction in force announced in February 2023, the Company recorded restructuring costs of $1.8 million in the accompanying statement of operations and comprehensive loss, related to severance and employee termination costs during the three months ended March 31, 2023. The Company made cash payments of $0.4 million during the three months ended March 31, 2023. The outstanding balance of $1.4 million is reflected in accrued expenses within the accompanying balance sheet and in compensation and benefit costs in the above as of March 31, 2023, respectively.

8. Commitments and Contingencies

Leases

The Company currently has four active lease agreements for office and laboratory space and related equipment. The Company's cell processing facility lease is located on the University of Louisville campus in Louisville, Kentucky (the “Louisville Lease”). This lease has a termination date in November 2023, with an option to extend for three additional one-year renewals at the Company’s discretion. In May 2020, the Company added additional office and laboratory space to the Louisville Lease. In March 2023, the Company entered into an amended lease agreement for the Louisville Lease that increased the successive one-year renewal terms from three to five and reduces the written notice period for the successive one-year renewals from six months in advance to three months in advance.

As of March 31, 2023, the Company reviewed the cumulative impact of its announcements in February, March and April of 2023 to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials and initiate a reduction in force of 33% of its employees, pause enrollment in its FREEDOM-3 clinical trial and initiate a second reduction in force of 95% of its remaining employees, respectively, on its lease terms. Based on this analysis, the Company determined a triggering event had occurred and it is not reasonably certain to exercise its option to renew the Louisville Lease upon its original termination in November 2023. As a result of this determination, the Company remeasured the associated right-of-use asset and operating lease liability as of March 31, 2023. The Company prospectively modified the estimated useful lives of the existing leasehold improvements, which are included as a component of property and equipment, net on the accompanying balance sheet. These assets were subject to the non-cash impairment disclosed in Note 6 and the future depreciation expense is modified following the impairment allocation.

In September 2021, the Company entered into a sublease agreement for separate office space in Louisville, Kentucky. This sublease has a termination date in November 2023.

The Company maintains a lease for office space in Wellesley, Massachusetts (the "Boston Lease"), that had an original termination date in March 2021. In April 2021, the Company entered into an amended lease agreement providing for temporary space from April 2021 until an expansion of the Boston Lease was complete, from which the lease term extends 39 months from the expansion completion date. The expansion was completed in June 2022, resulting in the lease term extending to September 2025.

In July 2021, the Company entered into a lease agreement for laboratory space in Houston, Texas (the “Houston Lease”). The Houston Lease commenced in January 2022. The term of the lease is 36 months from the commencement date, terminating December 2024.

The future minimum rent payments relating to all four of the Company’s ongoing facility operating leases under the terms and conditions existing as of March 31, 2023, as well as amendments the Company has entered into between the date of these financial statements and the date they were available to be issued, are summarized as follows *(in thousands)*:

Years Ending December 31,		
2023	$	700
2024		411
2025		232
Total lease payments	$	1,343
Less: imputed interest		(71)
Present value of lease liabilities	$	1,272

The Company incurred rent expense of $0.2 million for the three months ended March 31, 2023 and 2022.

The following table summarizes the operating lease term and discount rate as of March 31, 2023:

	2023
Weighted-average remaining lease term (years)	1.9
Weighted-average discount rate	6.9%

Cash paid for amounts included in the measurement of the Company's operating lease liability was $0.3 million and $0.2 million for the three months ended March 31, 2023 and 2022, respectively.

License Agreement

In October 2018, the Company entered an amended and restated exclusive license agreement with ULRF related to certain licensed patent rights and know-how related to human facilitating cells for its Facilitated Allo-HSCT Therapy approach. Pursuant to the ULRF License Agreement, ULRF granted the Company an exclusive, worldwide license under such patents and a nonexclusive royalty-bearing, worldwide license for such know-how to research, develop, commercialize and manufacture FCR001 and products containing FCR001 in all fields, without limitation. ULRF also granted the Company the right to grant sublicenses in accordance with the ULRF License Agreement. Under the terms of the agreement, the Company is obligated to compensate ULRF three percent of net sales of all licensed products sold, one third of any non-royalty sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon the occurrence of specific events as outlined in the license agreement; and annual license maintenance fees.

In addition, upon execution of the ULRF License Agreement, the Company granted contingent equity consideration equal to 65,186 shares of common stock to ULRF. Coincident with the completion of the Company’s IPO, the Company issued 48,889 shares of common stock to ULRF and provided a cash payment of approximately $0.3 million in lieu of issuing the remaining 16,297 shares of common stock.

The Company incurred $0.1 million in expense in January 2023 related to an annual maintenance fee pursuant to the ULRF License Agreement for the year ended December 31, 2023. The Company incurred $0.1 million in expense in February 2022 related to an annual maintenance fee pursuant to the license agreement for the year ended December 31, 2022.

Legal Proceedings

The Company is not currently a party to any material legal proceedings. At each reporting date, the Company evaluates whether a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses the costs related to its legal proceedings as incurred.

The Company may be involved in litigation arising in the ordinary course of conducting business. The Company reviews all litigation on an ongoing basis when making accrual and disclosure decisions. The Company, in accordance with current accounting standards for loss contingencies and based upon information currently known by the Company, will establish reserves for litigation when it is probable that a loss associated with a claim or proceeding has been incurred and the amount of the loss or range of loss can be reasonably estimated. When no amount within the range of loss is a better estimate than any other amount, we accrue the minimum amount of the estimable loss. To the extent that such litigation against the Company may have an exposure to a loss in excess of the amount accrued, the Company believes that such excess would not be material to our financial condition, results of operations, or cash flows.

9. Common Stock

Common Stock

On April 30, 2021, the Company's stockholders approved the third amended and restated certificate of incorporation of the Company, which included the authorization of 10,000,000 shares of undesignated preferred stock with a par value of $0.0001, authorization of 140,000,000 shares of voting common stock and 10,000,000 shares of non-voting common stock. As of March 31, 2023, no undesignated preferred stock was outstanding.

Common Stock Reserved

The number of shares of common stock that have been reserved for outstanding stock-based awards granted and stock-based awards available for grant under the Company's 2021 Stock Option and Incentive Plan (the "2021 Plan") and the 2018 Equity Incentive Plan (the "2018 Plan") and shares reserved for issuance under the Company's 2021 Employee Stock Purchase Plan (the "2021 ESPP") are as follows:

	March 31, 2023	December 31, 2022
Restricted stock related to early exercise of common stock options	119,323	158,154
Restricted stock units outstanding	1,951,358	1,144,994
Outstanding common stock options	6,587,665	6,264,898
Outstanding stock appreciation rights	1,000,000	—
Shares reserved for issuance under equity incentive plans	476,491	758,434
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	1,584,319	1,166,444
Total	11,719,156	9,492,924

10. Stock-Based Compensation

2021 Employee Stock Purchase Plan

On January 1, 2023, an additional 417,875 shares were added to the 2021 ESPP, representing 1% of total common shares outstanding at December 31, 2022, pursuant to the terms of the plan. The expense incurred under this plan for the three months ended March 31, 2023 and 2022 was immaterial to the financial statements. The amounts have been included in the total stock-based compensation line items in the accompanying financial statements and disclosures.

Equity Incentive Plans

On January 1, 2023 an additional 2,089,379 shares were added to the 2021 Plan, representing 5% of total common shares outstanding at December 31, 2022, pursuant to the terms of the plan.

As of March 31, 2023, 476,491 shares remained available for future grant under the 2021 Plan. 9,464,257 stock-based award units were outstanding under the 2021 Plan and 2018 Plan as of March 31, 2023.

The Company's 2021 Plan provides for the Company to sell or issue common stock or restricted common stock or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, nonemployees and members of the board of directors of the Company. The 2021 Plan is administered by the board of directors or at the discretion of the board of directors by the compensation committee of the board. The exercise prices, vesting periods, and other restrictions are determined at the discretion of the compensation committee of the board of directors, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the contractual term of stock option may not be greater than 10 years. Stock options granted to date typically vest over four years.

Stock Option Valuation

The assumptions used to determine the fair values of stock options granted to employees and directors are presented as follows:

	Three months ended March 31,	
	2023	2022
Fair value of common stock	$1.73	$7.58 - 16.56
Dividend yield	—%	—%
Volatility	90.4%	82.7% - 82.9%
Risk-free interest rate	3.46%	1.46 % - 1.70%
Expected term (years)	5.5 - 6.25	6.25

Summary of Option Activity

The Company's stock option activity regarding employees, directors, and nonemployees is summarized as follows (*in thousands excepts share and per share amounts)*:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value
Options outstanding—December 31, 2022	6,264,898	$ 6.92	8.43	$ 42
Granted	1,000,000	1.73		
Exercised	(49,040)	0.94		
Cancelled	(25,912)	6.06		
Forfeited	(602,281)	7.06		
Options outstanding—March 31, 2023	6,587,665	$ 6.17	8.41	$ 593
Options exercisable—March 31, 2023	2,567,969	$ 6.31	7.72	

Additional information with regard to stock option activity involving employees and directors is as follows (*in thousands except per share amounts)*:

	Three months ended March 31,	
	2023	2022
Weighted-average grant-date fair value per option of total options granted	$ 1.28	$ 6.49
Aggregate intrinsic value of stock options exercised	47	76

As of March 31, 2023, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $16.0 million, which is expected to be recognized over a weighted-average period of 2.4 years.

Summary of Restricted Stock Unit Activity

The fair values of restricted stock units ("RSUs") are based on the fair market value of the Company's common stock on the date of grant. Each RSU represents a contingent right to receive one share of the Company's common stock upon vesting. In general, RSUs vest (i) annually in four equal installments on the grant anniversary or (ii) incrementally over two years. The following table summarizes the Company's RSU activity for the three months ended March 31, 2023:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at December 31, 2022	1,144,994	$ 6.76
Granted	1,419,000	1.73
Vested	(192,832)	9.09
Forfeited	(419,804)	4.76
Outstanding at March 31, 2023	1,951,358	$ 3.26

As of March 31, 2023, total unrecognized compensation cost related to the unvested awards to employees is $6.4 million, which is expected to be recognized over a weighted-average period of 1.4 years.

Stock Appreciation Rights Valuation

The assumptions used to determine the fair values of stock appreciation right ("SAR") awards granted to employees and directors under the 2021 Plan are presented as follows:

	Three months ended March 31, 2023
Fair value	$1.73
Dividend yield	—%
Volatility	90.8%
Risk-free interest rate	3.46%
Expected term (years)	4.0

Summary of Stock Appreciation Rights Activity

All SARs granted to date vest incrementally over two years. The Company's SAR grant activity regarding employees is summarized as follows (*in thousands excepts share and per share amounts)*:

	Number of SARs	Weighted-Average Exercise Price per SAR	Weighted-Average Remaining Contractual Life (in years)	Aggregate intrinsic value
Outstanding—January 1, 2023	—	$ —	—	$ —
Granted	1,000,000	1.73		
Exercised	—	—		
Forfeited	—	—		
Outstanding—March 31, 2023	1,000,000	$ 1.73	9.85	$ 150

As of March 31, 2023, total unrecognized compensation cost related to unvested awards to employees is $0.9 million, which is expected to be recognized over a weighted-average period of 1.3 years.

Stock-Based Compensation

The Company recorded stock-based compensation expense regarding its employees, directors, and nonemployees as follows *(in thousands)*:

	Three months ended March 31, 2023	2022
Research and development expense	$ 1,985	$ 1,276
General and administrative expense	1,674	921
Total	$ 3,659	$ 2,197

11. Net Loss Per Share Attributable to Common Stockholders

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company *(in thousands except share and per share amounts*).

	For the three months ended March 31,	
	2023	2022
Net loss and net loss attributable to common stockholders	$ (22,497)	$ (18,259)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.54)	$ (0.45)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	41,796,830	40,980,213

The Company's potential dilutive securities, which include convertible preferred stock, contingent stock liabilities, restricted stock related to early exercise of common stock options and common stock options, have been excluded from the computation of diluted net loss per share as the effect would be antidilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential dilutive securities, presented on an as converted basis, were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	For the three months ended March 31,	
	2023	2022
Options to purchase common stock	6,587,665	5,957,614
Restricted stock units	1,951,358	859,769
Restricted stock related to early exercise of options to purchase common stock	119,323	438,201
Stock appreciation rights	1,000,000	—
	9,658,346	7,255,584

12. Defined Contribution Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. Current Company match contributions to the plan are made to employees who meet minimum service requirements in the amount of 100% of the first 3%, and 50% of the next 2% of employee contributions, subject to certain limitations. For the three months ended March 31, 2023 and 2022, the Company made contributions in the amount of $0.2 million and $0.1 million, respectively.

13. Subsequent Events

The Company has evaluated subsequent events through May 15, 2023, the date the financial statements were available to be issued. The Company has concluded no subsequent events have occurred that require disclosure, except for those referenced below.

Reduction in Force

In April 2023, the Company announced the April Reduction in Force that is expected to result in the termination of approximately 95% of the Company's remaining workforce. The Company estimates that the April Reduction in Force will be substantially completed by May 2023.In connection with the April Reduction in Force, the following members of the Company's executive team are leaving or have left the Company on the dates indicated: (i) Scott Requadt, President and Chief Executive Officer, effective May 26, 2023; (ii) Nancy Krieger, Chief Medical Officer, effective April 28, 2023; (iii) Michael Zdanowski, Chief Technology Officer, effective April 28, 2023; and (iv) Andrew Farnsworth, Chief Human Resources Officer, effective May 26, 2023. The Company plans to enter into a strategic advisory agreement with Mr. Requadt that will, among other things, provide compensation to him, in an amount and on terms yet to be determined.

On April 14, 2023, the Company and Mary Kay Fenton, the Company's Chief Financial Officer, entered into a retention agreement (the "Retention Agreement"). Pursuant to the Retention Agreement, Ms. Fenton is eligible to receive a one-time cash retention bonus (the "Bonus") from the Company in consideration for Ms. Fenton's continued employment through and until the consummation of the Strategic Transaction (as defined in the Retention Agreement) or, in certain circumstances, upon liquidation or dissolution of the Company. The benefits provided to Ms. Fenton pursuant to the Retention Agreement are in addition to any payments she may become eligible for pursuant to the Company's Amended and Restated Executive Severance and Change in Control Plan.

Affected employees were offered separation benefits, including severance payments. The Company estimates it will incur cash-based severance and other employee termination-related costs of approximately $5.8 million in the second quarter of 2023 related to the April Reduction in Force. The Company's estimates are subject to a number of assumptions, and actual costs may differ.

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

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Financial Data" section of this Quarterly Report on Form 10-Q (this "Quarterly Report") and our financial statements and the related notes appearing elsewhere in this Quarterly Report. This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the "Risk Factors" section of this Quarterly Report.

Overview

We are a late-clinical stage, cell therapy company developing an innovative method of allogeneic hematopoietic stem cell transplantation ("allo-HSCT") that we believe has the potential to transform the standard of care in solid organ transplantation, certain severe autoimmune diseases and certain severe blood, immune and metabolic disorders. In the organ transplant setting, which is our initial focus, we believe our proprietary therapeutic approach, which we call "**Facilitated Allo-HSCT Therapy**", could prevent organ rejection without the morbidity and mortality that has been associated with the use of lifelong immunosuppression. Beyond the organ transplant setting, our Facilitated Allo-HSCT Therapy also has the potential to treat a range of severe blood, immune and metabolic disorders, in each case with potential for similar outcomes to what has previously been observed with HSCT, while mitigating the toxicities, morbidities and extended hospital stay associated with the fully myeloablative conditioning typically required by HSCT. We believe that these indications, individually and collectively, represent a significant unmet need and commercial opportunity.

We were incorporated as Regenerex, Inc. in 2018 under the laws of the State of Delaware, having converted from a limited liability company under the name Regenerex LLC. In 2019, we changed our corporate name from Regenerex, Inc. to Talaris Therapeutics, Inc.

Since our inception, we have devoted substantially all of our resources to developing our lead product candidate, FCR001, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have principally financed our operations through private placements of convertible preferred stock, payments under a former research collaboration with Novartis, Inc., research grants and most recently, our IPO. Through March 31, 2023, we had received net proceeds of $186.2 million from sales of our convertible preferred stock and net proceeds of $137.2 million, after deducting underwriting discounts and commissions and other expenses, from our IPO.

In February 2023, we announced the discontinuation of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant ("LDKT") recipients. This decision was primarily attributable to the pace of enrollment and the associated timelines to critical milestones.

In February 2023, we also announced a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of the Company's cell therapy CMC capabilities. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any additional cash distributions to our stockholders. In March 2023, pending the outcome of our review of strategic alternatives, we voluntarily paused enrollment in our FREEDOM-3 Phase 2 clinical trial, while continuing to evaluate patients for potential future enrollment.

In connection with the evaluation of strategic alternatives and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one-third, with remaining employees primarily focused on maintaining our cell therapy CMC capabilities and executing FREEDOM-3.

In April 2023, the Company announced the April Reduction in Force that is expected to result in the termination of approximately 95% of the Company's remaining workforce. The Company estimates that the April Reduction in Force will be substantially completed by May 2023.

We have incurred significant operating losses since inception. Our ability to generate revenue will depend heavily on the outcome of the strategic alternatives announced in February 2023 and/or whether we resume development of our product candidates, product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our current or future product candidates. Our net loss was $22.5 million for the three months ended March 31, 2023 and $73.9 million for

year ended December 31, 2022. As of March 31, 2023, we had an accumulated deficit of $187.2 million. We expect to continue to incur net losses for the foreseeable future.

We expect to continue to incur costs and expenditures in connection with the process of evaluating our strategic alternatives. There can be no assurance, however, that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

Should we resume development of our product candidates, our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. In addition, we will incur substantial research and development costs and other expenditures if we should resume development of our product candidates. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Based upon our current operating plan, we believe that our existing cash and cash equivalents and marketable securities of $165.8 million as of March 31, 2023 will be sufficient to fund our operating expenses and capital expenditure requirements for more than 12 months from the date of the issuance of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

License Agreement

In October 2018, we entered an amended and restated exclusive license agreement (“ULRF License Agreement”) with University of Louisville Research Foundation (“ULRF”) related to certain licensed patent rights and know-how related to human facilitating cells for our Facilitated Allo-HSCT Therapy approach. Pursuant to the ULRF License Agreement, ULRF granted us an exclusive, worldwide license under such patents and a nonexclusive royalty-bearing, worldwide license for such know-how to research, develop, commercialize and manufacture FCR001 and products containing FCR001 in all fields, without limitation. ULRF also granted us the right to grant sublicenses in accordance with the ULRF License Agreement. Under the terms of the agreement, we are obligated to compensate ULRF three percent of net sales of all licensed products sold, one third of any non-royalty sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon the occurrence of specific events as outlined in the license agreement; and annual license maintenance fees. As of March 31, 2023, we have paid ULRF $0.1 million in milestone payments and $0.2 million in annual maintenance fees, for a total of $0.3 million.

