

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended **June 30, 2022**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____
Commission File Number: **001-40384**

TALARIS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

93 Worcester St.
Wellesley, MA
(Address of principal executive offices)

83-2377352
(I.R.S. Employer
Identification No.)

02481
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of August 1, 2022, the registrant had 41,698,054 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:

- Our business substantially depends 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 late-stage clinical 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, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, development of our product candidate may be delayed or prevented, which 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. Our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable efficacy or safety in later clinical trials or receive regulatory approval.
- 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.
- Our product candidates, or associated conditioning regimens or treatment protocols, 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.
- 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.
- Even if our product candidates 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 and intend to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs for FCR001, which will require significant resources. 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 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 are 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 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 substantially on intellectual property licensed from the University of Louisville Research Foundation Inc. (“ULRF”), and termination of this license could result in the loss of significant rights, which would materially harm our business.
- We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.
- 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.
- Our business has been adversely affected by the ongoing 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.
- Geopolitical and military conflict such as the ongoing warfare in Ukraine, could cause a disruption of the development of our product candidates and adversely impact our business.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-1 contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). All statements other than statements of historical fact are “forward-looking statements” for purposes of this Annual Report on Form 10-K. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative or plural of those terms, and similar expressions.

Forward-looking statements include, but are not limited to, statements about:

- the success, cost and timing of our product development activities and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the potential for COVID-19 or other pandemic, epidemic or outbreak of an infectious disease, to disrupt our business plans, product development activities, ongoing clinical trials, including the timing and enrollment of patients, the health of our employees and the strength of our supply chain;
- our expectations regarding the safety or efficacy profile of our product candidates
- our ability to advance any product candidate into or successfully complete any clinical trial;
- our ability to obtain regulatory approval for any of our candidates;
- our ability to successfully manufacture our product candidates for future clinical trials or for commercial use, if approved;
- the ability to license additional intellectual property relating to any future product candidates and to comply with our existing license agreement;
- our ability to commercialize our products in light of the intellectual property rights of others;
- the success of competing therapies that are or become available;
- our ability to obtain funding for our operations, including funding necessary to complete further development and commercialization of our product candidates;
- the commercialization of our product candidates, if approved;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- future agreements with third parties in connection with the development or commercialization of our product candidates and any other approved product;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets;
- the rate and degree of market acceptance of our product candidates;
- regulatory and political developments in the United States and foreign countries, including but not limited to the Russia-Ukraine conflict and associated sanctions;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- the impact of laws and regulations; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Quarterly Report on Form 10-Q. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligations to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise. Therefore, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

TALARIS THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)
(unaudited)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,518	\$ 18,614
Marketable securities	181,594	225,357
Prepaid and other current assets	4,925	2,543
Total current assets	212,037	246,514
Property and equipment, net	5,730	4,804
Right-of-use assets	3,038	—
Other assets	111	104
Total assets	\$ 220,916	\$ 251,422
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,075	\$ 2,556
Accrued expenses	4,421	5,431
Lease liability, current	835	—
Total current liabilities	7,331	7,987
Share repurchase liability	392	593
Other liabilities	21	33
Lease liability, net of current	2,430	—
Total liabilities	10,174	8,613
Commitments and contingencies (Note 8)		
Stockholders' equity		
Common stock, \$0.0001 par value, 140,000,000 shares authorized and 39,995,881 issued and outstanding as of June 30, 2022 and 10,000,000 non-voting shares authorized and 1,150,000 issued and outstanding as of June 30, 2022 and 140,000,000 shares authorized and 39,763,049 issued and outstanding as of December 31, 2021 and 10,000,000 non-voting shares authorized and 1,150,000 issued and outstanding as of December 31, 2021	4	4
Additional paid-in-capital	339,083	333,730
Accumulated deficit	(127,202)	(90,847)
Accumulated other comprehensive loss	(1,143)	(78)
Total stockholders' equity	210,742	242,809
Total liabilities and stockholders' equity	\$ 220,916	\$ 251,422

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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating expenses				
Research and development	\$ 13,187	\$ 7,570	\$ 27,383	\$ 14,473
General and administrative	5,228	3,487	9,446	5,589
Total operating expenses	18,415	11,057	36,829	20,062
Loss from operations	(18,415)	(11,057)	(36,829)	(20,062)
Interest and other income (expense), net	319	(295)	474	(589)
Net loss	\$ (18,096)	\$ (11,352)	\$ (36,355)	\$ (20,651)
Unrealized gain (loss) on marketable securities	(217)	25	(1,065)	47
Total comprehensive loss	\$ (18,313)	\$ (11,327)	\$ (37,420)	\$ (20,604)
Net loss	\$ (18,096)	\$ (11,352)	\$ (36,355)	\$ (20,651)
Net loss per common share, basic and diluted	(0.44)	(0.41)	(0.89)	(1.19)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	41,088,085	27,373,165	41,034,447	17,322,734

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

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

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional	Accumulated	Accumulated	Total
	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Paid-in Capital	Deficit	Other Income (Loss)	Stockholders' Equity (Deficit)
Balance at December 31, 2020	40,000,000	\$ 37,383	28,000,000	\$ 34,272	62,499,993	\$ 114,496	7,087,130	\$ 1	\$ 4,879	\$ (43,014)	\$ (13)	(38,147)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	117,181	—	123	—	—	123
Stock-based compensation expense	—	—	—	—	—	—	—	—	835	—	—	835
Net loss	—	—	—	—	—	—	—	—	—	(9,299)	—	(9,299)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	22	22
Balance at March 31, 2021	40,000,000	37,383	28,000,000	34,272	62,499,993	114,496	7,204,311	1	5,837	(52,313)	9	(46,466)
Issuance of common stock, net of underwriting discounts and issuance costs of \$12,858,764	—	—	—	—	—	—	8,825,000	1	137,165	—	—	137,166
Conversion of convertible preferred stock to common stock	(40,000,000)	(37,383)	(28,000,000)	(34,272)	(62,499,993)	(114,496)	24,392,498	2	186,149	—	—	186,151
Issuance of contingent common stock	—	—	—	—	—	—	48,889	—	831	—	—	831
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	100,436	—	102	—	—	102
Stock-based compensation expense	—	—	—	—	—	—	—	—	896	—	—	896
Net loss	—	—	—	—	—	—	—	—	—	(11,352)	—	(11,352)
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	25	25
Balance at June 30, 2021	—	\$ —	—	\$ —	—	\$ —	40,571,134	\$ 4	\$ 330,980	\$ (63,665)	\$ 34	\$ 267,353
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
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	101,851	0	102	—	—	102
Issuance of common stock under 2021 employee stock purchase plan	—	—	—	—	—	—	20,162	0	77	—	—	77
Stock-based compensation expense	—	—	—	—	—	—	—	—	2,846	—	—	2,846
Net loss	—	—	—	—	—	—	—	—	—	(18,096)	—	(18,096)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(217)	(217)
Balance at June 30, 2022	—	\$ —	—	\$ —	—	\$ —	41,145,881	\$ 4	\$ 339,083	\$ (127,202)	\$ (1,143)	\$ 210,742

