Pursuant to Rule 424(b)(4)
Registration No.333-255316

PROSPECTUS

8,825,000 Shares

talaris THERAPEUTICS

Common Stock

We are offering 8,825,000 shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. The initial public offering price of our common stock is $17.00 per share. Our common stock has been approved for listing on The Nasdaq Global Market under the symbol "TALS."

We are an "emerging growth company" and "smaller reporting company" as defined under the U.S. federal securities laws and will be subject to reduced public company reporting requirements for this prospectus and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

We have two classes of common stock: the voting common stock offered hereby and non-voting common stock. For a description of the rights of the voting common stock and non-voting common stock, please see "Description of Capital Stock" beginning on page 194 of this prospectus. We are offering voting common stock in this offering, and unless otherwise noted, all references in this prospectus to our "common stock," "common shares" or "shares" refer to our voting common stock.

Investing in our common stock involves a high degree of risk. Please see "Risk Factors" beginning on page 14 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	*Total*
Initial public offering price	*$17.00*	*$150,025,000.00*
Underwriting discounts and commissions (1)	*$1.19*	*$10,501,750.00*
Proceeds, before expenses, to us	*$15.81*	*$139,523,250.00*

(1) See "Underwriting" beginning on page 206 of this prospectus for additional information regarding underwriting compensation.

We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional 1,323,750 shares of common stock.

The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about May 11, 2021.

MORGAN STANLEY *SVB LEERINK* *EVERCORE ISI* *GUGGENHEIM SECURITIES*

Prospectus dated May 6, 2021.

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Neither we nor the underwriters have authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside of the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms, or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys, and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe that these sources are reliable; however, we have not independently verified the information contained in such publications. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled "Risk Factors" and elsewhere in this prospectus. Some data are also based on our good faith estimates.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes included elsewhere in this prospectus. You should also consider, among other things, the matters described under "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case appearing elsewhere in this prospectus. Unless the context otherwise requires, the terms "Talaris," "the Company," "we," "us," and "our" in this prospectus refer to Talaris Therapeutics, Inc.

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 non-malignant 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 non-malignant 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.

Our lead product candidate, **FCR001**, which is central to our Facilitated Allo-HSCT Therapy, is a novel allogeneic cell therapy comprised of stem and immune cells that are procured from a healthy donor, who is also the organ donor in the case of organ transplantation. FCR001 is rapidly processed in our GMP facility using our proprietary manufacturing methods. Then, at the time of the transplant, FCR001 is administered to the recipient following nonmyeloablative conditioning, which is designed to be less toxic than myeloablative conditioning. A fully myeloablative conditioning regimen consists of a combination of agents and high doses of total body irradiation that destroy hematopoietic stem cells (**HSCs**) in the bone marrow and results in profound depletion of HSC-derived cells within one to three weeks following administration that is irreversible, and in most instances is fatal unless rescued by a stem cell transplant. The nonmyeloablative conditioning for FCR001 entails lower doses of chemotherapy and total body irradiation, causes less depletion of blood cells and does not require stem cell support for the recipient to resume the production of blood cells and platelets. We do not outsource any key aspect of our cell processing. We are developing FCR001 as a pipeline-in-a-product with the potential to address the therapeutic areas described above.

We are currently enrolling patients in FREEDOM-1, a randomized, controlled, open-label Phase 3 registration trial in the United States of FCR001 in 120 adult living donor kidney transplant (**LDKT**) recipients. The goal of this trial is to evaluate the potential of FCR001, when administered the day after the kidney transplant, to induce durable, drug-free immune tolerance in the recipient of the transplanted kidney. Inducing durable immune tolerance to a transplanted organ without the morbidities associated with lifelong immunosuppression is a goal that has been broadly referred to in the transplant field as the "*Holy Grail*" of solid organ transplant. The primary endpoint of FREEDOM-1 is to evaluate the proportion of FCR001 treated recipients who are free from immunosuppression without biopsy-proven acute rejection (**BPAR**) at 24 months post-transplant. The secondary endpoint is to evaluate the change in renal function as measured by estimated glomerular filtration rate (**eGFR**), which estimates how much blood passes through the filters in the kidney that remove waste from the blood, from post-transplant baseline (month one) to month 24 in FCR001 recipients.