In addition, upon execution of the ULRF License Agreement, we granted contingent equity consideration equal to 65,186 shares of common stock to ULRF. Pursuant to the ULRF License Agreement, on or prior to our first underwritten public offering or any transaction that is treated as a deemed liquidation event, we are required to either issue to ULRF the 65,186 shares in common stock or make a cash payment equal to the 65,186 shares of common stock multiplied by either the price per share of common stock in the underwritten public offering or by the price per share of common stock received in connection with such deemed liquidation event. Coincident with the completion of our IPO in May 2021, we issued to ULRF 48,889 shares of common stock in addition to $0.3 million in a cash payment to fully satisfy the contingent stock liability to ULRF.

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the future, if at all. If our product candidates we are currently developing and that we may develop in the future are successful and result in

marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from a combination of product sales or payments from such collaboration or license agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development and research of our novel cell therapy, as well as unrelated discovery program expenses. We expense research and development costs as incurred. These expenses include:

- employee-related expenses, including salaries, related benefits and stock-based compensation expense, for employees engaged in research and development functions;
- external research and development expenses incurred under arrangements with third parties, such as CROs, investigational sites, and consultants;
- the cost of acquiring, developing, and manufacturing clinical study materials;
- costs associated with preclinical and clinical activities and regulatory operations;
- costs incurred in development of intellectual property; and
- an allocated portion of facilities and other infrastructure costs associated with our research and development activities.

We enter into consulting, research, and other agreements with commercial entities, researchers, universities, and others for the provision of goods and services. Such arrangements are generally cancelable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided by the respective vendors, including our clinical sites. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of us. Depending upon the timing of payments to the service providers, we recognize prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved, and experience with similar contracts. We monitor each of these factors and adjust estimates accordingly.

The successful clinical development and subsequent commercialization of product candidates is highly uncertain and we are not certain if or when we may resume development of our product candidates. This is due to the numerous risks and uncertainties with product development and commercialization, including significant variations in our clinical development costs as well as the following factors:

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

- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development program and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the U.S. Food and Drug Administration ("FDA") or any comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of our product candidate;
- the development of commercial scale manufacturing and distribution processes for our product candidates;
- establishing and maintaining agreements with third-party manufacturers for commercial manufacturing, if we pursue a third party manufacturing strategy outside of the United States, and if our product candidate is approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of our product candidate, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of our product candidate, if approved, by patients, the medical community and third-party payors;
- competition with other products; and
- a continued acceptable safety profile of our therapies following approval.

Should we resume development of our product candidates, we may never succeed in obtaining regulatory approval for any of our current and future product candidates, including FCR001, and may obtain unexpected results from our clinical trials. Should we resume development of our product candidates, we may elect to again discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our preclinical and clinical product candidates. For example, should we resume development of our product candidates, if the FDA or another regulatory authority were to require us to conduct clinical trials for FCR001 beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of any preclinical studies or execution or enrollment in clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. A change in the outcome of any of these variables with respect to the development of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Should we resume development of our product candidates, we may never succeed in obtaining regulatory approval for any of our product candidates.

Prior to the suspension of the development of our product candidates in February 2023, research and development activities accounted for a significant portion of our operating expenses. We expect our research and development expenses to decrease in the near future as we have discontinued our FREEDOM-1 and FREEDOM-2 clinical trials and have voluntarily paused enrollment in our FREEDOM-3 clinical trial, pending the outcome of our review of strategic alternatives.

We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates. Our direct research and development expenses are tracked on a program-by-program basis and consist primarily of external costs, including fees paid to consultants, contractors and CROs in connection with our development activities and the cost of acquiring, developing, and manufacturing clinical study materials. At this time, we do not fully allocate personnel costs to individual programs as many of our personnel are deployed across multiple programs.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, corporate and business development, human resources and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and administrative consulting services, insurance costs and other operating costs, including an allocated portion of facilities and other infrastructure costs associated with our general and administrative activities.

We anticipate that our general and administrative expenses may increase in the future as we explore strategic alternatives, including potential legal, accounting and advisory expenses and other related charges. We also anticipate that we will continue to incur accounting, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

Restructuring Costs

Restructuring costs consist of severance, employee termination costs and asset impairment related to our long-lived assets used primarily in our chemistry, manufacturing and controls ("CMC") operations.

We anticipate that our restructuring costs may increase in the future as we continue our comprehensive review of strategic alternatives focused on maximizing stockholder value, which includes additional restructuring as disclosed in Note 13 of the accompanying financial statements.

Other Income (Expense), Net

Other income (expense), net is comprised of interest income earned on cash reserves in our operating account and on our marketable securities and amortization expense and accretion income on our marketable securities.

Results of Operations

Comparison of Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,		
	2023	2022	Change
	(in thousands)		
Operating expenses			
Research and development	$ 13,415	$ 14,196	$ (781)
General and administrative	6,182	4,218	1,964
Restructuring costs	4,481	—	4,481
Total operating expenses	24,078	18,414	5,664
Loss from operations	(24,078)	(18,414)	(5,664)
Interest and other income, net	1,581	155	1,426
Net loss	$ (22,497)	$ (18,259)	$ (4,238)

Research and development expenses

	Three months ended March 31,		
	2023	2022	Change
	(in thousands)		
Direct research and development program expense:			
FCR001 clinical and pre-clinical programs	$ 3,340	$ 4,093	$ (753)
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	7,353	6,715	638
Facilities and other operating costs	2,722	3,388	(666)
Total research and development expenses	$ 13,415	$ 14,196	$ (781)

Research and development expenses were $13.4 million for the three months ended March 31, 2023, compared to $14.2 million for the three months ended March 31, 2022. The decrease of $0.8 million was primarily due to:

- An increase of $0.6 million in personnel costs primarily due to increased personnel in the first two months of the first quarter of 2023 as compared to 2022, necessary to conduct our FREEDOM-1 Phase 3 and FREEDOM-2 and FREEDOM-3 Phase 2 clinical trials, advance pre-clinical activities, including those related to our deceased donor program, and support medical affairs and patient recruitment activities. Such personnel costs include increases in stock-based compensation expense stemming from additional incentive equity grants;
- A decrease of $0.8 million in FCR001 external clinical program expenses related to the discontinuation of our FREEDOM-1 Phase 3 clinical trial and FREEDOM-2 Phase 2 clinical trial in February 2023; and

- A decrease of $0.7 million in other costs primarily due to a decrease in consulting, research collaborations, and other services related to the discontinuation of the FREEDOM-1 and FREEDOM-2 clinical trials in February 2023.

General and Administrative Expenses

The following table summarizes our general and administrative expenses to support our business activities for the three months ended March 31, 2023 and 2022:

	Three months ended March 31,		
	2023	2022	Change
		(in thousands)	
Personnel related (including stock-based compensation)	$ 3,417	$ 2,247	$ 1,170
Professional and consulting fees	1,086	562	524
Facility-related and other	1,679	1,409	270
Total general and administrative expenses	$ 6,182	$ 4,218	$ 1,964

General and administrative expenses were $6.2 million for the three months ended March 31, 2023 compared to $4.2 million for the three months ended March 31, 2022. The increase in general and administrative costs of $2.0 million was primarily due to:

- An increase of $1.2 million in personnel costs primarily due to increased personnel in the first quarter of 2023 as compared to 2022 in our general and administrative functions as we continued to expand our operations to support the organization, which includes increased stock-based compensation expense stemming from additional incentive equity grants;
- An increase of $0.5 million in professional and consulting fees related to an increase in legal fees as a result of our comprehensive review of strategic alternatives; and
- An increase of $0.3 million in facility-related and other expenses primarily due to increased IT expenses stemming from increased cyber security measures and increased personnel in the first two months of the first quarter of 2023 as compared to 2022.

Restructuring Costs

Restructuring costs in the three months ended March 31, 2023 was comprised of a $2.7 million non-cash asset impairment related to long-lived assets used primarily in our CMC operations and $1.8 million in severance and employee termination costs related to our reduction in force announced in February 2023. We did not incur any restructuring costs in the three months ended March 31, 2022.

Other Income, Net

Other income, net in the three months ended March 31, 2023 was comprised of $1.3 million of net accretion income on our marketable securities and $0.3 million in interest income from our marketable securities and operating cash balance. Other income, net in the three months ended March 31, 2022 was comprised of $0.2 million in interest income from our marketable securities and operating cash balance.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of products for several years, if at all. Since 2018, we have funded our operations primarily with proceeds from the sale of our convertible preferred stock and our IPO in May 2021. Through March 31, 2023, we had received net proceeds of $186.2 million from sales of our convertible preferred stock and net proceeds of $137.2 million, after deducting underwriting discounts and commissions and other expenses, from our IPO.

Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Our primary use of cash is to fund operating expenses, which historically has consisted primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses. As of March 31, 2023, we had cash and cash equivalents of $24.2 million and marketable securities of $141.6 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Three months ended March 31,		
	2023	2022	Change
		(in thousands)	
Net cash used in operating activities	$ (16,902)	$ (16,280)	$ (622)
Net cash provided by investing activities	27,410	20,427	6,983
Net cash provided by financing activities	46	30	16
Net increase (decrease) in cash and cash equivalents and restricted cash	$ 10,554	$ 4,177	$ 6,377

Cash Flow from Operating Activities

During the three months ended March 31, 2023, operating activities used $16.9 million of cash, due to our net loss of $22.5 million and $0.1 million of cash used from changes in our operating assets and liabilities, partially offset by non-cash charges of $5.7 million. Net cash used from changes in our operating assets and liabilities primarily consisted of a $1.2 million decrease in accounts payable and accrued expenses related to payment of accrued compensation arrangements and legal fees and a $0.2 million decrease in our operating lease liability. These were offset by a $1.3 million decrease in prepaids and other current assets driven by amortization of annual subscriptions and insurance premiums in the quarter. Non-cash charges primarily consisted of $3.7 million of stock-based compensation expense and a $2.7 million long-lived asset impairment, offset by a net $0.7 million of depreciation on fixed assets, accretion of marketable securities and amortization of right-of-use assets.

During the three months ended March 31, 2022, operating activities used $16.3 million of cash, due to our net loss of $18.3 million and $0.5 million of cash used from changes in our operating assets and liabilities, partially offset by non-cash charges of $2.5 million. Net cash used from changes in our operating assets and liabilities primarily consisted of a $0.3 million increase in prepaids and other current assets driven by annual subscriptions paid in the quarter and a net $0.3 million decrease in accounts payable and accrued expenses driven by compensation related accruals. These were offset by a $0.1 million increase in our operating lease liability. Non-cash charges primarily consisted of $2.2 million of stock-based compensation expense and $0.3 million of depreciation on fixed assets and amortization of marketable securities.

Cash Flow from Investing Activities

During the three months ended March 31, 2023, investing activities provided $27.4 million of cash, due to maturities of marketable securities of $53.0 million, partially offset by purchases of marketable securities of $25.3 million and purchases of property and equipment of $0.3 million.

During the three months ended March 31, 2022, investing activities provided $20.4 million of cash, due to maturities of marketable securities of $61.7 million, partially offset by purchases of marketable securities of $40.0 million and purchases of property and equipment of $1.3 million.

Cash Flow from Financing Activities

During the three months ended March 31, 2023, net cash provided by financing activities was an immaterial amount primarily consisting of proceeds from exercise of stock options.

During the three months ended March 31, 2022, net cash provided by financing activities was an immaterial amount primarily consisting of proceeds from exercise of stock options.

Future Funding Requirements

We currently expect our expenses to decrease in the near term due to our decision to discontinue our FREEDOM-1 and FREEDOM-2 clinical trials and conduct workforce reductions while we explore strategic alternatives. Pending the outcome of our review of strategic alternatives, should we decide to continue to advance the clinical development of our product candidates, we expect

to incur additional costs in connection with such activities. The timing and amount of such operating expenditures will depend largely on:

- the outcome, success, timing and cost of any strategic transactions, business combinations or divestiture;
- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates or any future product candidates we may develop;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities, including the potential for such authorities to require that we perform more preclinical studies or clinical trials than those that we currently expect or change their requirements on studies that had previously been agreed to;
- the cost to establish, maintain, expand, enforce and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with licensing, preparing, filing, prosecuting, defending and enforcing any patents or other intellectual property rights;
- the effect of competing technological and market developments;
- the costs of continuing to grow our business, including hiring key personnel and maintaining or acquiring operating space;
- market acceptance of any approved product candidates, including product pricing, as well as product coverage and the adequacy of reimbursement by third-party payors;
- the cost of acquiring, licensing or investing in additional businesses, products, product candidates and technologies;
- the cost and timing of selecting, auditing and potentially validating or expanding a manufacturing site for commercial-scale manufacturing;
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval and that we determine to commercialize; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

We believe that our existing cash and cash equivalents and marketable securities as of March 31, 2023, will enable us to fund our operating expenses and capital expenditure requirements for more than twelve months from the date of issuance of this Quarterly Report on Form 10-Q. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, our resource requirements could materially change depending on the outcome of our ongoing strategic review process, including to the extent we identify and enter into any potential strategic transaction. Because our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, we are unable to estimate the exact amount of our working capital requirements.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any product candidates or generate revenue from the sale of any product candidate for which we may obtain marketing approval. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, royalty-based financings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that 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. Debt financing, royalty-based financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through royalty-based financings, collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations

We are currently a party to four operating leases for our manufacturing facility in Louisville, Kentucky, laboratory space in Houston, Texas, corporate office space in Wellesley, Massachusetts, and additional corporate office space in Louisville, Kentucky. The future minimum lease obligations for these leases total $4.0 million over the next four years. Furthermore, as discussed elsewhere in this quarterly report, we are party to the ULRF License Agreement. Under the terms of the ULRF License Agreement, the Company is obligated to compensate ULRF three percent of net sales of all licensed products sold, one third of any non-royalty sublicensing income, and up to $1.625 million in regulatory and sales milestones on each licensed product upon occurrence of specific events as outlined in the ULRF License Agreement; and annual license maintenance fees.

We have entered into other contracts in the normal course of business with certain CROs and other third parties for nonclinical research studies and testing, as well as clinical trials. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which are prepared in accordance with generally accepted accounting principles (“GAAP”) in the United States. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our accompanying financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Contract Costs and Accruals

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include fees paid to vendors in connection with clinical development activities and CROs and investigative sites in connection with pre-clinical, non-clinical, and human clinical trials.

We base the expense recorded related to external research and development on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that supply, conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses. There have been no changes to our process of determining external research and development expense accruals during the three months ended March 31, 2023.

Stock Based Compensation Expense

We measure stock-based awards granted to employees, directors, and nonemployees based on their fair value on the date of the grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. For stock-based awards with service-based vesting conditions, we recognize compensation expense using the straight-line method. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and our expected dividend yield.

The fair value of each option to purchase common stock award is estimated on the date of grant based on the fair value of our common stock on that same date.

As there had been no public market for our common stock prior to the closing of our IPO, the estimated fair value of our common stock was determined by our board of directors as of the date of each option grant with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These independent third-party valuations of our equity instruments were performed contemporaneously with identified value inflection points. Our common stock valuation was prepared using the option-pricing method ("OPM"), which used a market approach to estimate our enterprise value, as well as the probability-weighted expected return method ("PWERM") and the hybrid method, a combination of OPM and PWERM.

For all stock-based awards granted ended after the closing of our IPO, we have not had to estimate the fair value of our common stock as it has been determined based on the quoted market price of our common stock. For the three months ended March 31, 2023, the quoted market price of our common stock was used in determining the fair value of our stock-based compensation awards and no other significant estimates were used in determining those amounts.

Emerging Growth Company and Smaller Reporting Status

In April 2012, the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" ("EGC") can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended ("Securities Act"), for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for 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 to the extent allowed by the standard.

We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (ii) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (iii) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (iv) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Off-Balance Sheet Arrangements

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

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our financial statements appearing at the beginning of this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our primary exposure to market risk relates to changes in interest rates. As of March 31, 2023 and December 31, 2022, we had cash and cash equivalents of $24.2 million and $13.7 million, respectively. As of March 31, 2023 and December 31, 2022, we had marketable securities of $141.6 million and $167.6 million, respectively. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, the net fair value of our interest sensitive marketable securities would not experience a material change in fair market value.

All of our employees and our operations are currently located in the United States. We have, from time to time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated, and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Inflation generally affects us by increasing our cost of labor. We continue to monitor the impact of rising inflation on our business and do not believe that inflation had a material effect on our business, financial condition or results of operations during the three months ended March 31, 2023 and year ended December 31, 2022.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act"), mean controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission (the "SEC") rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer (our Chief Executive Officer) and our principal financial officer (our Chief Financial Officer), as appropriate, to allow timely decisions regarding required disclosures.

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgement in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There has been no change in our internal controls over financial reporting as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act for the fiscal quarter ended March 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

All control systems have inherent limitations including the realities that judgements in decision making can be faulty and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. Because of such limitations, there is a risk that material misstatements will not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in litigation or other legal proceedings. As of March 31, 2023, we are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our financial statements and the related notes thereto and the section of this Quarterly Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" before you make an investment decision. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition or results of operations.

Risks Related to our Strategic Review Process

We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future could have negative consequences.

In February 2023, we announced that we are undertaking a comprehensive review of strategic alternatives focused on maximizing shareholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of the Company's cell therapy CMC capabilities. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

In addition, potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume the development of our product candidates, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly.

Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, an acquisition, merger, a business combination and/or divestiture, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of any potential business combination or any other result from our strategic assessment, are highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to integrate with any future business partner, our ability to obtain value for our cell therapy CMC capabilities, if divested, and our ability to generate future

shareholder value in the technology platform we may elect to pursue. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In connection with the evaluation of strategic alternatives and in order to extend our resources, in February 2023, we implemented a restructuring plan that included reducing our workforce by approximately one-third, with remaining employees focused at that time on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3, each pending the outcome of our review of strategic alternatives. In April 2023, we announced a further reduction in force (the "April Reduction in Force") that is expected to result in the termination of approximately 95% of our remaining workforce and possible divestiture of our CMC capabilities and FCR001 for use in scleroderma. We estimate that the April Reduction in Force will be substantially completed by May 2023. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

On February 15, 2023, in connection with the evaluation of strategic alternatives and in order to extend its resources, the Board of Directors of the Company approved a restructuring plan (the "Plan") that includes reducing the Company's workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3. In addition, the Plan includes a discontinuation of the Company's FREEDOM-1 and FREEDOM-2 clinical development programs and further prioritization of the Company's resources as it assesses strategic alternatives. In April 2023, the Company announced the April Reduction in Force that is expected to result in the termination of approximately 95% of the Company's workforce. The Company estimates that it will incur approximately $8.7 million for retention, severance and other employee termination-related costs in the first and second quarters of 2023. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Our workforce reduction activities may also yield unintended consequences, such as attrition beyond our reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Business and Product Candidates

Risks Related to Clinical Development

Should we resume development of our product candidates, our business will substantially depend upon the successful development and regulatory approval of FCR001, our lead product candidate. If we are unable to obtain regulatory approval for FCR001, our business may be materially harmed.

We currently have no products approved for sale and have invested substantially all of our efforts and financial resources in the development of our Facilitated Allo-HSCT Therapy, specifically in our lead product candidate, FCR001. However, we have ceased development of our product candidates. There is an additive degree of risk to any development program that is paused because the time to restart the program and the associated expense may be longer and more costly than previously anticipated. It may also not be possible to restart the program altogether. Should we resume development of our product candidates, the successful development and ultimate regulatory approval of FCR001 for any potential indications will be critical to the future success of our business. We will need to raise sufficient funds for, and successfully resume and complete, our clinical development programs of FCR001 for severe autoimmune diseases or any additional indications.

There is no guarantee that any of our product candidates will proceed in clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us

to address in order to obtain marketing approval as planned or, if at all. Should we resume development of our product candidates the potential regulatory approval of FCR001 or any other product candidate we may develop is subject to a number of risks, including the following:

- successful initiation and completion of clinical trials;
- successful patient enrollment in clinical trials;
- successful data from our clinical trials that supports an acceptable risk-benefit profile of our product candidates in the intended populations; and
- receipt and maintenance of marketing approvals from applicable regulatory authorities.

Furthermore, negative results in the development of FCR001, such as the patient death in our FREEDOM-1 trial, may impact our ability to obtain regulatory approval of FCR001 for other current and potential indications since the underlying platform, manufacturing process, development process, and cell therapy is the same for all of our current programs in development. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct our other clinical programs. Specifically, in February 2023, we announced the termination of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in LDKT recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones in those programs. In addition, in March 2023, pending the outcome of our review of strategic alternatives, we voluntarily paused enrollment in our FREEDOM-3 clinical trial evaluating FCR001's ability to induce tolerance in diffuse systemic scleroderma. Should we resume clinical development of our product candidates, we may face enrollment challenges in our clinical trials, such as those faced in our LDKT trials.

In addition, because we have limited financial and personnel resources and have placed significant focus on the development of our lead product candidate and our current indications, we may forgo or delay pursuit of opportunities with other future product candidates and 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 research and development programs and other product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate or indication, we may relinquish valuable rights to those product candidates or indications 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 to such product candidates or indications.

Many of these risks are beyond our control, including the risks related to clinical development, our proprietary manufacturing process and the regulatory submission process. If we are unable to resume and complete development and receive regulatory approval for FCR001 for the indications we are developing it for, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. Should we resume development of our product candidates, the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.

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

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and clinical trials.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the study designs and substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate’s clinical development and may vary

among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Should we resume development of our product candidates, our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical trials;
- failure to demonstrate to the satisfaction of regulatory agencies that FCR001, our lead product candidate, is safe and effective, or has a positive benefit/risk profile for its proposed indications;
- failure of clinical trials to meet the level of statistical significance required for approval;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application ("BLA") or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes, our own manufacturing facility, or facilities of third-party manufacturers with whom we may in the future contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Should we resume development of our product candidates, delays or difficulties in the enrollment of patients in clinical trials would have a material adverse effect on our business.

In February 2023, we announced the termination of our FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001 in LDKT. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. In addition, in March 2023, pending the outcome of our review of strategic alternatives, we voluntarily paused enrollment in our FREEDOM-3 clinical trial in severe scleroderma. We may not be able to resume, initiate or continue clinical trials for our product candidate if we or a potential future sponsor are unable to locate and enroll a sufficient number of eligible patients to participate in these continuing trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, because certain of our clinical trials are focused on indications with relatively small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates.

Furthermore, because we have historically investigated the treatment of complex indications that require specialized medical care by means of an HSCT procedure, which is itself a complex procedure performed by specialized physicians and treatment centers, we have faced inherent challenges in recruiting clinical trial sites to participate in our trials and to complete our trials on a timely basis. For example, in LDKT, each site that participated in our trials needed to identify a lead clinician from each of the solid organ transplant and HSCT departments, who are willing and able to coordinate closely on the care and follow-up of our patients. We have historically relied on our relationships with transplant centers of excellence to assist in identifying eligible patients and carrying out our clinical trials, and

any inability to secure or deterioration of those relationships could impede our ability to successfully enroll patients in a timely manner, if at all.

Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- patient eligibility criteria for the trial in question;
- nature of the trial protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceived risks and benefits of the product candidate under study;
- the occurrence of adverse events attributable to our lead product candidate;
- efforts to facilitate timely enrollment in clinical trials;
- the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical trials;
- the ability to monitor patients adequately during and after treatment;
- travel restrictions and other potential limitations by federal, state, or local governments affecting the workforce or affecting clinical research site policies implemented in response to the COVID-19 pandemic;
- delays in or temporary suspension of the enrollment of patients in our ongoing and planned clinical trials due to the COVID-19 pandemic;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

Even if we are able to enroll a sufficient number of patients in our clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our trials may be delayed or our trials could become too expensive to complete. Any delays in completing our clinical trials will increase our costs, delay or prevent our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any delays in completing

our clinical studies for our product candidates may also decrease the period of commercial exclusivity. Any of these occurrences may significantly harm our business, financial condition and prospects.

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

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

While there are currently no FDA- or European Medicines Agency ("EMA") approved cell-based therapies for the indications we were targeting, other approved or commonly used drugs and therapies for our target diseases, such as nintedanib to slow the rate of decline in lung function in patients with scleroderma-associated interstitial lung disease, are more well established and are accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. In addition, a number of companies, academic institutions and government agencies are seeking to address limitations of existing therapies that we also sought to address. For example, a number of third parties, such as Jasper Therapeutics, Inc., bluebird bio, Inc. and Magenta Therapeutics, Inc., are seeking to develop conditioning regimens for HSCT that have lower toxicities, morbidities and mortalities than the current standard of care. Similarly, Johns Hopkins University and the Fred Hutchinson Cancer Center have previously administered non-myeloablative conditioning treatments. A number of other companies are also seeking to decrease the incidence and severity of graft versus host disease (“GvHD”) in HSCT. If any of these endeavors prove to be successful, the anticipated advantages of our Facilitated Allo-HSCT Therapy in comparison to the then existing standard of care could be eliminated and the demand for our Facilitated Allo-HSCT Therapy could be materially impacted.

We expect that, if our one-time investigational therapy is approved, it will be priced in a manner that will reflect its long-term clinical, economic, and humanistic value. Such a pricing model may entail a single upfront cost or multiple installments contingent upon demonstration of continued benefit that will likely be more expensive than the upfront cost or initial annual costs of competitive generic products that must be taken chronically. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development. Many of our competitors or potential competitors have significantly greater market presence, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements or mergers with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop products that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

Should we resume development of our product candidates, delays in the clinical development or delays in or our ability to achieve regulatory approval, if at all, and commercialization of our product candidates, if approved, would have a material adverse effect on our business.

We may experience delays in our future clinical trials and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all, such as on account of the COVID-19 pandemic and its impact at clinical trials sites or on the third-party service providers on whom we rely. Should we resume development of our product candidates, clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on the design and implementation of clinical trials;

- delay or failure in obtaining authorization to commence a trial, including the delay or ability to generate sufficient preclinical data to support initiation of clinical trials, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;

- delay or failure in reaching agreement on acceptable terms with prospective contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- the inability of CROs to perform under these agreements, including due to impacts from the COVID-19 pandemic on their workforce;

- delay or failure in obtaining institutional review board ("IRB") approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;

- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;

- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;

- delay or failure in subjects completing a trial or returning for post-treatment follow-up;

- inability to identify and maintain a sufficient number of trial sites, including because potential trial sites may not have the capabilities required for the indication that we are treating;

- failure of our third-party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;

- delay or failure in adding new trial sites, including due to changes in policies of the clinical research sites or local IRBs;

- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;

- feedback from the FDA, the IRB, data safety monitoring boards ("DSMBs") or comparable foreign authorities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a trial;

- unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;

- failure to demonstrate a benefit from using a product candidate;

- lack of adequate funding to continue a trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials or increased expenses associated with the services of our CROs and other third parties; or

- changes in governmental regulations or administrative actions, failure by us or third parties to comply with regulatory requirements, or lack of adequate funding to continue a clinical trial.

Furthermore, clinical trials may be delayed, suspended or prematurely terminated for a variety of reasons, including as a result of clinical sites, investigators or other third parties deviating from the trial protocol, failing to conduct the trial in accordance with regulatory and contractual requirements, and/or dropping out of a trial.

In addition, disruptions caused by the COVID-19 pandemic, including any current or future emerging variants of the virus, may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned clinical trials. 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 DSMB 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 our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects including a suspected unexpected serious adverse reaction ("SUSAR"), such as the recent death of a patient in our FREEDOM-1 trial, failure to demonstrate a benefit from using a drug, 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 IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Risks Related to the Results of our Preclinical Studies and/or Clinical Trials

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Should we resume development of our product candidates, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and earlier clinical trials does not ensure that later clinical trials will generate findings consistent with our earlier clinical trials, including adequate data to demonstrate the efficacy and safety of FCR001 or any of other product candidates we may develop. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, to date, results may not be replicated in subsequent trials, and we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval of any product candidates we develop. Inaccuracies in our earlier clinical data and deviations from our clinical trial protocols can impact the integrity of those data, including safety data, and could impact the ability of those data to support regulatory approval. Additionally, certain of our clinical trial endpoints also may not be adequately powered in a particular subpopulation of our trial population. For example, our Phase 2 trial of FCR001 was a “single arm” trial for which there was no comparator arm to permit a comparison of our investigational therapy against standard of care treatment. Furthermore, all of our clinical trials conducted to date have been open-label trials. This means that both the patient and investigator know whether the patient is receiving our FCR001 therapy or standard of care therapy. Open-label clinical trials can be subject to various limitations that may exaggerate any therapeutic effect, as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias.” Moreover, patients selected for early clinical studies often include the most severe sufferers and their symptoms may have been bound to improve notwithstanding the new treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. While we believe our trials utilized objective assessment measures for measuring our primary endpoints and therefore were unlikely to be influenced in any manner by patient or investigator bias, such trials may utilize secondary endpoint patient reported outcome measures, and it is unknown whether the open-label design will be predictive of future clinical trial results with this or other product candidates for which we conduct an open-label clinical trial when studied in a controlled environment or with only objective endpoints. In addition, clinical data obtained from a clinical trial with an allogeneic product candidate such as FCR001 may not yield the same or better results on certain relevant outcome measures as compared to an autologous product candidate. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, which risk may be heightened in open-label trials where outcomes are subject to patient and investigator bias, and many companies that believed their product candidates performed satisfactorily in such trials nonetheless failed to obtain FDA, EMA or other necessary regulatory agency approval.

Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, no therapies for inducing immune tolerance to a transplanted organ or restoring tolerance to self in an autoimmune disease have been approved to date, and the FDA or other regulatory authorities may not agree with our interpretation and may require that we conduct additional clinical trials to support the regulatory approval of our product candidates. If we fail to obtain results in our planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development

timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Should we resume development of our product candidates, interim, "top line" or preliminary data from our clinical trials that we may announce or share with regulatory authorities 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.

Should we resume development of our product candidates, we may announce clinical updates or share with regulatory authorities interim "top line" or preliminary data from our clinical trials, from time to time, which is based on a preliminary analysis of then-available data. The outcome of preclinical development testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In particular, additional data from subsequent patients may not be comparable or positive with respect to efficacy, safety or target engagement. For example, in June 2022, we announced interim results from our FREEDOM-1 Phase 3 clinical trial, including limited efficacy and safety data for the first seven patients dosed. Subsequently, in October 2022, we reported that one of the first seven patients, who had experienced GvHD symptoms that were treatment responsive and resolved in June 2022, had been hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. These data and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of interim, "top line" or preliminary data, and we may not have received or had the opportunity to fully and carefully evaluate all data.

As a result, the top-line or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. 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. Preliminary or "top line" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, "top-line," or interim data and final data could impact the regulatory approval of, and significantly harm the prospects for any product candidate that is impacted by the applicable data.

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 business 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 others may not agree with what we determine is the 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 clinical updates, or the interim, "top-line," 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, our business, operating results, prospects or financial condition may be harmed.

Risks Related to Potential Side Effects and the Safety and Efficacy Profile of our Product Candidates

Should we resume production of our product candidates, or associated conditioning regimens or treatment protocols, they may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused or risks exacerbated by our product candidates or associated conditioning regimens or treatment protocols could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. Such side effects could include known side effects or safety risks that are exacerbated by the combination of HSCT and LDKT in our clinical trials. In such an event, our trials could be delayed, suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development

of or deny approval of our product candidates for any or all targeted indications. Additionally, during the course of our product development programs, FDA or comparable foreign regulatory authority review teams may change and new agency personnel may view the risk-benefit profile of any product candidates we may develop differently than prior agency review teams. Any negative views as to the risk-benefit profile of FCR001 or any product candidates we may develop in the future could lead FDA or comparable foreign regulatory authorities to require that we conduct additional clinical trials or could require more onerous clinical trial designs for any ongoing or future clinical trials. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, while we note the summary of safety findings we have gathered to date, certain populations of patients receiving our Facilitated Allo-HSCT Therapy may experience side effects in greater frequency or severity than others who may receive our product candidates and additional clinical research is planned to more fully understand the safety profile of our product candidates in our patient populations and indications of focus. Furthermore, we or others may later identify undesirable side effects caused by our products, including during any long-term follow-up observation period, such as that involved in our previous trials of FCR001.

In particular, LDKT and HSCT involve certain known potential post-procedure complications that may manifest several weeks or months after a transplant and which may be more common in certain patient populations. For example, up to 20% of patients with inherited metabolic diseases treated with HSCT experience primary engraftment failure, resulting in severe complications, including death. GvHD also accounts for approximately 10% of deaths following allogeneic HSCT. In June 2022, we reported three cases of low-grade acute GvHD in our FREEDOM-1 clinical trial, all of which had responded to treatment and were resolved. One of the three aGvHD patients was subsequently diagnosed with moderate chronic GvHD and was also responding to treatment at the time of the June 2022 update. In October 2022, we reported that the patient who had been diagnosed with chronic GvHD had died. The patient had been hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death. This event triggered a pre-specified, temporary stopping requirement and review by the FREEDOM-1 DMC. After their review of this case, the DMC determined that trial enrollment and dosing could continue. We also reported the event and the DMC's recommendation to the FDA.

Should we resume development of our product candidates, if these or other serious adverse events, undesirable side effects, or unexpected characteristics are identified during the development of any of our product candidates, it may be difficult to determine whether these complications were or were not related to our investigational therapy, and we may need to limit, delay or abandon our further clinical development of those product candidates, even if such events, effects or characteristics were potentially the result of HSCT, LDKT or related procedures generally, and not directly or specifically caused or exacerbated by our product candidates. All serious adverse events or unexpected side effects will be continually monitored per the clinical trial’s approved protocol. If serious adverse events are determined to be directly or specifically caused or exacerbated by our product candidates, we would follow the trial protocol’s requirements, which include certain pre-specified stopping requirements, and which call for our DSMB to review all available clinical data in making a recommendation regarding the trial’s continuation. However, there may be a failure by trial sites to effectively execute our clinical trial protocols, including during any long-term follow-up period for our clinical trials during the conduct of future clinical trials or following any product approval we may receive. In addition, HSCT is associated with an increased risk of cancer. Among the likely causes of this increased risk is the total body irradiation and high-dose chemotherapy used in myeloablative conditioning regimens. We believe non-myeloablative conditioning regimens have the potential to help obviate this increased risk, however, patients receiving Facilitated Allo-HSCT Therapy in clinical trials after non-myeloablative conditioning have developed cancer after transplant. For example, a patient, a lifelong smoker, in our Phase 2 clinical trial developed non-small cell carcinoma of the lung approximately four years after HSCT.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused or risks exacerbated 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 distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators 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 alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product form the marketplace;

- regulatory authorities may withdraw or change their approvals of that product;

- regulatory authorities may require additional warnings on the label or limit access of that 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 the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to sued and held liable for harm caused to subjects or patients; and
- the 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 the affected product candidate, if resume development and are approved by applicable regulatory authorities.

If we resume development of our product candidates and our clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or otherwise produce negative results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

Before obtaining regulatory approval for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and the outcome is uncertain. Despite preclinical and early clinical trial data, any product candidate can unexpectedly fail at any stage of further development. The historical failure rate for product candidates is high. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. In addition, if our clinical results are not successful, we may terminate clinical trials for a product candidate and abandon any further research or studies of the product candidate. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Risks Related to Combination Therapies

Should we resume development of our product candidates, we intend to develop FCR001, and potentially future product candidates, in other indications and in combination with other therapies, which exposes us to additional risks. Combination therapies and additional indications involve additional complexity and risk that could delay or cause our programs to stall or fail; development of such programs may be more costly, may take longer to achieve regulatory approval and may be associated with unanticipated adverse events.

Should we resume development of our product candidates, we intend to develop FCR001, and may develop future product candidates, for use in combination with nonmyeloablative conditioning and related conditioning drugs. Clinical development and commercialization of combination therapies involve additional complexity and risk, including without limitation, those involving drug-drug interactions, dose selection, unanticipated adverse events, clinical design and approvals of regulatory bodies and therapeutic development networks of patient advocacy groups. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. If we are unable to manage the additional complexities and risks of the development and commercialization of combination therapies, the development of FCR001 or any other product candidate could be delayed, halted or otherwise fail to receive or maintain approval and may be less successful commercially.