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

TALARIS THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Six months ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (36,355)	\$ (20,651)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	655	268
Accretion and amortization of marketable securities, net	(92)	302
Amortization of right-of-use assets	384	—
Stock-based compensation expense	5,043	1,731
Fair value adjustment of contingent stock liability	—	735
Changes in operating assets and liabilities:		
Prepaid and other current assets	(2,382)	(2,986)
Other assets	(7)	(75)
Accounts payable	(84)	497
Accrued expenses	(553)	150
Operating lease liability	(262)	—
Other liabilities	93	—
Net cash used in operating activities	<u>(33,560)</u>	<u>(20,029)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(2,433)	(522)
Purchases of marketable securities	(87,983)	(174,844)
Maturities of marketable securities	130,771	76,564
Net cash provided by (used in) investing activities	<u>40,355</u>	<u>(98,802)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock	—	139,523
Common stock issuance costs	—	(1,735)
Payment of partial settlement of contingent stock liability	—	(277)
Proceeds from exercise of stock options	32	28
Proceeds from issuance of common stock under 2021 employee stock purchase plan	77	—
Net cash provided by financing activities	<u>109</u>	<u>137,539</u>
Net increase in cash and cash equivalents	6,904	18,708
Cash and cash equivalents at beginning of period	18,614	17,589
Cash and cash equivalents at end of period	<u>\$ 25,518</u>	<u>\$ 36,297</u>
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment additions included in accounts payable and accrued expenses	\$ 174	\$ 72
Deferred issuance costs included in accounts payable and accrued expenses	\$ —	\$ 634
Issuance of shares of common stock in partial settlement of contingent stock liability accrued expenses	\$ —	\$ 831

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

TALARIS THERAPEUTICS, INC
NOTES TO FINANCIAL STATEMENTS
(unaudited)

1. Nature of Business and Liquidity

Talaris Therapeutics, Inc. (“Talaris” or the “Company”) is a late-clinical stage, cell therapy company developing an innovative method of allogeneic hematopoietic stem cell transplantation (“allo-HSCT”), called Facilitated Allo-HSCT Therapy, that the Company believes 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. The Company believes that these target indications, individually and collectively, represent a significant unmet need and commercial opportunity. The Company maintains corporate offices in Boston, Massachusetts, a laboratory in Houston, Texas and its cell processing facility in Louisville, Kentucky.

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

The accompanying 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 six months ended June 30, 2022 and the year ended December 31, 2021, the Company incurred a net loss of \$36.4 million and \$47.8 million, respectively, and used \$33.6 million and \$40.0 million in cash for operations, respectively. In addition, as of June 30, 2022, the Company had an accumulated deficit of \$127.2 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 \$25.5 million and marketable securities of \$181.6 million as of June 30, 2022, will be sufficient to fund its operating expenses and capital requirements for more than 12 months from the date the financial statements are available to be issued.

Additional funding will be needed to finance future clinical, pre-clinical, manufacturing and commercial activities. There is no assurance the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and it may not be able to enter into other arrangements. If the Company is unable to obtain funding, it could be forced to delay, reduce or eliminate our research and development programs, portfolio expansion or commercialization efforts, which could adversely affect its business prospects and ability to continue operations.

The Company is subject to risks common to companies in the biopharmaceutical industry. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for its intellectual property will be maintained, that any products developed will obtain required regulatory approval, or that any approved products will be commercially viable. Even if the development efforts are successful, it is uncertain when, if ever, the Company will generate significant product sales and ultimately net income.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. The worldwide COVID-19 pandemic has affected and may affect in the future the Company’s ability to initiate and complete preclinical studies, delay the initiation and completion of its current and planned clinical trials, disrupt regulatory activities or have other adverse effects on its business, results of operations, financial condition and prospects. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could adversely affect the Company’s business, operations and ability to raise funds to support its operations.

The Company cannot be certain what the overall impact of the COVID-19 pandemic will be on its business, and it has the potential to adversely affect its business, financial condition, results of operations and prospects.

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. For periods presented prior to the Company’s IPO, significant estimates were used in the determination of the fair value of the Company’s common stock. 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 June 30, 2022 and December 31, 2021, 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. No impairments have been identified as of June 30, 2022 and December 31, 2021.

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.

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).

The Company's contingent stock liability as of June 30, 2021 (see Note 3) is carried at fair value determined according to the fair value hierarchy described above (Level 3).

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 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 June 30, 2022 and December 31, 2021.

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 stockholders for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock were participating securities. These participating securities did not contractually require the holders of such shares to participate in the Company's losses. As such, net losses for the years presented were not allocated to the Company's participating securities. 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 and losses related to marketable securities for the six months ended June 30, 2022 and 2021.

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.

The Company determines if an arrangement is a lease at contract inception. The Company’s contracts are determined to contain a lease when all of the following criteria based on the specific circumstances of the arrangement are met: (1) there is an identified asset for which there are no substantive substitution rights; (2) the Company has the right to obtain substantially all of the economic benefits from the identified asset; and (3) the Company has the right to direct the use of the identified asset.

At the commencement date, operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of future lease payments over the expected lease term. The Company’s lease agreements do not provide an implicit rate. As a result, the Company utilizes an estimated incremental borrowing rate to discount lease payments, which is based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term. Certain adjustments to the right-of-use asset may be required for items such as lease incentives received. Operating lease cost is recognized over the expected term on a straight-line basis.

The expected lease term for those leases commencing prior to January 1, 2022 did not change with the adoption of the new leasing standards. The expected lease term for leases commencing after the adoption of the new leasing standards includes noncancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

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.

The following table presents the cumulative effect of adoption of ASC 842 on January 1, 2022 (*in thousands*):

	January 1, 2022 (in thousands)		
	Prior to adoption of new leasing standards	Adjustment for adoption of new leasing standards	As adjusted
Right-of-use assets (1)	\$ —	\$ 3,422	\$ 3,422
Deferred rent (2)	\$ 105	\$ (105)	\$ —
Operating lease liability (3)	\$ —	\$ 645	\$ 645
Operating lease liability, net of current portion (3)	\$ —	\$ 2,882	\$ 2,882

(1) Represents capitalization of operating right-of-use assets

(2) Represents reclassification of deferred rent and incentives as a reduction of operating right-of-use assets

(3) Represents recognition of operating right-of-use assets

3. Fair Value of Financial Assets and Liabilities

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*):

	June 30, 2022			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	\$ 23,410	\$ 23,410	\$ —	\$ —
Marketable securities	181,594	36,619	144,975	—
Total financial assets measured at fair value	<u>\$ 205,004</u>	<u>\$ 60,029</u>	<u>\$ 144,975</u>	<u>\$ —</u>
	December 31, 2021			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	\$ 10,319	\$ 10,319	\$ —	\$ —
Marketable securities	225,357	27,186	198,171	—
Total financial assets measured at fair value	<u>\$ 235,676</u>	<u>\$ 37,505</u>	<u>\$ 198,171</u>	<u>\$ —</u>

The Company had a contingent stock liability that represented the fair value of contingent equity consideration equal to 65,186 shares of common stock contingently issuable to the University of Louisville Research Foundation Inc. ("ULRF") in connection with its amended and restated exclusive license agreement with the Company. In conjunction with the Company's IPO, the Company issued 48,889 shares of common stock and paid the cash equivalent fair value of 16,297 shares, or \$0.3 million, to ULRF in May 2021 (see Note 8). A rollforward of the contingent common stock liability, which was measured at fair value until the settlement in May 2021, is represented as follows (*in thousands*):

Fair value as of December 31, 2020	\$ 373
Change in fair value	735
Share issuance in partial settlement of contingent stock	(831)
Cash payment in partial settlement of contingent stock	(277)
Fair value as of June 30, 2021	<u>\$ —</u>

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs. Prior to the Company's IPO, the Company's contingent stock liability was classified within Level 3 of the fair value hierarchy because its fair value measurement is based, in part, on significant inputs not observed in the market, which incorporates assumptions and estimates to value the Company's common stock. As there was no public market for the Company's common stock prior to May 2021, the estimated fair value was determined by the Company's board of directors with input from management, considering the most recently available third-party valuations of common stock, and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of each valuation. Historically, these third-party valuations of the Company's common stock were performed contemporaneously when events occurred which management believed would have an impact on the valuation of the Company. The Company's common stock valuation was prepared using the option-pricing method, ("OPM"), which uses a market approach to estimate enterprise value.