We have robust, long-term Phase 2 data supporting our lead indication in LDKT. The primary endpoint of our Phase 2 trial was to determine whether the administration of FCR001 can induce durable tolerance to the donated kidney and substantially reduce or eliminate the requirement for immunosuppression within 12 months following transplant. In our Phase 2 trial, 26 of 37 LDKT patients treated with FCR001 (70%) were able to completely discontinue their chronic immunosuppression approximately one year after receiving their transplant. After mid-course optimizations to the Phase 2 protocol, 14 of the last 17 patients (82%) in the trial were able to discontinue their chronic immunosuppression by approximately one year post-transplant. Every transplant recipient who was weaned off immunosuppression has remained off chronic immunosuppression, without any organ rejection, for the duration of their follow-up. As of January 31, 2021, we have followed these patients for a median of over six years post-transplant, and the longest for over 11 years post-transplant. These results were achieved despite significant degrees of immune system human leukocyte antigen (**HLA**) mismatch between the donors and recipients, and the degree of immune mismatch between the donor and recipient did not appear to impact the safety or efficacy of our therapy candidate.

We have identified a near-term surrogate marker, chimerism, that we believe to be highly predictive of the ability of an organ transplant recipient to durably discontinue chronic immunosuppression at one year post-transplant without rejecting the transplanted organ. Chimerism refers to a state whereby the recipient's and donor's blood and immune cells co-exist in the recipient, creating a reciprocal state of immune tolerance called allogeneic tolerance. We use a simple blood test to measure and regularly monitor the degree of donor chimerism in the recipient, which has shown a close association in our research, to date, to predicting long-term immune tolerance in patients who have received FCR001. In our Phase 2 trial of FCR001, we observed that 26 of 27 recipients (96%) who achieved donor chimerism at six months post-transplant were successfully weaned off chronic immunosuppression over approximately the next six months, including recipients who were highly HLA-unmatched and/or unrelated to their donors. In addition, donor chimerism at three months post-transplant, which we observed in 26 of 29 recipients (90%), was also highly predictive of successful weaning off chronic immunosuppression at approximately one year post-transplant.

We continue to monitor the patients in our Phase 2 trial for long term safety and durability of effect. Through January 31, 2021, we have accumulated approximately 235 patient-years of exposure to FCR001 in LDKT, and the safety profile in our patients is generally consistent with that expected if a patient were to separately receive both a standard kidney transplant and an allo-HSCT with nonmyeloablative conditioning. Specifically, through January 31, 2021, there were three deaths and two cases of graft versus host disease (**GvHD**), which is a condition that occurs when donated stem cells attack the recipient. The most commonly reported serious adverse events were fever, deep vein thrombosis, including among several patients who had predisposing factors such as central venous catheter placements or Factor V deficiency, diarrhea, pneumonia and febrile neutropenia (or low white blood cell counts with a high fever). Preliminary data indicates that patients who were weaned off immunosuppression with FCR001 had preserved kidney function and third-party data suggests a markedly lower reliance on cardiovascular medications at four years post-transplant compared to traditional transplants with chronic immunosuppression over a similar time frame. Based on the data generated from our Phase 2 trial, FDA has granted Regenerative Medicine Advanced Therapy (**RMAT**) and Orphan Drug Designation for FCR001 for LDKT.

Under our open investigational new drug application (**IND**), the FDA has cleared us, based in part upon the data to date from our ongoing Phase 2 trial, to proceed with an updated protocol for our Phase 2 FREEDOM-2 trial, which we plan to initiate in the second half of 2021. In FREEDOM-2, we will evaluate the potential of FCR001 to induce durable immune tolerance in patients who have previously received a kidney from a living donor, which is a process called delayed tolerance. In this trial, FCR001 will be administered between three and twelve months after the initial kidney transplant. Positive results in this trial would be the first step to potentially extending the use of FCR001 to a portion of the prevalent LDKT population and could also support extending