Should we resume development of our product candidates, we may develop FCR001 or related product candidates for a number of different indications, including solid organ transplant, severe autoimmune diseases and other severe disorders for which allo-HSCT has

previously been observed to provide potential clinical benefit. Depending on the indication, patients may manifest a variety of differing co-morbidities, may be more or less vulnerable to our conditioning regimen, and may be more or less susceptible to certain severe adverse events or complications in the near or longer term, including cancer, infection, blood disorders and other life-threatening conditions. If any of these conditions or complications were to affect a patient who is participating in one of our clinical trials, it may be difficult or impossible to determine whether these adverse events or complications are related to the original or underlying condition or to our Facilitated Allo-HSCT Therapy. Given that our trials enroll a relatively small number of patients, even a small number of severe adverse events or serious complications could result in the delay or halt of development of our product candidates in one or more of our targeted indications.

Risks Related to Regulatory Matters and Approvals

Our product candidates represent a novel therapeutic approach that could result in heightened regulatory scrutiny. The regulatory landscape that applies to our Facilitated Allo-HSCT Therapy is rigorous, complex, uncertain and subject to change.

Given that our single-dose cell therapy represents a novel combination of nonmyeloablative conditioning, our investigational FCR001 product, and stem cell transplant-oriented treatment protocols, developing and commercializing our product candidates subjects us to a number of challenges, including obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of stem cell therapies.

Regulatory requirements governing the development of cell therapy products have changed frequently and may continue to change in the future. In 2016, the FDA established the Office of Tissues and Advanced Therapies ("OTAT") within the Center for Biologics Evaluation and Research ("CBER"), to consolidate the review of cell therapy, and related products, and to advise the CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products ("OTP") and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. Moreover, serious adverse events or developments in clinical trials of cell therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation. Adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy may cause the FDA, the EMA, and other regulatory bodies to amend the requirements for approval of any product candidates we may develop or limit the use of products utilizing cell therapies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for conditions in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other 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. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing cell therapies in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

We may not be able to maintain orphan drug designation for FCR001 or obtain orphan drug designation for our product candidates, or to obtain and maintain the benefits associated with orphan drug designation.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs or therapies for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the European Union, the prevalence of the condition must not be more than five in 10,000. The FDA has granted FCR001 orphan drug designation for the prophylaxis of organ rejection without the need for chronic immunosuppression in patients receiving LDKT. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication, for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. Even if we or our collaborators obtain

orphan designation to a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. The scope of exclusivity is limited to the scope of any approved indication, even if the scope of the orphan designation is broader than the approved indication. Additionally, exclusive marketing rights may be limited if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a product with the same active moiety for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (1) such condition affects no more than five in 10,000 persons in the E.U. when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the E.U. to justify the necessary investment. Moreover, in order to obtain orphan designation in the E.U. it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the E.U. or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the E.U., orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the E.U. can receive ten years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the E.U. for pediatric studies. However, the ten-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation-for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

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

If we do not receive or maintain orphan drug designation to product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates.

The incidence and prevalence of the target patient population for FCR001 are based on estimates and third-party sources. If the market opportunity for FCR001 or our other product candidates is smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations based on various third-party sources and internally generated analysis. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity for FCR001 in any given indication will depend on, among other things, acceptance of FCR001 by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with FCR001, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

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

In addition to regulations in the United States, to market and sell our product candidates in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure varies among countries and can involve additional testing and validation and additional administrative review periods. The time required to obtain approval may differ substantially from that

required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished. We do not have any product candidates approved for sale in any jurisdiction, including 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 our products will be unrealized.

Even if we resume development of our product candidates and receive regulatory approval, we will still face extensive ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense, and our products may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and product listing, as well as continued compliance by us and/or any future contract manufacturing organizations ("CMOs") and CROs for any post-approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of cell therapies and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices ("cGMP"), Good Clinical Practices ("GCP"), current good tissue practices ("cGTP"), and other regulations. For certain commercial prescription and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. 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 facility where the product is manufactured, a 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. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical trials;

- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

Should we resume development of our product candidates, the occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice ("DOJ"), the Office of Inspector General ("OIG") of the U.S. Department of Health and Human Services ("HHS"), state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any current or future product candidate. We 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 to the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained. Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Risks Related to Healthcare Legislation and Reform

Our relationships with customers, third-party payors, physicians and healthcare providers will be subject to applicable anti-kickback, fraud and abuse, and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Physicians, hospitals and third-party payors are often slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products. Patients are unlikely to use our product candidates unless insurance coverage is provided, and reimbursement is adequate, to cover a significant portion of the cost of our product candidates because patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services ("HHS"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is (i) a covered benefit under the payor's health plan; (ii) safe, effective and medically necessary; (iii) appropriate for the specific patient; (iv) cost-effective; and (v) neither experimental nor investigational.

Because our product candidates have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. Based on these and other factors, hospitals, physicians and payors may decide that the benefits of this new therapy do not or will not outweigh its costs. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable federal and varied state fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research as well as market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors,

federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include, but are not limited to, the following:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, paying or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation 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 the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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 federal False Claims Act or federal civil monetary penalties. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other;

- federal civil and criminal false claims laws, including the False Claims Act, and the civil monetary penalties law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. 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 federal False Claims Act. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;

- the federal beneficiary inducement statute, includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates, independent contractors or agents of covered entities, that perform services for them that involve the creation, maintenance, receipt, use, or disclosure of, individually identifiable health information as well as their covered subcontractors relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA"), including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires 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 or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. As of January 1, 2022, these reporting obligations now extend to include transfers of value by manufacturers that are made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. In addition, some states have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals.

Efforts to ensure that our current and future business arrangements with third parties, and our business generally, continue to comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with any such laws and regulations. If our operations, including our arrangements with physicians and other healthcare providers, are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, reputational harm, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements, and/or the curtailment or restructuring of our operations, as well as additional reporting obligations oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to similar penalties.

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. We expect that current laws, as well as 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 in additional downward pressure on the price that we, or any collaborators, may receive for any approved products.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

For example, in March 2010, the Affordable Care Act ("ACA") was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA of greatest importance to the pharmaceutical industry are that the ACA: made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on average manufacturer price, or AMP, on most branded prescription drugs and adding a new rebate calculation for "line extensions" (*i.e.*, new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP; imposed a requirement on manufacturers of branded drugs to provide a 50% point-of-sale discount (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of January 1, 2019) off the negotiated price of branded drugs dispensed to Medicare Part D beneficiaries in the coverage gap (*i.e.*, "donut hole") as a condition for a manufacturer's outpatient drugs being covered under Medicare Part D;

- extended a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded the entities eligible for discounts under the 340B Drug Discount Program;
- established a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, and
- established the Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products. The ACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect that there will be additional challenges and amendments to the ACA in the future. 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. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business. In addition, other legislative and regulatory changes have been proposed and adopted in the United States since the ACA was enacted:

- On August 2, 2011, the U.S. Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which remain in effect through 2031. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation.
- On January 2, 2013, the U.S. American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.
- On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at containing or lowering the cost of healthcare. Should we resume development of our product candidates, 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to drug pricing practices. Specifically, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, and review the relationship between pricing and manufacturer patient programs.

- At the federal level, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drugs and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. On September 25, 2020, CMS stated drugs imported by states under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. If implemented, importation of drugs from Canada may materially and adversely affect the price we receive for any of our product candidates.

- On November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation ("MFN") Model under which Medicare Part B reimbursement rates would have been calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. However, on December 29, 2021, CMS rescinded the Most Favored Nations rule.
- Additionally, on November 30, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to court order, the removal and addition of the aforementioned safe harbors were delayed and recent legislation imposed a moratorium on implementation of the rule until January 1, 2026. This deadline was pushed back further to January 1, 2027 by the Bipartisan Safer Communities Act and could potentially be pushed back to January 1, 2032 by the Inflation Reduction Act.
- Further, on December 31, 2020, CMS published a new rule, effective January 1, 2023, requiring manufacturers to ensure the full value of co-pay assistance is passed on to the patient or these dollars will count toward the Average Manufacturer Price and Best Price calculation of the drug. On May 17, 2022, the U.S. District Court for the District of Columbia granted the Pharmaceutical Research and Manufacturers of America's ("PhRMA") motion for summary judgment invalidating the accumulator adjustment rule

- The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one rare disease designation and for which the only approved indication is for that disease or condition. If a product receives multiple rare disease designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The effects of the IRA on our business and the healthcare industry in general is not yet known.
- In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products, if licensed;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and 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, financial condition, results of operations 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 drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Risks Related to Privacy and Data Security Laws

We are subject to stringent and changing privacy and data security laws, contractual obligations, self-regulatory schemes, government regulation, and standards related to data privacy and security. The actual or perceived failure by us, our collaborators, vendors or other relevant third parties to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business, operations and financial performance.

We collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect and share personal information and other information, including information we collect about patients and healthcare providers in connection with clinical trials.

There are numerous federal, state, local and international laws, regulations and guidance regarding privacy, information security and processing, the number and scope of which is changing, subject to differing applications and interpretations, and which may be inconsistent among jurisdictions, or in conflict with other rules, laws or data protection obligations. Data protection laws and data

protection worldwide is, and is likely to remain, uncertain for the foreseeable future, and our failure or perceived failure to address or comply with these laws could: increase our compliance and operational costs; expose us to regulatory scrutiny, actions, fines and penalties; result in reputational harm; lead to a loss of customers; reduce the use of our products; result in litigation and liability; and otherwise result in other material harm to our business.

For example, in the United States, HIPAA, as amended by HITECH, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and, if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission ("FTC"), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act ("FTCA"), 15 U.S.C. § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations.

Additionally, U.S. States have begun introducing privacy legislation. For example, California recently enacted the California Consumer Privacy Act ("CCPA"), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA also provides for civil penalties for violations, as well as a private right of action for data breaches that may increase our risk to data breach class action litigation. The CCPA will be expanded substantially on January 1, 2023, when the California Privacy Rights Act of 2020 ("CPRA") becomes fully operative. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal information, establish restrictions on the retention of personal information, expand the types of data breaches subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. The CCPA and the CPRA could substantially impact our business.

Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, in the United States, we have witnessed significant developments at the state level. For example, in 2021, Virginia and Colorado enacted state legislation that becomes effective January 1, 2023. In 2022, Utah and Connecticut also enacted privacy legislation. With bills proposed in many other jurisdictions, it remains quite possible that other states will follow suit. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country will make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

The increasing number and complexity of regional, country and U.S. state data protection laws, and other changes in laws or regulations across the globe, especially those associated with the enhanced protection of certain types of sensitive data could lead to government enforcement actions and significant penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

We may also be subject to additional privacy restrictions in various foreign jurisdictions around the world in which we operate or process personal information. The collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the European Economic Area ("EEA"), including personal health data, is subject to the General Data Protection Regulation 2016/679 ("GDPR"). The GDPR is wide-ranging and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects

and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply.

In addition, GDPR prohibits the transfer of personal data from the EU to the U.S. and other countries in respect of which the European Commission or other relevant regulatory body has not issued a so-called “adequacy decision” (known as “third countries”), unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. One of the primary safeguards used for transfers of personal data to the U.S. was the EU-U.S. Privacy Shield framework administered by the U.S. Department of Commerce. However, certain recent EU court decisions cast doubt on the ability to use one of the primary alternatives to the EU-U.S. Privacy Shield, namely the European Commission’s Standard Contractual Clauses, to lawfully transfer personal data to the U.S. and other third countries. In addition, the European Commission has recently published new versions of the Standard Contractual Clauses, which must be used for all new transfers of personal data from the EEA to third countries (including the United States) as of September 2021, and all existing transfers of personal data from the EU to third countries relying on the existing versions of the Standard Contractual Clauses must be replaced by December 2022. The implementation of the new Standard Contractual Clauses will necessitate significant contractual overhaul of our data transfer arrangements with customers, sub-processors and vendors. Use of both the existing and the new Standard Contractual Clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals, and additional supplementary technical, organizational and/or contractual measures and/or contractual provisions may need to be put in place.

At present, there are few if any viable alternatives to the Standard Contractual Clauses, and there remains some uncertainty with respect to the nature and efficacy of such supplementary measures in ensuring an adequate level of protection of personal data. As supervisory authorities issue further guidance on personal data export mechanisms (including circumstances where the Standard Contractual Clauses can and cannot be used) and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines. In addition, if we are unable to transfer personal data between and among countries and regions in which we operate and/or engage providers and/or otherwise transfer personal data, this could affect the manner in which we receive and/or provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results and generally increase compliance risk as a result. Additionally, other countries outside of Europe have enacted or are considering enacting similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

Furthermore, following Brexit, the relationship between the U.K. and the EEA in relation to certain aspects of data protection law remains somewhat uncertain. In June 2021, the European Commission issued an adequacy decision under the GDPR which allows transfers (other than those carried out for the purposes of U.K. immigration control) of personal data from the EEA to the U.K. to continue without restriction for a period of four years. After that period, the adequacy decision may be renewed only if the U.K. continues to ensure an adequate level of data protection. During these four years, the European Commission will continue to monitor the legal situation in the U.K. and could intervene at any point if the U.K. deviates from the level of data protection in place at the time of issuance of the adequacy decision. If the adequacy decision is withdrawn or not renewed, transfers of personal data from the EEA to the U.K. will require a valid “transfer mechanism” and we may be required to implement new processes and put new agreements in place, such as Standard Contractual Clauses, to enable transfers of personal data from the EEA to the U.K. to continue, which could disrupt our operations.

In addition, while the U.K. data protection regime currently permits data transfers from the U.K. to the EEA and other third countries covered by a European Commission adequacy decision, and currently includes a framework to permit the continued use of the existing version of the Standard Contractual Clauses for personal data transfers from the U.K. to third countries, this is subject to change in the future, and any such changes could have implications for our transfers of personal data from the U.K. to the EEA and other third countries. In particular, the U.K. Information Commissioner’s Office has stated that it is working on its own bespoke version of the Standard Contractual Clauses and it is not clear whether the new Standard Contractual Clauses published by the European Commission will be accepted as a valid mechanism to permit the transfer of personal data from the U.K. to third countries and/or whether any U.K. version of the Standard Contractual Clauses will supersede the existing and/or new EU version of the Standard Contractual Clauses.

This could necessitate the implementation of both U.K. and EU versions of Standard Contractual Clauses, which would require significant resources and result in significant cost to implement and manage.

We are also subject to the terms of our external and internal privacy and security policies, representations, certifications, standards, publications and frameworks, and contractual obligations to third parties related to privacy, information security and processing.

With applicable data protection laws, privacy policies and data protection obligations imposing complex and burdensome obligations, and with substantial uncertainty over the interpretation and application of these requirements, we have faced and may face additional challenges in addressing and complying with them, and making necessary changes to our privacy policies and practices, and may incur material costs and expenses in an effort to do so, any of which could materially adversely affect our business operations and financial results, and may reduce the overall demand for our products.

We strive to comply with applicable data protection laws, privacy policies and data protection obligations to the extent possible, but we may at times fail to do so, or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our personnel, collaborators or vendors do not comply with applicable data protection laws, privacy policies and data protection obligations. Any failure or perceived failure by us or our collaborators, service providers and contractors to comply with federal or foreign laws or regulation, our internal policies and procedures, representations or our contracts governing the processing of personal data could result in negative publicity, disruptions or interruptions in our operations, fines, penalties, lawsuits, liability, inability to process personal data, diversion of time and effort, proceedings against us by governmental entities, or other adverse effects to our business.

Risks Related to Our Dependence on Third Parties

We have historically been dependent on a limited number of suppliers and, in some cases sole suppliers, for some of our components and materials used in our product candidates.

The manufacturing process for FCR001, like that of a number of other cell therapy companies, is characterized by limited numbers of suppliers, and in some cases sole source suppliers, with the manufacturing capabilities and know-how to create or source the reagents, materials and equipment necessary for the production of our product candidates. For example, like many other cell therapy companies, our manufacturing process for FCR001 depends on certain cell manipulation equipment and related reagents, all of which are available from Miltenyi Biotec ("Miltenyi") as the sole supplier.

We cannot be sure that our suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that decides not to continue producing these materials for us. Additionally, during a public health emergency, there is a potential for certain manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, which may make it more difficult to obtain materials or reagents for our product candidates for our clinical trials or for commercial production, if approved, which could lead to delays in these trials or issues with our commercial supply. Our use of a sole or a limited number of suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. While we try to mitigate these risks by purchasing excess supplies, some of these components, such as reagents, typically expire after approximately four to six months. This short expiration period means that stocking the reagents in large quantities for future needs would not be an effective strategy to mitigate against the risk of shortage due to disruption of the supply chain or termination of our business relationship. We also pursue multiple sources for the critical components of our manufacturing process, but there are, in general, relatively few alternative sources of supply for these components and we may not be successful in securing these additional sources at all or on a timely basis. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the FDA or EMA could require additional supplemental data, manufacturing data and comparability data up to and including clinical trial data if we rely upon a new supplier. Any disruption in supply from any supplier or manufacturing location, including as a result of or impact from the COVID-19 pandemic, could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects. If we are required to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, adversely affecting our business. Establishing additional or replacement suppliers may not be accomplished quickly. While we seek to maintain adequate inventory of the components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to conduct our clinical trials and, if our product candidates are approved, to meet the demand of our customers and cause them to cancel orders.

In addition, as part of the FDA’s approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers and CMOs. Some of

our current suppliers may not have undergone this process, and may not have had any components included in any product approved by the FDA.

Our historical reliance on external suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- the interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term commercial supply arrangements for key components with our suppliers;
- the inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- a delay in delivery due to our suppliers prioritizing other customer orders over ours; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to conduct our clinical trials and, if our product candidates are approved, to meet demand for our products could be impacted. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production of our product candidates.

We have historically relied, and may in the future rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our clinical trials ourselves. As a result, we have historically been, and may in the future be, dependent on third parties to conduct any future clinical trials of our product candidates, including but not limited to governmental agencies and university laboratories, CMOs, CROs, distribution and supply (logistics) services organizations, contract testing organizations ("CTOs"), consultants or consultant organization with specialized knowledge-based expertise. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs, CTOs, and other third parties does not relieve us of our regulatory responsibilities. For example, we relied on a single third-party investigator to provide ongoing data from our Phase 2 clinical trial. We, our CROs and clinical sites are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our current product candidates and any future product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs, and in particular, our single third-party investigator for our Phase 2 company-sponsored trial, or clinical trial sites fail to adhere to our clinical trial protocols or to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process. 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 trial. 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 marketing approval of our product candidates.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. Further, the performance of our CROs has been, and may again in the future be interrupted by the COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. In August 2022, a software vendor, which is responsible for providing logistics support for apheresed material from the donor to our manufacturing facility and back to the clinical site, shutdown operations. As there are few alternative vendors providing similar services, we may be required to utilize a manual, paper-based chain of custody process that could add risk to our manufacturing process.