4. Marketable Securities

The fair value of the Company's marketable securities as of June 30, 2022 and December 31, 2021 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 six months ended June 30, 2022 and the year ended December 31, 2021. 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 June 30, 2022 and December 31, 2021, none of the Company's investments were determined to be other than temporarily impaired.

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

	June 30, 2022			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	\$ 136,544	\$ 30	\$ (558)	\$ 136,016
Government and agency securities	40,139	—	(551)	39,588
Corporate debt securities	6,054	—	(64)	5,990
Total	<u>\$ 182,737</u>	<u>\$ 30</u>	<u>\$ (1,173)</u>	<u>\$ 181,594</u>

	December 31, 2021			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	\$ 179,151	\$ 38	\$ (47)	\$ 179,142
Corporate debt securities	31,244	—	(58)	31,186
Government and agency securities	15,040	—	(11)	15,029
Total	<u>\$ 225,435</u>	<u>\$ 38</u>	<u>\$ (116)</u>	<u>\$ 225,357</u>

5. Prepaid and Other Current Assets

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

	June 30, 2022	December 31, 2021
Prepaid insurance	\$ 2,220	\$ 1,121
Prepaid research and development expenses	1,816	782
Other current assets	889	640
Total prepaid and other current assets	<u>\$ 4,925</u>	<u>\$ 2,543</u>

6. Property and Equipment, Net

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

	June 30, 2022	December 31, 2021
Equipment	\$ 6,001	\$ 4,449
Leasehold improvements	1,164	821
Computer equipment	1,043	953
Furniture and fixtures	661	426
Construction in progress	313	952
Total property and equipment	9,182	7,601
Less accumulated depreciation	(3,452)	(2,797)
Property and equipment, net	<u>\$ 5,730</u>	<u>\$ 4,804</u>

Depreciation expense was \$0.4 million and \$0.7 million for the three and six months ended June 30, 2022, respectively, and \$0.1 million and \$0.3 million for the three and six months ended June 30, 2021, respectively.

7. Accrued Expenses

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

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Compensation and benefit costs	\$ 2,497	\$ 3,320
Research and development expenses	1,120	854
Professional fees, consulting and other	804	1,257
Total accrued expenses	<u>\$ 4,421</u>	<u>\$ 5,431</u>

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 years at the Company's discretion. In May 2020, the Company added additional office and laboratory space to the Louisville Lease. 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. From April 2021 through June 2022, the Company maintained a month-to-month lease agreement while seeking to expand the Boston Lease, which commenced in June 2022. The term of the lease is 39 months from the commencement date, terminating 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 June 30, 2022, 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*):

<u>Years Ending December 31,</u>		
2022	\$	481
2023		1,064
2024		935
2025		756
2026 and beyond		437
Total lease payments	\$	3,673
Less: imputed interest		(408)
Present value of lease liabilities	<u>\$</u>	<u>3,265</u>

The Company incurred rent expense of \$0.2 million and \$0.5 million for the three and six months ended June 30, 2022, respectively, and \$0.1 million and \$0.3 million for the three and six months ended June 30, 2021, respectively.

The following table summarizes the operating lease term and discount rate as of June 30, 2022:

	<u>As of June 30, 2022</u>
Weighted-average remaining lease term (years)	3.8
Weighted-average discount rate	6.5%

Cash paid for amounts included in the measurement of the Company's operating lease liability was \$0.2 million and \$0.4 million for the three and six months ended June 30, 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. Pursuant to the ULRF License Agreement, on or prior to the Company's first underwritten public offering or any transaction that is treated as a deemed liquidation event, the Company is 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 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. As of June 30, 2022 and June 30, 2021, the contingent stock liability was fully satisfied (see Note 3).

The Company incurred \$0.1 million in expense in February 2022 related to an annual maintenance fee pursuant to the ULRF License Agreement for the year ended December 31, 2022. The Company incurred \$0.1 million in expense in February 2021 related to an annual maintenance fee pursuant to the license agreement for the year ended December 31, 2021.

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 as incurred the costs related to its legal proceedings.

9. Convertible Preferred Stock

Upon the completion of the Company's IPO in May 2021, all Convertible Preferred Stock was converted to shares of common stock or non-voting common stock. Series A Convertible Preferred Stock was converted into 7,476,632 shares of common stock, Series A-1 Convertible Preferred Stock was converted into 5,233,637 shares of common stock and Series B Convertible Preferred Stock was converted into 10,532,229 shares of common stock and 1,150,000 shares of non-voting common stock. Refer to the Company's Annual Report on Form 10-K for the year ended December 31, 2021 for further disclosure regarding historical balances of Convertible Preferred Stock.

10. 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 June 30, 2022, no undesignated preferred stock was outstanding.

Common Stock Reserved

The number of shares of common stock that have been reserved for the potential conversion of Preferred Stock, outstanding stock options granted and stock options 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:

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Restricted stock related to early exercise of common stock options	338,064	538,340
Restricted stock units outstanding	860,263	—
Outstanding common stock options	6,178,773	3,643,796
Shares reserved for issuance under equity incentive plans	1,367,931	2,702,995
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	1,231,439	837,088
Total	<u>9,976,470</u>	<u>7,722,219</u>

11. Stock-Based Compensation

2021 Employee Stock Purchase Plan

In April 2021, the Company’s board of directors and stockholders approved the 2021 ESPP. The 2021 ESPP became effective immediately prior to the effectiveness of the Company’s registration statement on Form S-1 for its IPO. The 2021 ESPP provides employees the opportunity to purchase shares at a 15% discount at the lower of the share price at the beginning or end of six-month offering periods. 852,971 shares have been reserved and approved for this purpose for the 2021 plan year. Beginning on January 1, 2022, the number of shares reserved and available for issuance under the plan will increase on each January 1 through January 1, 2031, by the lesser of (A) 3,000,000 shares of common stock, (B) 1% of the cumulative number of shares of common stock issued and outstanding on the immediately preceding December 31st or (C) such lesser number of shares of common stock as determined by the Board. On January 1, 2022, an additional 414,513 shares were added to the 2021 ESPP, representing 1% of total common shares outstanding at December 31, 2021. The expense incurred under this plan for the three and six months ended June 30, 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

In April 2021, the Company’s board of directors and stockholders approved the 2021 Plan and terminated the 2018 Plan with respect to any unissued awards. The 2021 Plan became effective immediately prior to the effectiveness of the Company’s registration statement on Form S-1 for its IPO. The 2021 Plan provides for the issuance of up to 3,015,907 new share-based awards, as well as the 3,381,382 options to purchase common stock then outstanding under the 2018 Plan, for a total of 6,397,289 shares. To the extent outstanding options granted under the 2018 Plan are cancelled, forfeited, or otherwise terminated without being exercised and would otherwise have been returned to the share reserve under the 2018 Plan, the number of shares underlying such awards will be available for future grant under the 2021 Plan. Beginning on January 1, 2022, the number of shares reserved and available for issuance under the 2021 Plan will increase on each January 1 through January 1, 2031 by the lesser of (A) 5% percent of the number of shares of stock issued and outstanding on the immediately preceding December 31st or (B) such lesser number of shares of common stock as determined by the Board. On January 1, 2022 an additional 2,072,569 shares were added to the 2021 Plan, representing 5% of total common shares outstanding at December 31, 2021.

As of June 30, 2022, 2,228,194 shares remained available for future grant under the 2021 Plan. 6,104,007 options were outstanding under the 2021 Plan and 2018 Plan as of June 30, 2022.