If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our current product candidates and any future product candidates.

Risks Related to Manufacturing

Risks Related to our Manufacturing Facility

We currently operate our own manufacturing facility. Should we resume development of our product candidates, we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

We operate our own dedicated cGMP cell processing facility, located on the campus of the University of Louisville, where we had manufactured our product candidates for our current and planned clinical trials. Although we had been operating our manufacturing facility, our operations remained subject to review and oversight by the FDA, and the FDA could object to our use of our manufacturing facility or the processes used therein.

We had begun to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs for FCR001 for LDKT. While those scale-up efforts have been deferred, in order to scale-up our manufacturing capabilities and facility in the future to support our anticipated commercial needs, we will require substantial additional funds and will need to hire and retain significant additional personnel and comply with extensive cGMP regulations applicable to a commercial facility. If we fail to complete any construction in an efficient manner, recruit the required personnel and generally manage our growth effectively, the development and production of our product candidates could be curtailed or delayed. Our manufacturing facility would also need to be licensed for the production of our product candidates by the FDA. Even if our manufacturing facility is approved by the FDA, we would be subject to ongoing periodic unannounced inspection by the FDA, corresponding state agencies and potentially third-party collaborators to ensure strict compliance with cGMPs and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

We believe that our manufacturing processes can be scaled-up to address our commercial needs. However, there can be no assurance that we will not encounter difficulties in scaling out our manufacturing processes. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional FDA approvals. We may encounter difficulties in scaling out production, including problems involving raw material suppliers, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. The actual cost to manufacture and process our product candidates could also be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Any of these difficulties, if they occur and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for such product candidate. These risks become more acute as we scale-up for commercial quantities, where a reliable source of product becomes

critical to commercial success. The commercial viability of any of our product candidates, if approved, will depend on our ability to produce our personalized cell therapy at a large scale. Failure to achieve this level of supply could jeopardize the successful commercialization of our therapy.

The manufacture of a cell therapy is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, shortages of raw materials, as well as compliance with strictly enforced federal, state and foreign regulations. For example, in late 2021, we were required to undertake an additional apheresis of a donor when quality testing revealed that the product prepared from that donor's stem cells was contaminated. While there can be no assurance at what point the donor blood product was contaminated, whether at the point of apheresis or during the manufacturing process, we nonetheless have reviewed and enhanced our quality control procedures and believe the risk of future contamination to be low. Furthermore, if contaminants are discovered in our cell therapy or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot ensure that any stability or other issues relating to the manufacture of our product candidates will not occur in the future.

We may fail to manage the logistics of collecting and shipping donor cell material to the manufacturing site and shipping the product candidate to the patient. Logistical and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could cause breakage or contamination of our products and prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to donor material as it moves to the manufacturing facility, through the manufacturing process, and to the recipient. Failure to maintain chain of identity and chain of custody could result in patient death, loss of product or regulatory action.

Though our supply chain has not been materially impacted by the COVID-19 pandemic to date, our manufacturing capabilities could be affected by cost-overruns, resource constraints, unexpected delays, equipment failures, labor shortages or disputes, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, jeopardize our ability to provide our product candidates to patients, and have a material adverse effect on our business, financial condition, results of operations and prospects.

If our manufacturing facility is damaged or destroyed or production at our manufacturing facility is otherwise interrupted, our business would be negatively affected.

Damage to our manufacturing facility or disruption to our operations for any reason, including due to natural disaster (such as earthquake, wildfires and other fires or extreme weather), power loss, communications failure, cyberattack, unauthorized entry or other events, such as a flu or other health epidemic (such as the COVID-19 pandemic, including any current and future variants), could affect our manufacturing processes.

In particular, our manufacturing facility, located on the Health Science Center campus of the University of Louisville, has supplied all of our clinical needs, and any damage or disruption to that facility could cause a loss of products or materials or otherwise adversely affect our ability to manufacture our current and any future product candidates in support of our clinical trials. It may require substantial lead time to repair, and we may not have control over such repairs. The property damage and business interruption insurance coverage on our facility that we maintain might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs.

Any damage or disruption to the University of Louisville's operations, including the foregoing events, may also adversely affect our business. For example, disruption to any of the utilities provided to our facility by University of Louisville (HVAC, electrical, water, etc.) could inhibit or prevent us from being able to manufacture our product candidates. Moreover, if we are unable to obtain key inputs used in our manufacturing process, disinfectants or other materials required to maintain "clean room" sterility in our manufacturing facility, we may be unable to manufacture products entirely. Any failure of our building systems could also adversely affect our operations, including but not limited to equipment malfunctions, failure to follow specific protocols and procedures, and issues relating to air handling and other utilities. Any significant disruption to our manufacturing facility or processes would likely have an adverse impact on our business.

Any adverse developments affecting manufacturing operations for our current and any future product candidates may result in lot failures, inventory shortages, shipment delays, product losses or other interruptions in the supply of our product candidates for an undetermined period of time. We may also have to write off raw material and drug product inventory, incur other charges and expenses for key manufacturing inputs that fail to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the clinical demand for our product candidates could damage our reputation and the reputation of our

products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

Our manufacturing process needs to comply with regulations relating to the quality and reliability of such processes. Should we resume development of our product candidates, any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. Further, as our preclinical and clinical programs and the manufacture of our product candidates are dependent on human donor material, we are or could be subject to additional regulations and requirements.

The FDA, EMA and comparable foreign regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, cGTP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA and comparable foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards, including for the manufacture, packaging or testing of biological products.

We may encounter difficulties in achieving quality control and quality assurance or meeting regulatory expectations. Our facilities are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP, cGTP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our product candidates as a result of our failure to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

In addition, our clinical programs and the manufacture of our product candidates have been dependent on human donor material. Procurement of certain human organs for transplantation is subject to the National Organ Transplant Act of 1984 (“NOTA”), which prohibits the acquisition, receipt, or transfer of any human organ for valuable consideration for use in human transplantation. We depend on third parties who arrange for living donor kidney transplants ("LDKT") to comply with applicable NOTA requirements and we do not know whether any failure by such third parties to comply with NOTA requirements could impact the integrity or usability of data in our clinical trials.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects.

The process for treatment using cell therapies is subject to human and systemic risks.

The “vein-to-vein” cycle for treating patients using our Facilitated Allo-HSCT Therapy and other cell-based targeted therapies typically takes approximately four to twelve weeks and involves a large number of steps, as well as human participants. In the United States,

samples of the final product are subjected to several release tests which must fulfill specified criteria for the drug product to be released for infusion. These include sterility, identity, purity, potency and other tests. We are subject to stringent regulatory and quality standards in the course of our cell therapy treatment process. We cannot assure you that our quality control and assurance efforts will be successful or that the risk of human or systemic errors in these processes can be eliminated. Our cell therapies are uniquely manufactured for each recipient, so they must be administered only to the recipient matched to the donor from which the cellular source material was collected. While we implement specific identifiers, lot numbers and labels with cross checks for our products and operations from collection of cellular source material, through manufacture of drug product, transport of product to the clinical site up to thawing and administration of the product, it is possible that a product may be administered into the wrong patient. If our cell therapies were to be administered into the wrong recipient, the recipient could suffer harm, including experiencing a severe adverse immune reaction and this event, should it happen, could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to the Manufacturing of our Product Candidates

Our product candidates are uniquely manufactured for each patient, and should we resume development of our product candidates, we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities.

The manufacturing process used to produce our product candidates is novel and has not been validated for commercial production. Our product candidates comprise a composition of hematopoietic stem cells ("HSCs"), facilitating cells ("FCs") and Alpha Beta T-cell Receptor Cells ("αßTCR+ T cells"), the dose of each of which is tailored to the recipient using our proprietary manufacturing process. Due to the personalized nature of the product candidate, we expect the cost to manufacture our product candidates to be high.

Although we have qualified and obtained positive initial FDA feedback on our potency assays for each of our active cell components in FCR001, we must validate the potency assays prior to submission of a marketing application for FCR001. Potency assays have traditionally proven difficult to develop for cell-based products and must be validated prior to approval. There can be no assurance that we will be able to validate our potency assays to FDA's satisfaction, or that FDA will not want us to develop different or alternative potency assays for FCR001 or other product candidates. Any such development could delay or prevent approval of FCR001 or our other product candidates.

There is a risk of manufacturing issues associated with the differences in donor starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from our normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. If for any reason we lose a donor's starting material or one of our custom-manufactured products at any point in the process, the manufacturing process for that recipient will need to be restarted and the resulting delay may adversely affect that recipient's outcome. Because our product candidate is manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing facility, through the manufacturing process and on to the patient. Further, as our product candidate is developed through preclinical to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. If we make these types of changes, we may not achieve our intended objectives and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of clinical trials.

Although we continually attempt to optimize our manufacturing process, doing so is a difficult and uncertain task and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale-up our manufacturing processes, we may encounter lengthy delays in commercializing our product candidates. We may continue to manufacture our product ourselves or we may ultimately decide to outsource our manufacturing to a third party CMO. We may not be successful in transferring our production system to such manufacturer, or the manufacturer(s) on whom we rely may not have the necessary capabilities to complete the implementation and development process. If we are able to adequately validate and scale-up the manufacturing processes for our product candidates with a contract manufacturer, we will still need to negotiate an agreement for commercial supply with that contract manufacturer and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are approved and commercialized.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval processes and, if we choose to outsource our commercial production, we will need to contract with manufacturers who we believe can meet applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce our cell therapy candidate to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance

that either we or any CMOs we may contract with in the future will be able to manufacture the approved product to specifications and under cGMPs acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Should we resume development of our product candidates, our future success will depend on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements. Our inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any personalized product lot, together with the protocols showing the results of applicable tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a specific product 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, financial condition, results of operations and prospects. Problems in our manufacturing process could restrict our ability to meet market demand for our products.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs.

Should we resume development of our product candidates, they will require specific shipping, storage, handling and administration at the clinical sites, including cold-chain logistics, which could subject our product candidates to risk of loss or damage.

Our product candidates are sensitive to temperature, storage and handling conditions. They must be stored at very low temperatures in specialized freezers or specialized shipping containers until immediately prior to use. For administration, the cryopreserved product container must be carefully removed from storage, and rapidly thawed under controlled temperature conditions in an area proximal to the patient's bedside and administered into the patient. The handling, thawing and administration of the cryopreserved therapy product must be performed according to specific instructions, typically using specific disposables, specific bags and in some steps within specific time periods. Failure to correctly handle our product, including the potential breakage of the cryopreservation bags or to follow the instructions for thawing and administration and or failure to administer our product within the specified period post-thaw could negatively impact the efficacy and or safety of our product, or cause a loss of product.

In addition, our product candidates must be cryopreserved/frozen using specialized equipment and following specific procedures in order to be stored without damage in a cost-efficient manner and without degradation. We may encounter difficulties in further optimization of freezing and thawing methodologies, and also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen or thawed form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze FCR001 or other cell-based therapies we may develop for storage and shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing production facilities, will be limited.

Even if we are able to successfully freeze and thaw FCR001 without damage in a cost-efficient manner and without degradation to the satisfaction of the FDA to support regulatory approval, we will still need to scale-up a cost-effective and reliable cold-chain distribution and logistics network, which we may be unable to accomplish. Failure to effectively scale-up our cold-chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for commercial supply. For these and other reasons, we may not be able to manufacture FCR001 or other cell-based therapies we may develop at commercial scale or in a cost-effective manner.

The process of manufacturing cell therapies is inherently susceptible to contamination. If microbial, viral or other contaminations are discovered in any product candidate or in our manufacturing facility, our manufacturing facility may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our cell therapy product candidates are manufactured from the cells of third-party donors, the process of manufacturing is susceptible to the availability of the third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized

equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. These types of contaminations could result in manufacturing delays which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects.

Risks Related to Our Intellectual Property

Risks Related to our Intellectual Property Licensed from ULRF

We depend on intellectual property licensed from the ULRF, and termination of this license could result in the loss of significant rights, which would materially harm our business.

We depend on the ULRF License for our intellectual property, data and know-how. The ULRF License imposes, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us. This license may be terminated upon certain conditions. Any termination of this license could result in the loss of significant rights and could harm our ability to commercialize our product candidate. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those related to:

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

If disputes over intellectual property that we have licensed, or license in the future, 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. In addition, the resolution of any such disputes 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.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

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 such licensed intellectual property, our ability to commercialize products could suffer.

Risks Related to our Intellectual Property Protection

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

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements that we own or possess or that are owned or possessed by our collaborators that are in-licensed to us under licenses, including the ULRF License, to protect the intellectual property related to our technology and product candidates. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. For example, our product candidates and Facilitating Allo-HSCT Therapy are protected by patents or patent applications of ULRF that we have licensed and as confidential know-how and trade secrets. Additionally, our earlier stage product candidates are not yet protected by any patents or patent applications. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is highly uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office ("USPTO") and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. Further, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Thus, we may be unaware of prior art that could be used to invalidate an issued patent or prevent a pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, ownership, enforceability or scope thereof, which may result in these patents being narrowed, invalidated, circumvented, or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same or similar effects as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

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

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain patents licensed from third parties. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We and our collaborators have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent

applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our collaborators were the first to file any patent application related to a product candidate. We or our collaborators may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and *inter partes* and post-grant review proceedings before the USPTO, the European Patent Office and other non-U.S. patent offices.

Even if granted, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent generally occurs 20 years after the earliest U.S. non-provisional application is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. 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. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman Act”), which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit. The Bayh-Dole Act also provides federal agencies with “march-in rights”. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself. Some of our licensed patents are subject to the provisions of the Bayh-Dole Act.

Should we resume development of our clinical products, we may not be able to protect our intellectual property rights throughout the world.

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

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

other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our future collaborators. We or our future collaborators may not prevail in any lawsuits that we or our collaborators initiate, and even if we or our collaborators are successful, the damages or other remedies awarded, if any, may not be commercially meaningful.

In some jurisdictions, including European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our future collaborators are forced to grant a license to third parties under patents relevant to our business, or if we or our future collaborators are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

Should we resume development of our product candidates, 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, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

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

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

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

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.

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. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors 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 unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Risks Related to Potential Third Party Claims

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

Our commercial success depends, in part, on us and our future collaborators not infringing the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and *inter partes* and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. For example, we are aware of certain issued patents that may cover some of our product candidates, and while we believe these patent claims are not valid and would not establish a basis for our operations to be enjoined, we may be subject to litigation and be obligated to pay reasonable royalties to the patent owners. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

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

If we or our future collaborators are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third-party patents were held by a court of competent jurisdiction to be valid and enforceable and cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expires. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Additionally, in the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or technically infeasible, or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable

intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we have employed individuals who are or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. In particular, our founder and former Senior Scientific Advisor, Suzanne T. Ildstad, MD, is the Jewish Hospital Distinguished Professor of Transplantation Research, Director of the Institute for Cellular Therapeutics, and a Professor in the Department of Surgery with associate appointments in the Departments of Physiology & Biophysics and Microbiology & Immunology at the University of Louisville School of Medicine. Our former Chief Technology Officer, Michael Zdanowski, and certain other employees or consultants were previously employed at Medeor Therapeutics, Inc., which is developing a cell therapy similar to ours. Although we try to ensure that our employees, consultants and independent contractors 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 intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact 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 may face claims that we misappropriated, or otherwise acted unjustly or in bad faith with respect to, the confidential information or trade secrets of third parties, including collaborators or former collaborators. If we are found to have misappropriated a third party's trade secrets, or otherwise to have acted unjustly or in bad faith with respect to such trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates, or may be otherwise subject to monetary damages.

We may face claims that we misappropriated, or otherwise acted unjustly or in bad faith with respect to, the confidential information or trade secrets of third parties, including collaborators or former collaborators. Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. Parties making claims against us may be able to sustain the costs of litigation more effectively than we can because they have substantially greater resources. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. Any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. As a result of all of the foregoing, any actual or threatened intellectual property claim, including claims that we acted unjustly or in bad faith with respect to the intellectual property of others, could prevent us from developing or commercializing a product candidate, subject us to monetary damages, or force us to cease some aspect of our business operations.

We cannot ensure that additional 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 have issued and pending U.S. and foreign patent applications in our portfolio, however, we cannot predict:

- if and when additional patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will 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 enforce and/or defend our patent rights which will be costly whether we win or lose; and

- 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.

We cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the USPTO or by patent offices in foreign countries. 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. The examination process may require us to narrow our claims, which may limit the scope of patent protection that we may obtain. Even if the patents are issued based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. 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.

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

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our collaborators may elect to initiate legal proceedings to enforce or defend our or our collaborators' intellectual property rights, to protect our or our collaborators' trade secrets or to determine the validity, ownership, enforceability or scope of our intellectual property rights. Any claims that we or our collaborators assert against perceived infringers could also provoke these parties to assert counterclaims against us or our collaborators alleging that we or our collaborators infringe their intellectual property rights or that our intellectual property rights are invalid or unenforceable.

Interference or derivation proceedings provoked by third parties, brought by us or our collaborators, or declared by the USPTO may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our collaborators may also become involved in other proceedings, such as reexamination or opposition proceedings, *inter partes* review, post-grant review or other pre-issuance or post-grant proceedings before the USPTO or in non-U.S. jurisdictions relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could result in us losing our valuable intellectual property rights, require us or our collaborators to cease using the related technology and commercializing our product candidates, or require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our collaborators a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our collaborators. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

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

public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected.

Risks Related to Intellectual Property Laws and Regulations

Some intellectual property has been discovered through government-funded programs and thus may be subject to federal regulations such as certain reporting requirements, a preference for U.S.-based companies, and the possibility of "march-in" rights. Compliance with such regulations or the inability to obtain a waiver for meeting such requirements may limit our ability to contract with non-U.S. manufacturers, or, in the unlikely event of the government exercising their "march-in" rights, may limit our exclusive rights.

Some of our intellectual property rights were generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in certain of our current or future product candidates pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). To our knowledge, however, the U.S. government has, to date, not exercised any march-in rights on any patented technology that was generated using U.S. government funds. The U.S. government also has the right to take title to these inventions if we or the applicable grantee fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

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

Changes in either the patent laws or interpretation of the patent laws in the United States or non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability 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 us 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 of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. 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 (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affects patent litigation. 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 and, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of

our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

Risks Related to Our Financial Condition and Capital Needs

We are a biotechnology company and we have incurred net losses since our inception. We anticipate that we will continue to incur significant net losses for the foreseeable future, and may never achieve or maintain profitability.