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 under the 2021 Plan and 2018 Plan are presented as follows:

	Six months ended June 30,	
	2022	2021
Fair value of common stock	\$6.54 - \$16.56	\$5.72 - \$16.80
Dividend yield	—%	—%
Volatility	82.49% - 86.69%	80.60% - 91.25%
Risk-free interest rate	1.46% - 3.08%	0.50% - 1.07%
Expected term (years)	5.50 - 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, 2021	3,643,796	\$ 5.75	8.69	\$ 34,754
Granted	2,838,284	8.95		
Exercised	(12,393)	2.56		
Cancelled	(4,566)	5.30		
Forfeited	(286,348)	7.31		
Options outstanding—June 30, 2022	6,178,773	\$ 7.15	8.83	\$ 2,328
Options exercisable—June 30, 2022	1,532,178	\$ 4.71	7.93	

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

	Six months ended June 30,	
	2022	2021
Weighted-average grant-date fair value per option of total options granted	\$ 6.40	\$ 5.52
Aggregate intrinsic value of stock options exercised	89	138

As of June 30, 2022, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is \$26.3 million, which is expected to be recognized over a weighted-average period of 3.1 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 six months ended June 30, 2022:

	Number of Restricted Stock Units	Weighted-Average Grant Date Fair Value
Outstanding at January 1, 2022	—	\$ —
Granted	909,848	9.03
Vested	—	—
Forfeited	(49,585)	9.09
Outstanding at June 30, 2022	860,263	\$ 9.02

As of June 30, 2022, total unrecognized compensation cost related to the unvested awards to employees is \$7.2 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Stock-Based Compensation

The Company recorded stock-based compensation expense regarding its employees, directors, and nonemployees, included in the accompanying Statements of Operations as follows (*in thousands*):

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Research and development expense	\$ 1,703	\$ 417	\$ 2,979	\$ 743
General and administrative expense	1,143	479	2,064	988
Total	<u>\$ 2,846</u>	<u>\$ 896</u>	<u>\$ 5,043</u>	<u>\$ 1,731</u>

12. 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*).

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Net loss and net loss attributable to common stockholders	\$ (18,096)	\$ (11,352)	\$ (36,355)	\$ (20,651)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (0.41)	\$ (0.89)	\$ (1.19)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	41,088,085	27,373,165	41,034,447	17,322,734

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:

	Six months ended June 30,	
	2022	2021
Options to purchase common stock	6,178,773	3,533,831
Restricted stock units	860,263	—
Restricted stock related to early exercise of options to purchase common stock	338,064	739,107
	<u>7,377,100</u>	<u>4,272,938</u>

13. Subsequent Events

The Company has evaluated subsequent events through August 15, 2022, 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.

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 anti-rejection medicines, also known as chronic immunosuppression. Beyond the organ transplant setting, our Facilitated Allo-HSCT Therapy also has the potential to treat a range of severe autoimmune diseases and 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 conditioning regimen typically required by HSCT. We believe that our target 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, an initial public offering (“IPO”). Through June 30, 2022, 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.

We have incurred significant operating losses since inception. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of our product and any future product candidates. Our net loss was \$36.4 million for the six months ended June 30, 2022 and \$47.8 million for year ended December 31, 2021. As of June 30, 2022, we had an accumulated deficit of \$127.2 million. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses and capital expenditures to continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our product candidates, as well as hire additional personnel, pay fees to outside consultants, lawyers and accountants, and incur other increased costs associated with being a public company. In addition, if we obtain marketing approval for any product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

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 \$207.1 million as of June 30, 2022 will be sufficient to fund our operating expenses and capital expenditure requirements through 2024. 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.

Recent Developments

On June 30, 2022, we announced a clinical update on our ongoing FREEDOM-1 Phase 3 clinical trial in living donor kidney transplant (“LDKT”) recipients.

Through June 15, 2022, we had enrolled 22 donor-recipient pairs in the FREEDOM-1 Phase 3 clinical trial of FCR001. Seven patients had been successfully dosed with FCR001 at five different trial sites. All three patients who were dosed more than 12 months prior to the data cutoff date had been successfully weaned off all chronic anti-rejection drugs without evidence of rejection and with stable kidney function. All of these patients, including the first patient who is now 24 months post-transplant, continued to remain off all anti-rejection drugs as of the data cutoff date. Furthermore, all patients treated with FCR001 at least three months prior to the data cutoff date had achieved and maintained T-cell chimerism levels >50% at each of the 3-, 6- and 12-month timepoints post-transplant. The safety profile observed was generally consistent with that expected in patients receiving a kidney transplant and an allo-HSCT. Three cases of low-grade acute graft-versus-host disease (“aGvHD”) were reported, all of which were treatment-responsive and had resolved. One of these patients was more than 12 months post-transplant and was successfully weaned off all anti-rejection drugs. Additionally, one of the three aGvHD patients was subsequently diagnosed with moderate chronic GvHD and was also responding to treatment. As a result of an internal review triggered by the GvHD cases, we have modified our mobilization protocol and added a second post-transplant dose of cyclophosphamide for GvHD prophylaxis. We are continuing to enroll patients in the clinical trial.

Impact of COVID-19 on Our Business

The ongoing worldwide COVID-19 pandemic and recent emergence of variants of the virus have affected and may affect in the future our ability to initiate and complete preclinical studies, delay the initiation and completion of our current and planned clinical trials, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects. For example, screening and enrollment in our ongoing FREEDOM-1 Phase 3 clinical trial in the United States have been adversely impacted by the ongoing COVID-19 pandemic. In addition, we and the third-party manufacturers, contract research organizations (“CROs”), and academic collaborators that we engage may face future disruptions that could affect our ability to initiate and complete preclinical studies or clinical trials, including disruptions in procuring items that are essential for our research and development activities, such as, for example, raw materials used in the manufacture of our product candidates and laboratory supplies for our preclinical studies and clinical trials, in each case, for which there may be shortages because of ongoing efforts to address the ongoing COVID-19 pandemic. We cannot be certain what the overall impact of the ongoing COVID-19 pandemic will be on our business, and it has the potential to adversely affect our business, financial condition, results of operations and prospects.

In response to recommendations from state and local government authorities, we have adopted a variety of workplace safety policies and procedures, including vaccination and masking policies, designed to maintain the health and safety of our workforce. We plan to continue monitoring COVID-19 in the areas in which we operate and may change our policies and procedures from time to time in response to changing health conditions.

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 June 30, 2022, 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 (see Note 8 in the accompanying financial statements). As of June 30, 2022 and December 31, 2021, we had no liability to ULRF for contingent common stock.

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.

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.

The successful clinical development and subsequent commercialization of product candidates is highly uncertain. 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.

We may never succeed in obtaining regulatory approval for any of our current and future product candidates, including FCR001. We may obtain unexpected results from our preclinical studies and clinical trials including FREEDOM-1, FREEDOM-2, and FREEDOM-3. We may elect to 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 current and future preclinical and clinical product candidates. For example, 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 of our preclinical studies or execution or enrollment in any of our 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. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and development activities account for a significant portion of our operating expenses. We expect our research and development expenses to increase for the foreseeable future as we continue to implement our business strategy, which includes advancing FCR001 through clinical development of FREEDOM-1, FREEDOM-2 and FREEDOM-3 as well as other product candidates into clinical development, expanding our research and development efforts, including hiring additional personnel to support our research efforts, our clinical and product development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials.

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, 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 will increase in the future as we increase our headcount to support development of our product candidates and our continued research activities. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with being a public company.

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, amortization expense and accretion income on our marketable securities and expense incurred in relation to the change in fair value of our contingent stock liability with ULR.