We are a biotechnology company with a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. Since our inception, we have devoted substantially all of our resources to developing our product candidate, FCR001, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net loss was $19.8 million for the three months ended March 31, 2023 and $73.9 million for the year ended December 31, 2022. As of March 31, 2023, we had an accumulated deficit of $184.5 million. We expect to continue to incur net losses for the foreseeable future, including costs associated with our review of strategic alternatives. These expenses could increase or change depending on the outcome of such review.

We anticipate that our expenses will increase substantially if and as we resume development of our product candidates, including if we:

- resume conducting clinical trials for our product candidate, FCR001;
- seek to identify additional product candidates and initiate research, preclinical and clinical development efforts for any future product candidates;
- seek regulatory approvals for FCR001 or any future product candidates that successfully complete clinical development;
- scale our in-house manufacturing process to address anticipated commercial needs;
- seek to meet regulatory requirements for our in-house manufacturing process;
- add operational, financial and management information systems and personnel, including personnel to help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, manufacturing, commercial and administrative personnel, to support our product candidate development;
- maintain, expand and protect our intellectual property portfolio;

- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any product candidates for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical trials in addition to those that we currently expect, if there are any delays in establishing appropriate manufacturing arrangements for our product candidates, or if we experience delays in the initiation or completion of our clinical trials or the development of any of our product candidates for any reason, including as a result of the COVID-19 pandemic.

Raising capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. Market volatility resulting from the COVID-19 pandemic or other factors may further adversely impact our ability to access capital as and when needed. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business.

Risks Related to Our Business, Growth and Industry

Risks Related to the COVID-19 Pandemic

Our business has been adversely affected by the COVID-19 pandemic, and could be further adversely affected by the effects this and other of public health epidemics in regions where we, or third parties on which we rely have significant research, development or production facilities, concentrations of clinical trial sites or other business operations.

Our business has been adversely affected by the COVID-19 pandemic, and could be further adversely affected by this and other public health epidemics in regions where we, and third parties on which we rely, such as CROs or suppliers, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of those third-parties, and adversely affect our business. For example, enrollment in our Phase 3 FREEDOM-1 clinical trial, prior to being discontinued, consistently lagged both our original and revised enrollment projections, significantly limiting the data which we were able to report at periodic medical conferences. In November 2021, when we provided the first interim data in connection with the American Association of Nephrology meeting, we reported data on five dosed patients, only three of whom had met the three-month post-transplant milestone. We believe the COVID-19 pandemic significantly impacted the ability of our clinical trial sites to attract and enroll clinical trial subjects, which contributed to our decision to discontinue the clinical trial. Furthermore, the performance of our CROs may also be delayed or disrupted by the COVID-19 pandemic and current and future variants of the virus, including due to travel or quarantine policies, availabilities of staff, exposure of CRO staff to COVID-19 or re-prioritization of CRO resources as a result of the pandemic.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential further economic impact brought by, and the duration or reemergence of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

Risks Related to Employees

Our recent reductions in force may negatively impact employee morale and productivity.

In connection with the evaluation of strategic alternatives that we announced in February 2023, and in order to extend our resources, we implemented a restructuring plan that included reducing our workforce by approximately one-third. In April 2023, we announced the April Reduction in Force that is expected to result in the termination of approximately 95% of our remaining workforce. We estimate that the April Reduction in Force will be substantially completed by May 2023. In order to retain remaining employees to evaluate and assist with the evaluation of strategic alternatives, we offered assurance of severance arrangements and retention benefits to a very limited number of remaining personnel. There can be no assurance that these programs will allow us to retain the personnel necessary to implement our strategic assessment plans.

Our employees, principal investigators, consultants and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee and third party fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, litigation and serious harm to our reputation. It is not always possible to identify and deter employee and third-party 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 significant impact on our business and results of operations, including the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Risks Related to Business Disruptions

If our security measures are compromised now, or in the future, or the security, confidentiality or integrity or availability of our information technology, software, services, communications or data is compromised, limited, or fails, this could result in a materially adverse impact, including without limitation, damage to our reputation, significant financial and legal exposure, breach or triggering of data protection laws, privacy policies and data protection obligations, disruption to our clinical trial or administrative activities, or loss of customers or collaborators.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our business, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information, as well as intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors, consultants and relevant third parties are vulnerable to several threats, including without limitation damage from computer viruses, unauthorized access, terrorism, war, natural disasters, and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, phishing attacks, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. Although we have not, to our knowledge, experienced a material security incident, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches.

We may be required to expend significant resources, fundamentally change our business activities and practices, or modify our services, software, operations or information technology in an effort to protect against security breaches and to mitigate, detect, and remediate

actual and potential vulnerabilities. Applicable data protection laws, privacy policies and other data protection obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches.

If we, our service providers, collaborators, or other relevant third parties have experienced or in the future experience, any security incident(s) that result in any data loss, deletion or destruction, unauthorized access to, loss of, unauthorized acquisition or disclosure of, or inadvertent disclosure of sensitive information or compromise related to the security, confidentiality, integrity or availability of our (or their) information technology, software, services, communications or data, it may result in a material adverse impact, including without limitation, legal liability, government investigations an inability to conduct our clinical trials, regulatory investigations, enforcement actions, indemnity obligations, the disruption of our operations, delays to the development and commercialization of our product candidates, negative publicity and financial loss. A failure by us or relevant third parties to detect, anticipate, measure or detect such security incidents could result in similar material adverse impacts.

Additionally, applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security breaches, including affected individuals, customer and regulators. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to material adverse impacts, including without limitation, negative publicity, a loss of customer confidence in our products or security measures or a breach of contract claim. There can be no assurances that the limitations of liability in our contract would be enforceable or adequate or would otherwise protect us from liabilities or damages.

Failures or significant downtime of our information technology or telecommunication systems or those used by our third-party service providers could cause significant interruptions in our operations and adversely impact the confidentiality, integrity and availability of sensitive or confidential information. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

While we maintain general liability insurance coverage and coverage for errors or omissions, we cannot assure that such coverage will be adequate or otherwise protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, data loss, regulatory actions or other material adverse impacts arising out of our privacy and security actions we may experience, or that such coverage will continue to be available on acceptable terms or at all. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or that results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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

Our manufacturing operations, and those of our CROs, suppliers and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

Market conditions such as inflation, volatile energy costs, geopolitical issues, unstable global credit markets and financial conditions could lead to periods of significant economic instability, diminished liquidity and credit availability, diminished expectations for the global economy and expectations of slower global economic growth going forward. Our business and operations may be adversely affected by such instability, including any such inflationary fluctuations, economic downturns, volatile business environments and continued unstable or unpredictable economic and market conditions. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, 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 collaborators may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Global economic uncertainty and weakening product demand caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business and financial performance.

Economic uncertainty in various global markets caused by political instability and conflict and economic challenges caused by the COVID-19 pandemic has resulted, and may continue to result, in weakened demand for our products and services and difficulty in forecasting our financial results and managing inventory levels. Political developments impacting government spending and international trade, including current or potential government-imposed sanctions, potential government shutdowns and trade disputes and tariffs, may negatively impact markets and cause weaker macro-economic conditions. The effects of these events may continue due to potential U.S. government shutdowns and the transition in administrations, and the United States' ongoing trade disputes with China and other countries. The continuing effect of any or all of these events could adversely impact demand for our products, harm our operations and weaken our financial results.

Risks Related to Laws and Regulations that May Affect our Business

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

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

Our ability to use our U.S. federal and state net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Under current law, unused U.S. federal net operating losses generated for tax years beginning after December 31, 2017 are not subject to expiration and may be carried forward indefinitely. Such U.S. federal net operating losses generally may not be carried back to prior taxable years, except that, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, the amount of net operating loss carryforwards generated in taxable years beginning after December 31, 2017 that we are permitted to deduct in a taxable year beginning after December 31, 2020, is limited to 80% of our taxable income in each such taxable year to which the net operating loss carryforwards are applied. In addition, both our current and our future unused U.S. federal net operating losses and tax credits may be subject to limitations under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. Our net operating losses and tax credits may also be impaired or restricted under state law. As of December 31, 2022, we had U.S. federal net operating loss carryforwards of approximately $96.9 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

We are subject to U.S. anti-corruption laws and regulations and can face serious consequences for violations.

We are subject to anti-corruption laws, including the U.S. domestic bribery statute contained in 18 U.S.C. 201, the U.S. Travel Act, and the U.S. Foreign Corrupt Practices Act of 1977, as amended. These anti-corruption laws generally prohibit companies and their employees, agents, and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. Violations of anti-corruption laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Likewise, any investigation of

potential violations of anti-corruption laws could also have an adverse impact on our reputation, our business, results of operations and financial condition.

If product liability lawsuits are brought against, we may incur substantial liabilities and may be required to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to study subjects or patients;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our share price.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to Ownership of Our Common Stock

Risks Related to our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- actual or anticipated variations in quarterly operating results;
- the outcome of our evaluation of strategic alternatives;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or cell therapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property or stockholder litigation;
- changes in the structure of health care payment systems;
- general political and economic conditions, including impacts from the COVID-19 pandemic; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical 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 market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market 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, financial condition, results of operation and future prospects.

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

Our executive officers, directors, and 5% stockholders beneficially owned approximately 64.0% of our outstanding voting common stock as of March 31, 2023. The voting power of this group may increase to the extent they convert shares of non-voting common stock they hold into common stock. 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.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. For instance, rising interest rates have impacted the Company's net income. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company's product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

Risks Related to our Filer Status

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act"), reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding 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 offering in May 2021, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock and non-voting common stock that are held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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 not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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

Risks Related to our Certificate of Incorporation and Bylaws

Anti-takeover provisions under our certificate of incorporation and bylaws and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the sole and exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act (the "Federal Forum Provision"). In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Adverse developments involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ("SVB"), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC"), as receiver. The Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money, including funds held in uninsured deposit accounts, after only one business day of closure. Similarly, on May 1, 2023, First Republic Bank ("FRB") was closed by the California Department of Financial Protection and Innovation and the FDIC was appointed as receiver. JPMorgan Chase Bank, National Association (N.A.) acquired all of FRB's deposit accounts and substantially all of its assets. The U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

We do not hold cash deposits or securities at SVB or FRB and have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations. However, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners, or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which the Company has credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which the Company has financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets and termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors

described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, a critical vendor, CDMO, or business partner could be adversely affected by any of the liquidity or other risks that are described above as factors, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any CDMO, business partner, or supplier bankruptcy or insolvency, or any breach or default by a CDMO, business partner, or supplier, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by economic and political changes in the location in which we, or our suppliers and vendors, maintain operations. For example, out business may be generally exposed to the impact of political or civil unrest or military action, including the current conflict between Russia and Ukraine and, while we do not have direct exposure to Ukraine, we do have interests in securing regulatory approval in Europe. The approval process may be impacted based upon the events taking place there. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which will require, among other things, that we file with the Securities and Exchange Commission (the "SEC"), annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

Actions of activist stockholders could cause us to incur substantial costs, divert management's attention and resources, and have an adverse effect on our business.

Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. From time to time, we may be subject to proxy solicitations or proposals by activist stockholders urging us to take certain corporate actions, or otherwise effect changes or assert influence on our board of directors and management. For example, volatility in the price of our common stock or other reasons may in the future cause us to become the target of stockholder activism. If activist stockholder activities ensue, our business could be adversely affected because responding to proxy contests and reacting to other actions by activist stockholders can be costly and time-consuming, disrupt our operations and divert the attention of management and our employees. For example, we may be required to retain the services of various professionals to advise us on activist stockholder matters, including legal, financial and communications advisors, the costs of which may negatively impact our future financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential

business opportunities, harm our ability to enter into strategic transactions, harm our ability to attract new investors, customers, employees and joint venture partners and cause our stock price to experience periods of volatility or stagnation.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

On May 11, 2021, we completed our initial public offering, (our "IPO"), in which we issued and sold 8,825,000 shares of common stock, $0.0001 par value per share, at a price to the public of $17.00 per share. The offer and sale of the shares in the IPO was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-255316) that was filed with the SEC on May 3, 2021 and declared effective on May 6, 2021. The underwriters of the offering were Morgan Stanley & Co. LLC, SVB Leerink LLC, Evercore Group L.L.C. and Guggenheim Securities, LLC. Our IPO commenced on May 7, 2021.

We raised approximately $137.2 million in net proceeds after deducting underwriting discounts and commissions of $10.5 million and other offering expenses of approximately $2.4 million payable by us. No underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors or officers (or their affiliates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

We are holding a significant portion of the balance of the net proceeds in a variety of capital preservation investments, including money market funds, short-term investment-grade, interest bearing instruments and U.S. government securities. Since our IPO through February 2023, there had been no material change in the planned use of proceeds, as described in our final prospectus filed with the SEC on May 10, 2021 pursuant to Rule 424(b) under the Securities Act. In February 2023, we announced a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, an acquisition, merger, possible business combinations and/or a divestiture of our cell therapy CMC capabilities. The planned use of our remaining net proceeds from our IPO will be dependent on the resolution of this review of strategic alternatives. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any additional cash distributions to our stockholders.

Issuer Repurchases of Equity Securities

Not applicable.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Form 8-K (File No. 001-40384) filed on May 11, 2021)
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Form 8-K (File No. 001-40384) filed on May 11, 2021).
10.1*	Lease Agreement between the Registrant and the University of Louisville, dated as of November 1, 2018, as amended on July 1, 2019, February 1, 2020, May 15, 2020 and March 1, 2023
10.2	Retention Agreement between the Registrant and Mary Kay Fenton (incorporated by referenced to Exhibit 10.1 to the Registrant's Form 8-K (File No. 001-40384) Filed on April 14, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to be furnished with this Quarterly Report and will not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

TALARIS THERAPEUTICS, INC.

Date: May 15, 2023 By: /s/ Scott Requadt

Scott Requadt
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2023 By: /s/ Mary Kay Fenton

Mary Kay Fenton
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

UNIVERSITY OF LOUISVILLE
LEASE AGREEMENT

This Lease Agreement ("**Agreement**"), made and entered into with effect as of November 1, 2018 (**the** "**Effective Date**"), by and between the University of Louisville, an agency of the Commonwealth of Kentucky and an institution of higher education ("**Lessor**"), and Regenerex, Inc. ("**Lessee**"). The parties agree as follows:

1. Leased Premises. Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, certain property located at 570 S. Preston Street, Louisville, Kentucky, commonly referred to as the Donald E. Baxter Biomedical Research Building Center (Baxter 1), consisting of approximately 6,780.97 (exclusively 6,418.74) square feet of space on the first and fourth floors, as more particularly described on Exhibit A, attached hereto and incorporated herein ("**Principal Space**"), and approximately 2,401.36 square feet of space on the fourth floor, as more particularly described on Exhibit B, attached hereto and incorporated herein ("**Cleanroom Space**"). For purposes of this Agreement, Principal Space and Cleanroom Space shall be collectively referred to as the "**Leased Premises**." The lease of the Leased Premises includes the right, together with other tenants of Baxter 1 and such tenants' invitees, to use the common and public areas within Baxter 1 ("**Common Areas**").

2. Equipment. Lessor hereby permits Lessee to use the equipment identified on Exhibit C, attached hereto and incorporated herein, during the Term of this Agreement ("**Equipment**"). Lessee shall have the right, upon thirty (30) days' prior written notice to Lessor, to discontinue its use of any of the Equipment, in which case, as of the effective date of such discontinuation, such Equipment shall be removed from Exhibits C and F, the applicable dollar amounts in Exhibit F shall be adjusted or removed accordingly (as applicable), and Lessee shall not have any further obligation to pay any fees with respect to such Equipment. Lessee shall immediately cease the use of any such Equipment and shall permit the Lessor reasonable access to the Leased Premises to remove the Equipment, or if moving the Equipment is impractical, as determined in Lessor's reasonable discretion, then simultaneous with notice to Lessor of discontinued use, Lessee shall provide a statement of assurance of discontinued use. Lessee shall have no rights or other property interest in the Equipment, except for the right to use the Equipment pursuant to the terms of this Agreement. Lessee shall be responsible for any loss, damage to or necessary repairs to the Equipment caused by the acts of Lessee, its agents or its employees. No improvements or modifications (normal operational adjustments excepted) shall be made to the Equipment without the prior written consent of Lessor.

3. **Permitted Use(s)**. Lessee shall use the Leased Premises and the Equipment only for the operations described in Exhibit D, attached hereto and incorporated herein ("Permitted Use"). The Permitted Use shall be subject to the Rules and Regulations set forth on Exhibit E, as may be amended from time to time, attached hereto and incorporated herein ("Rules and Regulations"). During the Term of this Agreement, Lessor will acquire the services of consultant(s) to conduct periodic monitoring and audits of the Leased Premises to verify compliance with then applicable laws, regulations, FDA requirements, cGMP standards and other applicable rule, regulation, requirement or standard relating to the Permitted Use on a frequency

not to exceed quarterly. Lessee will be responsible for reimbursement to Lessor for the expenses of consultant(s) and any remediation necessary to address any deficiencies. During the Term of this Agreement, Lessee shall provide Lessor, on an annual basis, with written reports certifying compliance with then-applicable laws and regulations, FDA requirements, cGMP standards, and any other applicable rule, regulation, requirement or standard relating to the Permitted Use.

4. Rent. In exchange for the rights afforded herein with respect to the Leased Premises and Equipment, Lessee shall pay to Lessor the amounts set forth on Exhibit F on a monthly basis. Such payments shall be made to Lessor via wire transfer pursuant to wire instructions provided by Lessor to Lessee on or before the first day of each month. Unless otherwise specified in this Agreement, all then- applicable assessments and fees are included in this Agreement.

The Lessor shall furnish to the Lessee during the occupancy of the Leased Premises, under the terms of this Agreement, as part of the rental consideration the following:

None Gas ☒ Water ☒ Sewer ☒ Electric ☒
Custodial ☒ (excluding hazardous waste, which shall be considered as Specialized Maintenance, as further defined herein) Parking
Trash Removal ☒ (excluding hazardous waste, which shall be considered as Specialized Maintenance)___ Snow Removal ___
Other _____.