Results of Operations

Comparison of Three Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

	Three months ended June 30,		Change
	2022	2021 (in thousands)	
Operating expenses			
Research and development	\$ 13,187	\$ 7,570	\$ 5,617
General and administrative	5,228	3,487	1,741
Total operating expenses	18,415	11,057	7,358
Loss from operations	(18,415)	(11,057)	(7,358)
Interest and other income (expense), net	319	(295)	614
Net loss	<u>\$ (18,096)</u>	<u>\$ (11,352)</u>	<u>\$ (6,744)</u>

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended June 30, 2022 and 2021:

	Three months ended June 30,		Change
	2022	2021 (in thousands)	
Direct research and development program expense:			
FCR001 clinical and pre-clinical programs	\$ 3,018	\$ 1,940	\$ 1,078
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	7,349	4,062	3,287
Facilities and other operating costs	2,820	1,568	1,252
Total research and development expenses	<u>\$ 13,187</u>	<u>\$ 7,570</u>	<u>\$ 5,617</u>

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance FCR001 through clinical trials, including our FREEDOM-1 Phase 3 clinical trial, and we continue to develop additional product candidates.

Research and development expenses were \$13.2 million for the three months ended June 30, 2022, compared to \$7.6 million for the three months ended June 30, 2021. The increase of \$5.6 million was primarily due to:

- An increase of \$3.3 million in personnel costs related to (i) the need for additional staff to conduct our FREEDOM-1 Phase 3 clinical trial and our FREEDOM-2 and FREEDOM-3 Phase 2 clinical trials, (ii) advance pre-clinical activities, including

those related to our deceased donor program, (iii) support medical affairs and patient recruitment activities, and (iv) increases in stock-based compensation expense related to additional stock option and RSU grants in 2022;

- An increase of \$1.2 million in other costs related to patient advocacy efforts, medical communications development, consulting, research collaborations, increased medical conference activity and other services in support of ongoing and planned clinical trials; and
- An increase of \$1.1 million in direct FCR001 clinical program expenses related to increased activity in our FREEDOM-1 Phase 3 trial resulting from treating additional subjects and activating additional clinical sites and activating additional clinical sites in our FREEDOM-2 and FREEDOM-3 Phase 2 clinical trials.

General and Administrative Expenses

The following table summarizes our general and administrative expenses to support our business activities for the three months ended June 30, 2022 and 2021:

	Three months ended June 30,		Change
	2022	2021	
	(in thousands)		
Personnel related (including stock-based compensation)	\$ 2,472	\$ 1,470	\$ 1,002
Professional and consulting fees	808	460	348
Facility-related and other	1,948	1,557	391
Total general and administrative expenses	<u>\$ 5,228</u>	<u>\$ 3,487</u>	<u>\$ 1,741</u>

General and administrative expenses were \$5.2 million for the three months ended June 30, 2022 compared to \$3.5 million for the three months ended June 30, 2021. The increase in general and administrative costs of \$1.7 million was primarily due to:

- An increase of \$1.0 million in personnel costs primarily due to hiring in our general and administrative functions as we continued to expand our operations to support the organization, which includes increased stock compensation expense stemming from additional stock option and RSU grants;
- An increase of \$0.4 million in facility-related and other expenses primarily due to increased director and officer insurance expense following our IPO in May 2021 and increased information technology infrastructure costs for additional personnel as compared to same quarter in 2021; and
- An increase of \$0.3 million in professional and consulting fees related to increased accounting and consulting fees necessary to comply with public company reporting requirements.

Other Income (Expense), Net

Other income (expense), net in the three months ended June 30, 2022 was comprised of \$0.2 million in interest income from our marketable securities and operating cash balance and \$0.1 million of net accretion income on our marketable securities. Other income (expense), net in the three months ended June 30, 2021 was comprised of \$0.2 million in interest income from our marketable securities and operating cash balance, \$(0.1) million of net amortization expense on our marketable securities, and \$(0.4) million in expense related to a fair value adjustment of our contingent stock liability.

Comparison of Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,		Change
	2022	2021	
	(in thousands)		
Operating expenses			
Research and development	\$ 27,383	\$ 14,473	\$ 12,910
General and administrative	9,446	5,589	3,857
Total operating expenses	<u>36,829</u>	<u>20,062</u>	<u>16,767</u>
Loss from operations	(36,829)	(20,062)	(16,767)
Interest and other income (expense), net	474	(589)	1,063
Net loss	<u>\$ (36,355)</u>	<u>\$ (20,651)</u>	<u>\$ (15,704)</u>

Research and Development Expenses

The following table summarizes our research and development expenses for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,		Change
	2022	2021	
		(in thousands)	
Direct research and development program expense:			
FCR001 clinical and pre-clinical programs	\$ 7,111	\$ 3,789	\$ 3,322
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	14,064	7,836	6,228
Facilities and other operating costs	6,208	2,848	3,360
Total research and development expenses	<u>\$ 27,383</u>	<u>\$ 14,473</u>	<u>\$ 12,910</u>

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we advance FCR001 through clinical trials, including our FREEDOM- 1 Phase 3 clinical trial, and we continue to develop additional product candidates.

Research and development expenses were \$27.4 million for the six months ended June 30, 2022, compared to \$14.5 million for the six months ended June 30, 2021. The increase of \$12.9 million was primarily due to:

- An increase of \$6.2 million in personnel costs related to (i) the need for additional staff to conduct our FREEDOM-1 Phase 3 clinical trial and our FREEDOM-2 and FREEDOM-3 Phase 2 clinical trials, (ii) advance pre-clinical activities, including those related to our deceased donor program, (iii) support medical affairs and patient recruitment activities, and (iv) increases in stock-based compensation expense related to additional stock option and RSU grants in 2022;
- An increase of \$3.4 million in other costs related to patient advocacy efforts, medical communications development, consulting, research collaborations, increased medical conference activity and other services in support of ongoing and planned clinical trials; and
- An increase of \$3.3 million in direct FCR001 clinical program expenses related to increased activity in our FREEDOM-1 Phase 3 trial resulting from treating additional subjects and activating additional clinical sites, and activating additional clinical sites in our FREEDOM-2 and FREEDOM-3 Phase 2 clinical trials.

General and Administrative Expenses

The following table summarizes our general and administrative expenses to support our business activities for the six months ended June 30, 2022 and 2021:

	Six months ended June 30,		Change
	2022	2021	
		(in thousands)	
Personnel related (including stock-based compensation)	\$ 4,720	\$ 2,408	\$ 2,312
Professional and consulting fees	1,370	1,181	189
Facility-related and other	3,356	2,000	1,356
Total general and administrative expenses	<u>\$ 9,446</u>	<u>\$ 5,589</u>	<u>\$ 3,857</u>

General and administrative expenses were \$9.5 million for the six months ended June 30, 2022 compared to \$5.6 million for the six months ended June 30, 2021. The increase in general and administrative costs of \$3.9 million was primarily due to:

- An increase of \$2.3 million in personnel costs primarily due to hiring in our general and administrative functions as we continued to expand our operations to support the organization, which includes increased stock compensation expense stemming from additional stock option and RSU grants;
- An increase of \$1.4 million in facility-related and other expenses primarily due to increased director and officer insurance expense following our IPO in May 2021; and
- An increase of \$0.2 million in professional and consulting fees related to increased accounting and consulting fees necessary to comply with public company reporting requirements.

Other Income (Expense), Net

Other income (expense), net in the six months ended June 30, 2022 was comprised of \$0.4 million in interest income from our marketable securities and operating cash balance and \$0.1 million of net accretion income on our marketable securities. Other income (expense), net in the six months ended June 30, 2021 was comprised of \$0.4 million in interest income from our marketable securities and operating cash balance, \$(0.3) million of net amortization expense on our marketable securities, and \$(0.7) million in expense related to a fair value adjustment of our contingent stock liability.

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 June 30, 2022, 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 consist 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 June 30, 2022, we had cash and cash equivalents of \$25.5 million and marketable securities of \$181.6 million.