5. Term. The initial term of this Agreement shall commence as of the Effective Date hereof and shall last for a period of five (5) years ("**Term**"). This Agreement may be renewed by Lessee upon six (6) months' prior written notice to Lessor for up to three (3) successive one (1) year renewal periods (each a "**Renewal Term**").During the Term or any Renewal Term hereof, Lessee shall notify Lessor of its intent not to renew this Agreement by providing at least six (6) months' prior written notice. For purposes of this Agreement, references to the Term shall include a Renewal Term.

6. Termination. Either party may terminate this Agreement upon the material breach of the other party of either one of the terms or conditions of this Agreement or the Rules and Regulations, provided the non-breaching party provides the breaching party of written notice of the material breach and the breaching party does not cure the material breach within an applicable reasonable cure period, and in the event no such cure period is specified, the default shall be thirty (30) days of the date of notice.

7. Alterations or Improvements. Except as noted in the following sentence, Lessee may make no alterations to the Leased Premises, but may request in writing that Lessor make alterations or improvements to the Leased Premises. Notwithstanding the foregoing sentence, Lessee may, in consultation with Lessor and upon Lessor's approval, make such alterations or improvements to the Leased Premises as are necessary to enable Lessee to use the Leased Premises for the Permitted Use. Lessee shall pay all costs with regard to such alterations or improvements. Any alterations or improvements approved by Lessor will be performed by the Lessor or by a contractor selected by Lessor, in consultation with Lessee, in accordance with its Office of Procurement procedures. Any such alterations or improvements shall become the property of

Lessor upon the expiration or termination of this Agreement. At the written request of Lessor upon the expiration or termination of this Agreement, Lessee shall pay to remove any alterations or improvements and restore the Leased Premises to its original condition, normal wear and tear excepted.

Lessee hereby expressly acknowledges and agrees that no alterations, additions, repairs or improvements to the Leased Premises of any kind are required or contemplated to be performed as a prerequisite to the execution of this Agreement and the effectiveness thereof according to its terms. Lessee acknowledges that, to its knowledge, the Leased Premises are complete and usable for the purposes set forth in this Agreement and that this Agreement is in no way conditional on Lessee making or being able to make alterations, additions, repairs or improvements to the Leased Premises.

All trade fixtures and equipment installed by Lessee in the Leased Premises shall be new or in good working condition and shall remain the property of Lessee. Lessee shall have the right, at the termination of this Agreement, to remove any and all trade fixtures, equipment and other items of personal property not constituting a part of the Leased Premises, which it may have stored or installed in the Leased Premises, which are susceptible of being moved without damage to the Leased Premises; provided this right is exercised before this Agreement expires or during the ten (10) day period immediately following such termination; provided Lessee pays Lessor the prorated amount on a per diem basis for each day beyond Lessee's scheduled termination date that such items are being removed. Lessee, at no cost to Lessor, shall repair any damage to the Leased Premises caused by Lessee's removal of its trade fixtures, equipment and other items of personal property. The right granted to Lessee in this Section shall not include the right to remove any plumbing or electrical fixtures or equipment, heating or air conditioning equipment, floor-coverings (including wall-to-wall carpeting) glued or fastened to the floors or any paneling, tile or other materials fastened or attached to the walls ceilings, all of which shall be deemed to constitute a part of the Leased Premises, and as a matter of course, shall not include the right to remove any furniture, fixtures or machinery that were furnished or paid for by Lessor.

8. Repairs and Maintenance. Lessor shall keep or cause to be kept in good operating order and condition (reasonable wear and tear excepted) and, in a reasonable and timely manner, repair and maintain the Leased Premises, including but not limited to, the basic plumbing, heating, ventilating, air conditioning, roofing systems, and electrical systems installed or furnished by Lessor, unless such maintenance and repairs are caused in part or in whole by the act, neglect, fault of or omission of any duty by Lessee, its agents, servants, employees or invitees, in which case Lessee shall pay to Lessor, in addition to the amounts due hereunder, the reasonable cost of such maintenance and repairs. Lessor shall not be liable for any failure to make any such repairs or to perform any maintenance unless such failure shall persist for ten (10) working days, or an unreasonable time given the circumstances, after Lessee gives written notice of the need of such repairs or maintenance. There shall be no abatement of the amounts due hereunder and no liability of Lessor by reason of any injury to or interference with Lessee's operations arising from the making of any repairs, alterations or improvements in or to any portion of the Leased Premises, or in or to fixtures, appurtenances and equipment therein, unless Lessor determines in its reasonable discretion that the Leased Premises are not habitable or useable for the Permitted Use. In the event Lessor declares that the Leased Premises are not useable, in its reasonable discretion and in consultation with Lessee, Lessor shall first have the right to provide alternative space substantially

comparable, as determined in the Lessor's reasonable discretion, to the Leased Premises (the "Alternative Space"). Should Alternative Space be offered to the Lessee, there shall be no abatement of the amounts due hereunder. If Lessor declares that the Leased Premises are not useable and does not offer Lessee Alternative Space, the amounts due hereunder shall be abated based on the number of days that Lessor determines in its reasonable discretion the Leased Premises are not useable for the Permitted Use.

Lessee waives the right to make repairs at Lessor's expense under any law, statute or ordinance now or hereafter in effect. Lessee shall bear the costs of all maintenance and repairs which are uniquely attributed to its use of the Leased Premises, including but not limited to any repairs or services by the Lessor's Physical Plant Department beyond what is customary for Physical Plant to provide, as determined by Lessor, and any repairs, maintenance, consulting services or monitoring of the Leased Premises necessary to maintain GMP status or required for the Permitted Use by Lessee ("Specialized Maintenance") provided by Lessor or by third parties at Lessor's request. Lessee shall work with Lessor to secure services contracts for all Specialized Maintenance, in full observance of the Lessor's procurement policies and rules. The parties acknowledge that this Agreement shall supersede in its entirety that certain Service Level Agreement by and between the University of Louisville Physical Plant Department, Lessee, and the Institute for Cellular Therapeutics, dated January 1, 2015.

So long as Lessee pays the prescribed rent and costs of Specialized Maintenance, and performs or observes all of the terms, conditions, covenants, and obligations of this Agreement required to be performed or observed by it hereunder, Lessee shall, at all times during the Term hereof, have the peaceable, quiet and effective enjoyment, possession, occupancy, and use of the Leased Premises and the associated Common Areas without any unreasonable interference from Lessor; provided, however, Lessor shall have the right to enter the Leased Premises in accordance with Section 12 of this Agreement.

9. Surrender. Upon expiration or termination of this Agreement, Lessee shall immediately surrender possession of the Leased Premises to Lessor together with all keys or other access devices or passes. If Lessee shall fail to remove its trade fixtures or other property at the expiration of this Agreement or during the ten business (10) day period immediately following such termination, such fixtures and other property not removed by Lessee shall be deemed abandoned by Lessee, and Lessor may either remove such items at Lessee' expense or, at the option of Lessor, shall become the property of Lessor.

10. Indemnification. Except to the extent of Lessor's gross negligence, intentional act or willful misconduct, Lessee hereby agrees to indemnify and hold harmless Lessor, its trustees, administrators, officers, agents, and employees, from and against any and all claims, demands, causes of action, liabilities, loss or expense, including reasonable attorneys' fees, arising out of or related to the acts or omissions of Lessee, its agents, employees, invitees, volunteers or guests.

11. Insurance. Lessee shall be responsible for procuring and continuously maintaining insurance coverages in the type and amounts set forth below:

MINIMUM COVERAGE AMOUNT

Type of Insurance	*Minimum Limits of Liability*
General Liability*	$5,000,000.00 Each Occurrence
Including: Completed Products	$10,000,000.00 General Aggregate
Personal and Advertising Injury	
Products/Completed Operations	
Sexual Abuse & Molestation	
Professional Liability (E&O)	$1,000,000 Each Occurrence
	$3,000,000 General Aggregate
Auto Liability* **(all owned, hired and non-owned vehicles)**	$1,000,000 Combined Single Limit (Bodily Injury, Property Damage)
Workers Compensation	Statutory Limits — Kentucky and the state(s) of domicile of Lessor's contractor and any subcontractor(s). The all state and voluntary compensation endorsement is to be attached to the policy.
Employers Liability	$1,000,000 (each employee, each accident and policy limit)

* Occurrence coverage is required. Claims-made coverage is not acceptable.

These policies (except Workers' Compensation) shall name the Lessor, its trustees, officers, employees and agents as Additional Insured and shall contain a covenant requiring no less than thirty (30) days written notice to the Lessor before cancellation, reduction or other modification of coverage/s.

These policies shall be primary and noncontributing with any insurance carried by the Lessor, and shall contain a severability of interests clause in respect to cross liability, protecting each Additional Insured as though a separate policy had been issued to each. Certificates of the above policies shall be furnished, to the Lessor, at least thirty (30) days prior to the commencement of this Agreement.

All Certificates of Insurance must clearly state that the Lessee's insurance(s) is PRIMARY. If Lessee's policy has deductibles, self-insured retentions or co-insurance penalties, then all such costs shall be solely borne by Lessee and not by the Lessor. The Lessor will not share in any policy deductibles.

It is hereby agreed that in the event of a claim arising under this policy, the insurance provider(s) will not deny liability by reason of the Additional Insured being a state, county, municipal corporation or governmental agency.

The limits listed above may be accomplished through a combination of primary and excess/umbrella liability policies written on a "follow form" basis or forms no more restrictive than the primary policies.

12. Right of Entry. Subject to Lessee's reasonable policies, Lessor reserves, and shall with reasonable notice, have the right to enter the Leased Premises to monitor and inspect the same and to alter, improve or repair the Leased Premises, all without being deemed guilty of any eviction of Lessee, and without abatement of any amounts due hereunder, and may, in order to carry out such purposes, erect scaffolding and other necessary structures where reasonably required by the character of the work to be performed, provided that the business and Permitted Use of the Lessee shall not be unduly interfered with, and provided further that if Lessor proposes to enter Cleanroom Space, Lessee may require Lessor's agent to follow standard cGMP practices for access to such space. In the case of an emergency, as determined in the sole reasonable discretion of Lessor, no notice whatsoever shall be required for Lessor to enter into the Leased Premises. For each of the aforesaid purposes, Lessor shall at all times have and retain a key with which to unlock all of the doors in, upon and about the Leased Premises, and Lessor shall have the right to use any and all means which Lessor may deem proper to open said doors in an emergency in order to obtain entry to the Leased Premises, and any entry to the Leased Premises obtained by Lessor by any of said means, or otherwise, shall not under any circumstances be construed or deemed to be a forcible or unlawful entry into, or a detainer of, the Leased Premises, or an eviction of Lessee from the Leased Premises or any portion thereof, and any damages caused on account thereof shall be paid by Lessee.

It is understood and agreed that no provision of this Agreement shall be construed as obligating Lessor to perform any maintenance, repairs, alterations or decorations except as otherwise expressly agreed herein to be performed by Lessor. Lessee shall not change the locks on the entries to the Leased Premises without first obtaining the written consent of Lessor, and in such event Lessee's new locks shall be tied into Lessor's master locking system.

Notwithstanding the foregoing, Lessor acknowledges and agrees that research and other activities to be conducted in the Leased Premises may result in the generation of data and the development of inventions, know-how, works of authorship and other developments (collectively, the "Research Developments"), and Lessee asserts that the Research Developments constitute valuable confidential information of Lessee. Lessor will implement appropriate access controls limiting access to the Leased Premises to those authorized to access the Leased Premises, in consultation with Lessee, subject to and in compliance with any applicable regulation or laws that govern access to the Leased Premises and the Research Developments.

13. Assignment. Lessee may assign this Agreement (a) to their successor in interest in connection with an investment in Lessee or as part of a Change in Control, as further defined herein, provided that, if Lessee is then in material breach of any provision of this Agreement and Lessor has provided written notice to Lessee of such material breach, Lessee must obtain Lessor's prior written consent to such assignment, which Lessor shall not unreasonably withhold, condition or delay, and (b) to an Affiliate, as further defined herein, of Lessee. Notwithstanding the foregoing, any permitted assign shall execute an assignment and assumption agreement upon one of the events specified in the foregoing subsection a or b.

For purposes of this Agreement, Change in Control shall mean and refer to (a) the sale of all or substantially all the assets of a Party; (b) any merger, consolidation or acquisition of a party with, by or into another corporation, entity or person; or (c) any change in the ownership of more than fifty percent (50%) of the voting capital stock of a Party in one or more related transactions.

For purposes of this Agreement, Affiliate shall mean any entity that, as of the applicable point in time during the Term of this Agreement, directly or indirectly controls Lessee, is controlled by Lessee, or is under common control with Lessee. For purposes of this definition, "control" means (a) having the actual, present capacity to elect a majority of the directors of such entity, or (b) having the power to direct at least fifty percent (50%) of the voting rights entitled to elect directors for such entity.

14. Fire or Other Casualty. If the Leased Premises are destroyed by fire or other casualty, this Agreement shall immediately terminate. In the case of partial destruction or damage so as to render the Leased Premises untenantable or unsuitable for the Permitted Use, as determined in the reasonable discretion of Lessor, the Lessee may terminate or suspend this Agreement by giving written notice to the Lessor within fifteen (15) days after such partial destruction or damage, and, if so suspended, no rent shall accrue after the date of such partial destruction or damage until such damage is repaired and premises are considered tenantable. If the Lessee so suspends, but does not terminate, the Agreement within such fifteen (15) day period based on the Lessor's commitment to repair such damage and render the Leased Premises tenantable or suitable for the Permitted Use, as the case may be, within one hundred-twenty (120) days following such partial destruction or damage, and the Lessor fails to do so, then the Lessee may terminate this Agreement effective upon notice to the Lessor.

15. Limitation of Remedies, Remedies Cumulative. In the event that any court or governmental authority shall limit any amount that Lessor may be entitled to recover under this Agreement, Lessor shall be entitled to recover the maximum amount permitted under law. Nothing in this paragraph or in this Agreement shall be deemed to limit Lessor's recovery from Lessee of the additional amount permitted under law or of any other sums or damages which Lessor may be entitled to recover in addition to the damages set forth herein. No remedy conferred or reserved to either party in this Agreement or in law or equity will be considered exclusive of any other remedy, but the same shall be cumulative and shall be in addition to every other remedy given hereunder or now or hereafter existing at law or in equity or by statute, and every power and remedy given by this Agreement to a party hereto may be exercised from time to time and as often as the occasion may rise or as may be deemed expedient. No delay or omission of either party to exercise any right or power arising from any default shall impair any such right or power or shall be construed to be a waiver of any such default or any acquiescence therein. No waiver of any breach of any of the covenants of this Agreement shall be construed, taken or held to be a waiver of any other breach or waiver, acquiescence in or consent to any further or subsequent breach of the same covenant.

16. Relationship of the Parties. Lessor shall not by virtue of this Agreement or occupancy of the Leased Premises by Lessee become or be deemed a partner, joint venturer or controlling party of Lessee in the conduct of Lessee' business.

17. Additional Covenants. Lessee shall keep the Leased Premises free from any Hens or claims of Hen arising out of work performed, materials furnished or obligations incurred by or for Lessee. In the event that any liens are filed arising out of work performed, materials furnished or obligations incurred by, for or at the insistence of Lessee and Lessee fails to bond, pay or otherwise extinguish such liens within thirty (30) days after Lessor notifies Lessee of the existence thereof, Lessor may, without waiver of any other rights or remedies, bond, pay or otherwise extinguish such hens and any expenses incurred by Lessor in connection with these hens shall be paid by Lessee to Lessor upon demand as additional costs hereunder. Lessor shall maintain reasonable insurance on the Leased Premises and the building and facilities in which it is located. Notwithstanding anything to the contrary contained in this Agreement or under statutory or common law, Lessor shall have no lien rights against any personal property, equipment or fixtures owned by Lessee and located in the Leased Premises.

18. Conflicts of Interest. Lessee represents and warrants that upon careful inquiry, no fee, commission or other pecuniary or real benefit has been provided or promised to any person or organization, other than the Lessor on account of this Agreement or related benefits. Lessee covenants that it will notify University Counsel's Office in writing promptly upon learning of any change in this warranty or proposal for such change, upon establishment of any pecuniary relationship with any employee or Trustee of the Lessor, including investments or grants of equity. Lessee, its agents, officers, shareholders, and employees hereby agrees to abide by and comply with Lessor's Conflicts of Interest policies at all times during the Term of this Agreement.

19. Party Names. Neither party shall use the name or logo of the other party or any of its respective affiliates for any purpose without prior written permission of the other party.

20. Notices. Any notices required or desired to be given under this Agreement shall be in writing and shall be deemed given when hand-delivered, emailed with receipt acknowledgement, or mailed postage prepaid registered or certified mail return receipt requested to the following address:

To LESSOR:	University of Louisville 323 E. Chestnut Street Louisville, Kentucky 40202 Attn: AVP for Facilities and Management
To LESSEE:	Regenerex, Inc. 201 East Jefferson Street, Suite 110B Louisville, KY 40202

21. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Kentucky, without giving effect to any choice or conflict of law provision or rule that would cause the application of laws of any jurisdiction other than those of the Commonwealth of Kentucky.

22. Intellectual Property Developed within Leased Premises. Ownership of any Intellectual Property developed in the Leased Premises or with the Equipment shall be governed by Lessor's Intellectual Property Policy, as amended from time to time, and other agreements between the parties.

23. Entire Understanding. This Agreement represents the entire understanding and agreement between the parties relating to the use of the Leased Premises and Equipment, and supersedes all prior negotiations and agreements relative thereto. The language in all parts of this Agreement shall in all cases be construed as a whole according to its fail meaning and not strictly for or against either Lessor or Lessee. No provision of this Agreement may be amended or added to except by agreement in writing signed by the parties hereto or their respective successors in interest.

24. Partial Invalidity. If any term, covenant or condition of this Agreement or the application thereof to any person or circumstances shall, to any extent, be invalid or unenforceable, the remainder of this Agreement, or the application of such term, covenant or condition to persons or circumstances other than those to which it is held shall be valid and be enforced to the fullest extent permitted by law.

25. Applicable Laws/Standards. Lessee agrees to comply with all laws, regulations and other legal requirements applicable to Lessee in its use/occupation of the Leased Premises and Equipment. Lessee shall comply with all standards set by the Department of Housing, Buildings and Construction, Division of Building Codes Enforcement, and that of the Kentucky Occupational Safety and Health Standards Board and the Americans with Disabilities Act (ADA).

26. Ownership. The Lessee agrees to notify the Lessor within ten (10) days of all persons owning or upon any change or transfer of ownership involving five percent (5%) or more ownership interest or the power to direct the conduct and management of Lessee's business affairs. Non-compliance may result in termination of this Agreement.