Cash Flows

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

	Six months ended June 30,		Change
	2022	2021	
		(in thousands)	
Net cash used in operating activities	\$ (33,560)	\$ (20,029)	\$ (13,531)
Net cash provided by (used in) investing activities	40,355	(98,802)	139,157
Net cash provided by financing activities	109	137,539	(137,430)
Net increase in cash and cash equivalents and restricted cash	\$ 6,904	\$ 18,708	\$ (11,804)

Cash Flow from Operating Activities

During the six months ended June 30, 2022, operating activities used \$33.6 million of cash, due to our net loss of \$36.4 million and \$3.2 million of cash used from changes in our operating assets and liabilities, partially offset by non-cash charges of \$6.0 million. Net cash used from changes in our operating assets and liabilities primarily consisted of a \$2.4 million increase in prepaids and other current assets driven by annual director and officer insurance premium paid in the quarter ending June 30, 2022, a net \$0.6 million decrease in accounts payable and accrued expenses driven by compensation related accruals and a \$0.3 million decrease in operating lease liability driven by lease payments. These were offset by an increase of \$0.1 million in other liabilities. Non-cash charges primarily consisted of \$5.0 million of stock-based compensation expense, \$0.6 million of depreciation on fixed assets and amortization of marketable securities and \$0.4 million of amortization of right-of-use assets.

During the six months ended June 30, 2021, operating activities used \$20.0 million of cash, due to our net loss of \$20.7 million and \$2.4 million of cash used from changes in our operating assets and liabilities, partially offset by non-cash charges of \$3.1 million. Net cash used from changes in our operating assets and liabilities primarily consisted of a \$3.0 million increase in prepaids and other current assets and a \$0.1 million increase in other assets related to deposits for our Wellesley, MA amended lease agreement. These were offset by a \$0.7 million increase in accounts payable and accrued expenses driven by timing and IPO issuance cost accruals. Non-cash charges primarily consisted of \$1.7 million of stock-based compensation expense, \$0.7 million of expense related to the fair value adjustment of our contingent stock liability and \$0.6 million of depreciation expense on fixed assets and amortization of marketable securities.

Cash Flow from Investing Activities

During the six months ended June 30, 2022, investing activities provided \$40.4 million of cash, due to maturities of marketable securities of \$130.8 million, partially offset by purchases of marketable securities of \$88.0 million and purchases of property and equipment of \$2.4 million.

During the six months ended June 30, 2021, investing activities used \$98.8 million of cash, due to purchases of marketable securities of \$174.8 million and purchases of property and equipment of \$0.5 million, partially offset by maturities of marketable securities of \$76.6 million.

Cash Flow from Financing Activities

During the six months ended June 30, 2022, net cash provided by financing activities was \$0.1 million primarily consisting of proceeds from ESPP share issuances and exercise of stock options.

During the six months ended June 30, 2021, net cash provided by financing activities was \$137.5 million due to net proceeds after deducting underwriting discounts and commissions of \$139.5 million from our IPO partially offset by other IPO expenses paid of \$1.7 million and payment in satisfaction of ULRP contingent stock liability of \$0.3 million.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the late-stage clinical development of our product candidates. In addition, we expect to incur additional costs associated with operating as a public company. The timing and amount of our operating expenditures will depend largely on:

- 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 June 30, 2022, will enable us to fund our operating expenses and capital expenditure requirements through 2024. 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. We expect that we will require additional funding to (i) further develop FCR001 in our ongoing Phase 3 registrational trial, FREEDOM-1, through evaluation of its primary endpoint, including in-house manufacturing and quality assurance of clinical trial material, third-party clinical trials costs, clinical development and trial management, and personnel associated with each; (ii) continue research and development of FCR001 in additional pipeline programs such as living donor kidney transplant delayed tolerance induction and scleroderma in our FREEDOM-2 and FREEDOM-3 trials, respectively, through evaluation of their primary endpoints, including in-house manufacturing and quality assurance of clinical trial material, third-party clinical trials costs, clinical development and trial management, and personnel associated with each; (iii) develop expanded Chemistry Manufacturing and Controls ("CMC") operations to facilitate scale-up and commercialization of FCR001, or to engage a third-party manufacturer to undertake such commercialization; and (iv) develop our preclinical programs towards Investigational New Drug application ("IND") filings and/or into clinical trials. If we receive regulatory approval for any of product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize those product candidates ourselves.

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 \$3.7 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 and, as a result, are not included in the table of contractual obligations and commitments above. 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 makes 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 and six months ended June 30, 2022.

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 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 and six months ended June 30, 2022, 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 \$1.07 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 June 30, 2022 and December 31, 2021, we had cash and cash equivalents of \$25.5 million and \$18.6 million, respectively. As of June 30, 2022 and December 31, 2021, we had marketable securities of \$181.6 million and \$225.4 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 and certain supply costs. 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 six months ended June 30, 2022 and year ended December 31, 2021.

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 June 30, 2022. 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 June 30, 2022, 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 June 30, 2022 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 June 30, 2022, 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 Business and Product Candidates

Risks Related to Clinical Development

Our business substantially depends 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 are investing substantially all of our efforts and financial resources in the development of our Facilitated Allo-HSCT Therapy, specifically in our lead product candidate, FCR001. Successful continued development and ultimate regulatory approval of FCR001 for our initial and potential additional indications is critical to the future success of our business. We will need to raise sufficient funds for, and successfully enroll and complete, our clinical development programs of FCR001 for living donor kidney transplantation ("LDKT") and 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. 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 for our lead indication may also 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.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidate and our lead 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 current and future research and development programs and other future 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 future product candidate or indication, we may relinquish valuable rights to those future 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 future 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 develop 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.

We may not successfully identify, develop or commercialize new indications for FCR001 or identify any additional product candidates and may be unable to expand our product pipeline through acquisition or in-licensing.

A key part of our business strategy is to leverage FCR001 by identifying and validating new indications, including other transplant settings and patients with autoimmune or immune-mediated diseases. In the event that FCR001 does not receive regulatory approval or is not successfully commercialized in our currently planned indications, then the success of our business will depend on our ability to expand FCR001 into additional indications or our product pipeline to include other product candidates through our own internal research and discovery efforts, in-licensing or other acquisitions. We may be unable to identify relevant product candidates or indications. If we do identify such product candidates or indications, we may be unable to develop these programs for a number of reasons, including insufficient capital or other resources.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and 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 U.S. Food and Drug Administration (“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.

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.

If we experience delays or difficulties in the enrollment of patients in clinical trials, development of our product candidate may be delayed or prevented, which would have a material adverse effect on our business.

We may not be able to initiate or continue clinical trials for our product candidate if we are unable to locate and enroll a sufficient number of eligible patients to participate in these 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. For example, our initial indications focus on orphan diseases, which affect fewer than 200,000 individuals in the United States. Specifically, approximately 6,500 LDKT are performed on an annual basis in the United States and, in addition, we have prioritized development of FCR001 in a severe form of scleroderma known as diffuse cutaneous systemic sclerosis with a prevalence of approximately 70,000 to 80,000 individuals in the United States.

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 are investigating 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 face inherent challenges in recruiting clinical trial sites to participate in our trials and to complete our trials on a timely basis. For LDKT, each site that participates in our trial will need 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 rely 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 ongoing and evolving COVID-19 pandemic;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical trials may be delayed or terminated. We have already experienced meaningful delays to our clinical trials as a result of the impact of COVID-19 on both our clinical sites and the willingness of stem cell donors and transplant recipients to travel to our clinical 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 are currently targeting, other approved or commonly used drugs and therapies for our current or future target diseases, such as use of tacrolimus and MMF for prevention of organ transplant rejection, or 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 are also seeking 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 vs. 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.