[**Signatures appear on next page.**]

IN WITNESS WHEREOF, the parties have executed this Lease Agreement as of the date first set forth above.

LESSOR: **UNIVERSITY OF LOUISVILLE**

By: /s/ Dan Durbin
Dan Durbin, CFO

LESSEE: **REGENEREX, INC.**

By: /s/ Suzanne Tollerud
Suzanne Tollerud
Director of Business Operations

[Signature Page to Lease Agreement]

Execution Copy

FIRST AMENDMENT TO
LEASE AGREEMENT

THIS FIRST AMENDMENT TO LEASE AGREEMENT ("Amendment") is made and entered into effective as of the 1st day of July, 2019, by and between the University of Louisville ("Lessor"), and Talaris Therapeutics, Inc. ("Lessee").

W I T N E S S E T H:

WHEREAS, Lessor and Lessee, under its former name Regenerex, Inc., are parties to that certain Lease Agreement dated November 1, 2018 (the "Agreement"); and

WHEREAS, the parties mutually desire to modify the Agreement upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lessor and Lessee hereby agree as follows:

1. Defined Terms. Capitalized terms contained but not defined in this Amendment shall have the meaning ascribed to such terms in the Agreement.

2. Modification to Section 1. Section 1, *Leased Premises*, is hereby deleted and replaced in its entirety with the following:

> Lessor hereby leases to Lessee, and Lessee hereby leases from Lessor, certain property located at 570 S. Preston Street, Louisville, Kentucky, commonly referred to as the Donald E. Baxter Biomedical Research Building Center ("Baxter 1"), consisting of specified space on the first and fourth floors, and certain property located at 580 S. Preston Street, Louisville, Kentucky, commonly referred to as the Delia B. Baxter Biomedical Research Building ("Baxter 2"), consisting of specified space on the first floor, as more particularly described on Exhibit A, attached hereto and incorporated herein ("Leased Premises"). The lease of the Leased Premises includes the right, together with other tenants of Baxter 1 and Baxter 2, and such tenants' invitees, to use the common and public areas within Baxter 1 and Baxter 2 ("Common Areas").

3. Modification to Section 7. Section 7, Alterations or Improvements, is hereby modified to delete the last sentence of the first paragraph, and replace with the following:

> Upon the termination or expiration of this Agreement, Lessee shall pay to remove any alterations or improvements, including but not limited to communications and/or electronic wiring, and restore the Leased Premises or other affected space of Lessor to its original condition, normal wear and tear excepted.

4. Modification to Section 12. Section 12, *Right of Entry,* is hereby modified to add the following language at the end of the first paragraph:

> Following the Changeover Date (as defined in Exhibit A), Lessor shall retain the right, on its own behalf and on behalf of its tenants, to access and pass through Baxter I 499E hallway for purposes of loading or unloading materials or equipment on the freight elevator adjacent to Baxter 1 499H and for other ordinary business use, as determined by Lessor. Lessor or its tenant shall, when practicable, provide reasonable advance notice to Lessee of any such proposed use and access, with reasonable details of the proposed time and materials or cargo to transit through Lessee's premises.

5. Modifications to Exhibit A and Exhibit B. Exhibit A, *Principal Space,* and Exhibit B, *Cleanroom Space,* are hereby deleted and replaced in their entirety by Exhibit A, *Leased Premises,* attached hereto and incorporated herein. References to Principal Space and Cleanroom Space are hereinafter referred to collectively as Leased Premises, and all references individually to the space shall refer to the Leased Premises in its entirety.

6. Modification to Exhibit C. Exhibit C, *Equipment,* is hereby renamed Exhibit B, *Equipment.*

7. Modification to Exhibit D. Exhibit D, *Permitted Use(s),* is hereby renamed Exhibit C, *Permitted Use(s).*

8. Modification to Exhibit E. Exhibit E, *Rules and Regulations,* is hereby renamed Exhibit D, *Rules and Regulations.*

9. Modification to Exhibit F. Exhibit F, *Rent and Equipment Use Fee,* is hereby deleted and replaced in its entirety by and renamed Exhibit E, *Rent and Equipment Use Fee,* attached hereto and incorporated herein.

10. Miscellaneous. This Amendment may be executed by the parties hereto individually or in combination, in one or more counterparts, each of which shall be an original and all of which will constitute one and the same Amendment and may be delivered by facsimile or PDF via electronic mail in a legally binding manner. This Amendment shall be governed and construed in accordance with the laws of the Commonwealth of Kentucky and shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, executors, administrators, personal representatives, successors and permitted assigns.

11. No Further Modification. In the event of any inconsistency between the Agreement and this Amendment, the terms of this Amendment shall control. Except as otherwise modified herein, all terms and conditions in the Agreement shall remain in full force and effect.

[Signatures appear on next page.]

IN WITNESS WHEREOF, Lessor and Lessee have executed this Amendment effective as of the date first shown above.

LESSOR: **University of Louisville**

By: /s/ Mark Watkins
Print Name: Mark Watkins
Title: Sr Associate VP Operations 6-20-2019

LESSEE: **Talaris Therapeutics, Inc.**

By: /s/ Scott Requadt
Print Name: Scott Requadt
Title: Chief Executive Officer

SECOND AMENDMENT TO
LEASE AGREEMENT

THIS SECOND AMENDMENT TO LEASE AGREEMENT ("Second Amendment") is effective as of the 1st day of February, 2020 ("Effective Date"), by and between the University of Louisville ("Lessor"), and Talaris Therapeutics, Inc. ("Lessee") (collectively the "Parties").

W I T N E S E T H:

WHEREAS, Lessor and Lessee are parties to that certain Lease Agreement dated November 1, 2018 ("Original Lease Agreement"), as subsequently amended on July 1, 2019 ("Amendment") (collectively, the "Agreement");

WHEREAS, Lessor and Lessee are parties to that certain Additional Space Agreement effective November 15, 2019 ("Additional Space Agreement"), pursuant to which Lessor granted Lessee the use of additional space; and

WHEREAS, the parties mutually desire to modify the Agreement upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lessor and Lessee hereby agree as follows:

1. **Defined Terms**. Capitalized terms contained but not defined in this Second Amendment shall have the meaning ascribed to such terms in the Agreement.

2. **Modification to Section 2**. Section 2, *Equipment*, is hereby deleted and all references to Equipment in the Lease Agreement are hereby deleted. Lessor and Lessee acknowledge that the Parties are entering into a separate Equipment Lease Agreement contemporaneously with the execution of this Second Amendment, which shall govern all matters related to Equipment as of the Effective Date hereof.

3. **Modification to Section 4**. Section 4, *Rent*, is hereby amended to reflect the following revised list of services Lessor shall provide to Lessee:

None Gas ☒ Water ☒ Sewer ☒ Electric ☒
Custodial ☒* Parking Trash Removal ☒* Snow Removal
Other

* only in restrooms on 4th floor

4. **Modification to Section 7**. Section 7, Alterations or Improvements, is hereby modified to delete the last sentence of the first paragraph, and replace with the following:

Upon the termination or expiration of this Agreement, Lessee shall pay to remove any alterations or improvements, including but not limited to communications and/or electronic wiring, and restore the Leased Premises or other affected space of Lessor to its original condition, normal wear and tear excepted, as depicted, in part, in the attached Exhibit E, attached hereto and incorporated herein. Lessee shall provide Lessor with an annual report on the anniversary of this Agreement with a summary and depiction of all alterations or improvements made to the Leased Premises. If Lessee requests in writing for Lessor to review proposed alterations or improvements to the Leased Premises then, as part of the review and response, Lessor shall indicate in writing whether it will require Lessee to reverse such alteration or improvement at the termination or expiration of this Agreement. If Lessor consents in writing to retain such alteration or improvement, then Exhibit E shall be updated to include such alteration or improvement.

5. **Modification to Section 8**. Section 8, *Repairs and Maintenance*, is hereby modified to add the following new paragraph at the end of such Section:

Lessor acknowledges that Lessee is obligated by the FDA to maintain the Leased Premises in accordance with cGMP standards applicable to the processing of human cell therapies for clinical and commercial use in human subjects. These standards include the requirement that all personnel involved in processing or handling of cell therapies for use in humans shall not be exposed to animals, animal waste or animal-derived products or tissues (collectively, “Animal Materials”) within or while in transit to Lessee’s cell processing facility within the Leased Premises. Accordingly, Lessor will notify in writing the heads of all research labs using Animal Materials located in Baxter I of the presence of GMP cleanroom facilities in the building and of the responsibility to comply with the Lessor’s policy on the Transportation of Research Animals which requires that personnel of the Lessor must use freight elevators when transporting animals.

6. **Modification to Section 12**. Section 12, *Right of Entry*, is hereby modified to add the following to the end of the last paragraph:

The foregoing shall apply to any key card access given by Lessor to its agents, representatives, vendors, etc., which access shall be governed by University policies and procedures related to access controls, as amended from time to time, and as provided to Lessee by Lessor’s Assistant Vice President for Facilities on the Health Sciences Center.

7. **Modification to Section 26**. Section 26, *Ownership*, is hereby amended and restated in its entirety as follows:

The Lessee agrees to notify the Lessor of any change or transfer of ownership that would constitute a Change of Control of Lessee. Non-compliance with this provision may result in termination of this Agreement by Lessor if Lessee fails to timely cure the non-notification in accordance with Section 6 of this Agreement.

8. **Modification to Exhibit A**. Exhibit A, *Leased Premises*, is hereby amended and restated in its entirety with Exhibit A, *Leased Premises*.

9. **Modification to Exhibit B**. Exhibit B, *Equipment*, is hereby deleted in its entirety.

10. **Modification to Exhibit C**. Exhibit C, *Permitted Use(s)*, is hereby renamed Exhibit B, *Permitted Use(s)*.

11. **Modification to Exhibit D**. Exhibit D, *Rules and Regulations*, is hereby renamed Exhibit C, *Rules and Regulations*.

12. **Modification to Exhibit E**. Exhibit E, Rent and Equipment Use Fee, is hereby deleted and replaced in its entirety by and renamed Exhibit D, Rent, attached hereto and incorporated herein.

13. **Miscellaneous**. This Second Amendment may be executed by the parties hereto individually or in combination, in one or more counterparts, each of which shall be an original and all of which will constitute one and the same Second Amendment and may be delivered by facsimile or PDF via electronic mail in a legally binding manner. This Second Amendment shall be governed and construed in accordance with the laws of the Commonwealth of Kentucky and shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, executors, administrators, personal representatives, successors and permitted assigns.

14. **No Further Modification**. In the event of any inconsistency between the Original Lease Agreement, the Amendment, and this Second Amendment, the terms of this Second Amendment shall control. Except as otherwise modified herein, all terms and conditions in the Agreement shall remain in full force and effect.

[Signatures appear on next page.]

IN WITNESS WHEREOF, Lessor and Lessee have executed this Second Amendment effective as of the date first shown above.

LESSOR: **University of Louisville**

By: /s/ Mark Watkins
Print Name: Mark Watkins
Title: Chief Operating Officer

LESSEE: **Talaris Therapeutics, Inc.**

By: /s/ Scott Requadt
Print Name: Scott Requadt
Title: Chief Executive Officer

ADDITIONAL SPACE AGREEMENT

THIS ADDITIONAL SPACE AGREEMENT ("Additional Space Agreement") is made and executed as of the 15th day of May 2020, by and between the University of Louisville ("Lessor"), and Talaris Therapeutics, Inc. ("Lessee") (collectively the "Parties").

W I T N E S S E T H:

WHEREAS, Lessor and Lessee are parties to that certain Lease Agreement dated November 1, 2018 ("Original Lease Agreement"), as subsequently amended on July 1, 2019 ("Amendment") and on February 1, 2020 (collectively, the "Agreement");

WHEREAS, Lessor granted Lessee use of additional space as more particularly described on and at the rental rates set forth on Exhibit A, attached hereto and incorporated herein ("Additional Space"); and

WHEREAS, the parties desire to define the terms and conditions of Lessee's use of the Additional Space.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lessor and Lessee hereby agree as follows:

1. **Defined Terms**. Capitalized terms contained but not defined in this Additional Space Agreement shall have the meaning ascribed to such terms in the Amendment.

2. **Use of Additional Space**. Lessor and Lessee hereby agree and acknowledge that Lessor permitted Lessee the use of the Additional Space as of the dates and at the rates set forth on Exhibit A, and that such use is governed by the terms and conditions of the Amendment. Lessee hereby agrees to remit the total rental amount set forth on Exhibit A to Lessor upon execution of this Additional Space Agreement via wire transfer.

3. **Term**. This Additional Space Agreement shall be effective upon November 15, 2019, and shall continue in effect until the latter of the following: (1) such time as Lessee fully discharges its obligations hereunder; or (2) February 1, 2020.

4. **Miscellaneous**. This Additional Space Agreement may be executed by the Parties hereto individually or in combination, in one or more counterparts, each of which shall be an original and all of which will constitute one and the same Additional Space Agreement, and may be delivered by facsimile or PDF via electronic mail in a legally binding manner. This Additional Space Agreement shall be governed and construed in accordance with the laws of the State of Kentucky, and shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, executors, administrators, personal representatives, successors and permitted assigns.

[Signatures appear on next page].

IN WITNESS WHEREOF, Lessor and Lessee have executed this Additional Space Agreement as of the date first shown above.

LESSOR: **University of Louisville**

By: /s/ Mark Watkins
Print Name: Mark Watkins
Title: Chief Operating Officer

LESSEE: **Talaris Therapeutics, Inc.**

By: /s/ Scott Requadt
Print Name: Scott Requadt
Title: Chief Executive Officer

UNIVERSITY OF LOUISVILLE LEASE
AGREEMENT TALARIS THERAPEUTICS

THIS THIRD AMENDMENT TO LEASE AGREEMENT ("Third Amendment") is effective as of the 1st day of March, 2023 ("Effective Date"), by and between the University of Louisville ("Lessor"), and Talaris Therapeutics, Inc. ("Lessee") (collectively the "Parties").

W I T N E S E T H:

WHEREAS, Lessor and Lessee are parties to that certain Lease Agreement dated November 1, 2018 ("Original Lease Agreement"), as subsequently amended on July 1, 2019 ("Amendment") and on February 1, 2020 ("Second Amendment") (collectively, the "Agreement"); and

WHEREAS, the parties mutually desire to modify the Agreement upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Lessor and Lessee hereby agree as follows:

1. Defined Terms. Capitalized terms contained but not defined in this Third Amendment shall have the meaning ascribed to such terms in the Agreement.

2. Modification to Section 5. Section 5, *Term*, is hereby amended and restated in its entirety as follows:

The initial term of this Agreement shall commence as of November 1, 2018 and shall last for a period of five (5) years ("Term"). This Agreement may be renewed by Lessee by providing not less than three (3) months' prior written notice to Lessor, for up to five (5) successive one (1) year renewal periods (each a "Renewal Term"). The rent for the Leased Premises set forth in Exhibit F to the Lease Agreement, as stated in the Amendment of July 1, 2019, shall remain in effect for each of the first three (3) Renewal Terms. If the Lessee elects to renew beyond the third Renewal Term, the rent for the fourth Renewal Term shall increase over the rent for the third Renewal Term by the lesser of three percent (3%) or Consumer Price Index (CPI) – January of current year to Janaury of previous year; All Urban Consumers. The rent for the fifth Renewal Term shall increase over the rent for the fourth Renewal Term by the lesser of three percent (3%) or CPI. For purposes of this Agreement, references to the Term shall include a Renewal Term.

3. Modification to Section 13. Section 13, *Assignment*, is hereby amended and restated in its entirety as follows:

Lessee may assign this Agreement upon prior written notice to Lessor, provided that the assignee assumes in writing all obligations under this Agreement and provided further that Lessee must obtain Lessor's prior written consent to such assignment, which Lessor shall not unreasonably withhold, condition or delay.

4. Modification to Section 20. Section 20, *Notices*, is hereby amended and restated in its entirety as follows:

Any notices required or desired to be given under this Agreement shall be in writing and shall be deemed given when hand-delivered, or mailed postage prepaid registered or certified mail return receipt requested to the following address:

To LESSOR: University of Louisville 421 Cardinal Blvd
Louisville, KY 40208 Attn: Lease Administration

To LESSEE: Talaris Therapeutics, Inc.
570 S. Preston St., Suite 400
Louisville, KY 40202 Attn: Contracts

1.Modification to Section 22. Section 22 is deleted in its entirety; provided, however, that the deletion of Section 22 shall not alter or amend any existing license or other agreement between the parties relating to intellectual property rights, or the relative rights and obligations of the parties as set forth thereunder.

2.Modification to Exhibit B. The first paragraph of Exhibit B, *Permitted Use(s)*, is hereby replaced in its entirety with the following:

Lessee shall use the Leased Premises for the purpose of development of cellular or gene therapeutics and/or for drug discovery.

3.Miscellaneous. This Third Amendment may be executed by the parties hereto individually or in combination, in one or more counterparts, each of which shall be an original and all of which will constitute one and the same Third Amendment and may be delivered by facsimile or PDF via electronic mail in a legally binding manner. This Third Amendment shall be governed and construed in accordance with the laws of the Commonwealth of Kentucky and shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, executors, administrators, personal representatives, successors and permitted assigns.

4.No Further Modification. In the event of any inconsistency between the Original Lease Agreement, the Amendment, the Second Amendment, and this Third Amendment, the terms of this Third Amendment shall control. Except as otherwise modified herein, all terms and conditions in the Agreement shall remain in full force and effect.

[Signatures appear on next page.]

IN WITNESS WHEREOF, Lessor and Lessee have executed this Third Amendment effective as of the date first shown above.

LESSOR:

University of Louisville

By: /s/ Meg Campbell
Meg Campbell
Assistant Vice President of Planning, Design, and Construction

Date: 3-10-2023

By: /s/ Kevin Gardner
Kevin Gardner
Executive Vice President Research & Innovation

Date: 3-10-2023

LESSEE:

Talaris Therapeutics, Inc.

By: /s/ Scott Requadt
Scott Requadt
Chief Executive Officer

Date: 3-10-2023

Exhibit 31.1

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

I, Scott Requadt, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended March 31, 2023 of Talaris 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 15, 2023

By: /s/ Scott Requadt

Scott Requadt
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Mary Kay Fenton, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended March 31, 2023 of Talaris 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-13(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: May 15, 2023

By: /s/ Mary Kay Fenton

Mary Kay Fenton
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Talaris Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 15, 2023

By: /s/ Scott Requadt

Scott Requadt
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Talaris Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 15, 2023

By: /s/ Mary Kay Fenton

Mary Kay Fenton
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)