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 ongoing or 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 ongoing COVID-19 pandemic and its impact at clinical trials sites or on the third-party service providers on whom we rely. 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. For example, we rely on a single clinical investigator at Northwestern Medical Center (“Northwestern”) to provide ongoing data from our Phase 2 clinical trial. This investigator is our lead principal investigator for FREEDOM-1, and we anticipate that this investigator and site will be our highest enroller in our FREEDOM-1 and FREEDOM-2 clinical trials. In the event that our lead investigator at Northwestern or that site deviates materially from our trial protocol or our or the clinical site’s regulatory or contractual obligations, our clinical trials could be adversely affected.

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 and ongoing 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, 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. Our existing product candidates in clinical trials, and any other 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 our Phase 2 trial in LDKT does not ensure that later clinical trials, including our ongoing Phase 3 clinical trial of FCR001 in LDKT, will generate findings consistent with our Phase 2 trial 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 FCR001 or any future product candidates we develop. For example, inaccuracies in our earlier clinical data and deviations from our clinical trial protocols, such as from our Phase 2 clinical trial, 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. Our Phase 2 trial 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 ongoing and planned clinical trials to date have been or will be 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. Given that each of our planned and ongoing clinical trials include an open-label dosing design, while we believe our trials utilize objective assessment measures for measuring our primary endpoints and therefore are unlikely to be influenced in any manner by patient or investigator bias, our trials may utilize secondary endpoint patient reported outcome measures and, it is unknown whether the open-label design may not 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.

If later-stage clinical trials such as our FREEDOM-1 trial do not produce comparable or favorable safety or efficacy results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, 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.

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.

From time to time, we expect to announce clinical updates or share with regulatory authorities interim “top line” or preliminary data from our clinical trials, 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. 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. While we believe the limited efficacy and safety data observed to date is positive, the trial is in its early stages and additional data from subsequent patients may not be comparable or positive with respect to efficacy, safety or target engagement. 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

Our product candidates, or associated conditioning regimens or treatment protocols, 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 FREEDOM-1 trial and previous trials of FCR001 in LDKT.

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 responded to treatment and resolved. One of the three aGvHD patients was subsequently diagnosed with moderate chronic GvHD and is also responding to treatment. In LDKT, certain severe complications, such as severe infection requiring discontinuation of immunosuppression, graft rejection or loss, or even death, can occur. 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 are 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 from 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 approved by applicable regulatory authorities.

If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce positive 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 particular, we have conducted a Phase 2 trial of FCR001 in LDKT. We do not know whether FCR001 will perform in our subsequent planned clinical trials, including in diffuse systemic sclerosis and deceased donor kidney transplant, as it has performed in our initial LDKT Phase 2 trial. 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

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.

We intend to develop FCR001, and may develop future product candidates, for use in combination with nonmyeloablative conditioning and related conditioning drugs, and in our LDKT trials, we will administer FCR001 to patients taking standard of care immunosuppressive therapies. 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 current or future product candidate could be delayed, halted or otherwise fail to receive or maintain approval and may be less successful commercially.

We also intend to 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 will 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. The FDA has established the Office of Tissues and Advanced Therapies 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. 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. For example, we are utilizing transplant recipient chimerism as a surrogate marker for long-term immune tolerance in our ongoing Phase 3 trial of FCR001 in LDKT. We are evaluating this as a secondary endpoint, but it has not yet been validated by the FDA, EMA or other regulatory agencies, and as result, such agencies could reject such

an endpoint or interpret its significance differently than we do. 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.

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

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

In response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. Since March 2020, when foreign and domestic inspections have largely been on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

We may not be able to maintain orphan drug designation for FCR001 or obtain orphan drug designation for our future 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 have received Regenerative Medicine Advanced Therapy (“RMAT”) designation for FCR001 for LDKT. This designation may not necessarily lead to a faster development or regulatory review or approval process, and will not necessarily increase the likelihood that FCR001 will receive marketing approval.

We have received RMAT designation from the FDA for FCR001 for the prophylaxis of organ rejection without the need for chronic immunosuppression in patients receiving LDKT. A company may request RMAT designation of its product candidate, which designation may be granted if the product meets the following criteria: (1) it is a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and potential eligibility for

rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

RMAT designation does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

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 our product candidates 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.

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; 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 a new 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. These reductions went into effect on April 1, 2013 and, due to subsequent

legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the suspension, a 1% payment reduction began April 1, 2022 and continued through June 30, 2022, and the 2% payment reduction resumed on July 1, 2022.

- 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.
- 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.

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. 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 drug 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 biologics 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.
- On August 7, 2022 the U.S. Senate passed the Inflation Reduction Act of 2022, which among other things, allows for CMS to negotiate prices for certain single-source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation would also subject drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation would also cap Medicare beneficiaries’ annual out-of-pocket drug expenses at \$2,000, and cap Medicare beneficiaries’ insulin costs at \$35. President Biden is expected to sign the legislation imminently. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known.

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.

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 jurisdiction 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 are 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.

Our manufacturing process, 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, since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or reagents for our current and any future 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 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 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 are, and expect to remain, dependent on third parties to conduct our ongoing clinical trials and 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 rely 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 ongoing 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. 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.

We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses.

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

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

Risks Related to Manufacturing

Risks Related to our Manufacturing Facility

We currently operate our own manufacturing facility and intend to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs for FCR001, which will require significant resources. 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 manufacture our product candidates for our current and planned clinical trials. Although we are currently operating our manufacturing facility, our operations remain 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 have begun to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs for FCR001 for LDKT. In order to scale-up our manufacturing capabilities and facility, 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 expect to use the same manufacturing process and starting material for future programs as those that we have used in our Phase 2 and Phase 3 trials of FCR001 for LDKT, except that our starting materials and process may be different for programs where we derive our component cells from a deceased donor. However, our use of this manufacturing process in our Phase 2 and Phase 3 trials may not be successfully replicated in subsequent trials, which could adversely affect our ability to scale-up our manufacturing processes or obtain or maintain the requisite licenses and approvals from the FDA to commercialize our product candidates.

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-overs, 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. For example, since the beginning of the COVID-19 pandemic, several vaccines for COVID-19 have received Emergency Use Authorization by the FDA and a number of those later received marketing approval. Additional vaccines may be authorized or approved in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing supplies for, or timely manufacture, the products needed for our clinical trials, which could lead to delays in these trials.

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, supplies 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. 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 are 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 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 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 (“ $\alpha\beta$ TCR+ 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.

Our future success depends 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.

Our product candidate requires 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 substantially 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 substantially 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—both 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 effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek 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.

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.

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 reasonable terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. 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 employ 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 Chief Scientific Officer, 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 Chief Technology Officer, Michael Zdanowski, and certain other employees or consultants were previously employed at Medeor Therapeutics, Inc. ("Medeor Therapeutics"), 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 late-stage clinical 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 late-stage clinical 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 lead product, 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 \$36.4 million for the six months ended June 30, 2022 and \$47.8 million for year ended December 31, 2021. As of June 30, 2022, we had an accumulated deficit of \$127.2 million. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses and capital expenditures to continue to increase.

We anticipate that our expenses will increase substantially if and as we:

- continue to initiate and conduct clinical trials for our lead product candidate, FCR001, in our initial and potential additional indications;
- 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.

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.

We were first formed in February 2002 under the name Regenerex LLC, and engaged in operations with non-dilutive funding, or in collaboration with Novartis International AG (“Novartis”) from 2013 to 2016, until October 2018 when we closed our first external financing round, converted into a corporation and changed our name to Regenerex, Inc. and subsequently to Talaris Therapeutics, Inc. Since we commenced our operations, we have devoted substantially all of our resources to raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, establishing and protecting our intellectual property portfolio, developing and progressing FCR001 and preparing for clinical trials, and manufacturing initial quantities of FCR001. As an organization, we have not yet demonstrated an ability to successfully complete any Phase 3 clinical trials, obtain regulatory approval, consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for the successful commercialization of any of our product candidates. In addition, our Facilitated Allo-HSCT Therapy is novel and has only been evaluated in a limited number of patients to date. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be accurate given the limits of our operating history and lack of approved products.

In addition, given the limits of our operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities and may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, our financial results for any quarterly or annual periods may not be indicative of future operating performance.

We will require substantial additional funding to develop and commercialize our product candidates and identify and invest in new product candidates. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect to continue to spend substantial amounts of capital to continue the preclinical and clinical development of our current and future programs. If we are able to gain marketing approval for any product candidate we develop, including for any indication for which we are developing or may develop FCR001, we will require substantial additional funding in order to launch and commercialize such product candidates, to the extent that such launch and commercialization are not the responsibility of a collaborator that we may contract with in the future. We may also invest in preparations for launch and commercialization in advance of receiving regulatory approval for a product candidate, and such approval may not be received on a timely basis or at all. In addition, other unanticipated costs may arise in the course of our development efforts. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. Additionally, any

COVID-19-related program setbacks or delays due to changes in federal, state, or local laws and regulations or clinical site policies could impact the timing and cost of the development of our product candidates. Under the terms of the ULRF License Agreement, we are also obligated to make payments upon the achievement of certain development, regulatory and commercial milestones.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing FCR001 for our initial and potential additional indications, as well as any other product candidates we may develop, including any COVID-19-related delays or other effects on our development programs;
- the timing of, and the costs involved in, obtaining marketing approvals for FCR001 for our initial and potential additional indications, and any other product candidates we may develop;
- if approved, the costs of commercialization activities for FCR001 for any approved indications, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of scaling our manufacturing and establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of FCR001 for any approved indications or any other product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development, increase our office space, and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

As of June 30, 2022, we had cash, cash equivalents and marketable securities of approximately \$207.1 million. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

We believe that our cash, cash equivalents and marketable securities as of June 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements through 2024. This estimate may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds earlier than planned.

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 ongoing 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 ongoing 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 has consistently lagged both our original and revised enrollment projections, significantly limiting the data which we are 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. Furthermore, the performance of our CROs may also be delayed or disrupted by the ongoing 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.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could impact personnel at our manufacturing facilities, including our ability to manufacture FCR001, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and manufacturing activities.

In addition, our clinical trials have been and may be further affected by the ongoing COVID-19 pandemic, particularly as viral variants, such as the COVID-19 omicron variant and associated sub-variants, continue to proliferate in areas where we have clinical trials. Clinical site initiation and patient enrollment has been and may be further delayed due to prioritization of healthcare system resources toward the ongoing COVID-19 pandemic. For example, some of our patients may not be able to comply with clinical trial protocols and follow-ups if quarantines impede patient movement, interrupt healthcare services, reduce patient access to trial investigators, hospitals and trial sites, and limit on-site personnel support at various trial sites. Similarly, COVID-19 and current and evolving variants may adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, thereby adversely impacting our clinical trial operations and enrollment timelines.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration 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.

The global ongoing COVID-19 pandemic continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these potential effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

Risks Related to Employee and Growth Matters

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical

personnel, including Scott Requadt, our Chief Executive Officer; Suzanne T. Ildstad, MD, our founder and Chief Scientific Officer; Nancy Krieger, MD, our Chief Medical Officer; Michael Zdanowski, our Chief Technology Officer; and Mary Kay Fenton, our Chief Financial Officer. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business.

We conduct our main operations at our cell processing facility in Louisville, Kentucky, we maintain a corporate office in Wellesley, Massachusetts and a laboratory in Houston, Texas. Competition for skilled personnel, particularly in the rapidly growing cell and gene therapy (“CGT”) market, is intense, particularly in Massachusetts, which serves as headquarters to many other biopharmaceutical companies and many academic and research institutions, and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel. It may be difficult or time-consuming to recruit all the qualified personnel that we need in order to scale-up our manufacturing operations in Louisville.

We may need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2022, we had 128 employees, three of whom worked less than full-time, and 12 consultants. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, or as a result of any future acquisitions, we expect to need additional managerial, operational, manufacturing, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations to support this future growth. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

As our operations expand, we will also need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and preclinical and clinical studies effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

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, 2021, we had U.S. federal net operating loss carryforwards of approximately \$78.0 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;
- 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 76.9% of our outstanding voting common stock as of June 30, 2022. 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.

The dual class structure of our capital stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our capital stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Citadel Multi-Strategy Equities Master Fund Ltd. holds an aggregate of 1,150,000 shares of our non-voting common stock. This entity could convert a portion of these shares of non-voting common stock until it and its affiliates beneficially own up to an aggregate of 9.9% of our shares

of common stock at any time upon written notice. Consequently, if this holder of our non-voting common stock exercises its option to make this conversion, this will have the effect of increasing the relative voting power of the prior holder of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters.

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 Quarterly 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 \$1.07 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 Corporation 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

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, our 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.

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. As of June 30, 2022, we had used approximately \$63.6 million of the net offering proceeds, primarily to fund the advancement of our ongoing FREEDOM-1 Phase 3 trial, FREEDOM-2 Phase 2 trial and FREEDOM-3 Phase 2 trial, as well as for working capital and general corporate purposes. There has been no material change in the planned proceeds from our IPO, as described in our final prospectus filed with the SEC on May 10, 2021 pursuant to Rule 424(b) under the Securities Act.

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.

On August 15, 2022, the Company announced the transition of Suzanne T. Ildstad, MD, from her role as Chief Scientific Officer of the Company to that of Senior Scientific Advisor, effective as of August 31, 2022. In connection with Dr. Ildstad's transition, the Company entered into a transition and general release agreement with Dr. Ildstad (the "Transition Agreement"), pursuant to which, among other things, Dr. Ildstad will serve as Senior Scientific Advisor to the Company for a period of one year. Dr. Ildstad will receive \$35,000 per month in exchange for her advisory services. Dr. Ildstad will continue to serve on the Company's Board of Directors as a non-employee director. Pursuant to the Company's Non-Employee Director Compensation Policy, Dr. Ildstad will receive an option to purchase 14,501 shares of the Company's common stock, par value \$0.001 per share (the "Common Stock"), on September 1, 2022. The exercise price of the option will equal the closing price of the Common Stock on the Nasdaq Global Market on the grant date, and will vest upon the earlier of (x) the first anniversary of the date of grant or (y) the date of the Company's next annual meeting of stockholders, subject to Dr. Ildstad's continued service as a director through such date.

The foregoing description of the Transition Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Transition Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending September 30, 2022.

Item 6. Exhibits.

Exhibit Number	Description
3.1	<u>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)</u>
3.2	<u>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)</u>
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1**	<u>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.</u>
32.2**	<u>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.</u>
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.

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: August 15, 2022

By:

/s/ Scott Requadt

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

Date: August 15, 2022

By:

/s/ Mary Kay Fenton

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

**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 June 30, 2022 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 15, 2022

By: _____ /s/ Scott Requadt

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

**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 June 30, 2022 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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 15, 2022

By: _____
Mary Kay Fenton
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)

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

In connection with the Quarterly Report of Talaris Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that 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: August 15, 2022

By: _____ /s/ Scott Requadt
Scott Requadt
President and Chief Executive Officer
(Principal Executive Officer)

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

In connection with the Quarterly Report of Talaris Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that 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: August 15, 2022

By: _____
/s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer
(Principal Accounting Officer and Principal Financial Officer)