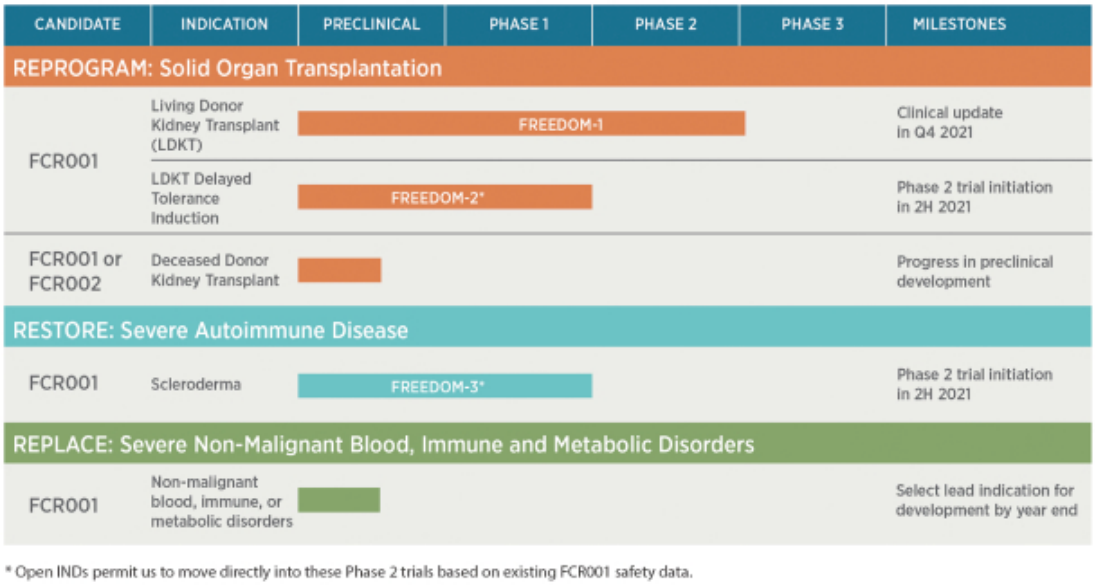
our Facilitated Allo-HSCT Therapy to deceased donor transplant procedures. Every year in the United States, there are approximately four times as many deceased donor solid organ transplants as living donor transplants. We are conducting preclinical research to evaluate whether we can procure the same types of stem and immune cells from a recently deceased donor as from a living donor. If our preclinical studies are successful, we intend to assess the ability of FCR001, or a product candidate similar to FCR001 (**FCR002**), to induce durable allogeneic tolerance in a recipient of an organ from a deceased donor.

Additionally, the FDA has cleared our IND, based in part upon the data to date from our ongoing Phase 2 trial, to proceed with our Phase 2 FREEDOM-3 trial, which we plan to initiate in the second half of 2021. In FREEDOM-3, we will evaluate the safety and efficacy of FCR001 in adults with a severe form of scleroderma, a debilitating autoimmune disease. In our Phase 2 LDKT trial, all seven LDKT patients who required a kidney transplant as a result of a kidney-related autoimmune disease, and who achieved durable chimerism and could be withdrawn from chronic immunosuppression at one year, have not experienced recurrence of their prior kidney-related autoimmune disease. We believe that this observation, as well as the current use of HSCT for severe scleroderma, supports the potential of our therapy in autoimmune diseases. We believe that positive data in the FREEDOM-3 trial in severe scleroderma patients could support the potential applicability of FCR001 to other severe, systemic autoimmune diseases.

There are also a number of severe non-malignant blood, immune and metabolic disorders for which allo-HSCT has already been observed to be potentially curative, but its use to date for these indications has been limited by two important considerations: (i) it necessitates matching the patient with a highly HLA-matched stem cell donor and (ii) it subjects the patient to the toxicities, morbidities and an extended hospital stay associated with fully myeloablative conditioning. Since our Phase 2 data suggest that our Facilitated Allo-HSCT Therapy can promote durable incorporation of the donated transplanted stem cells into the recipient where they will grow and reproduce, which is a process known as engraftment, and diverse immune reconstitution regardless of degree of HLA match and with a less toxic, nonmyeloablative (as opposed to myeloablative) conditioning regimen, with a low incidence of GvHD, we intend to explore the potential of our Facilitated Allo-HSCT Therapy in one or more such disorders. We expect to announce the first of these initiatives by the end of 2021.

Our Pipeline

Based on the clinical evidence we have observed in our Phase 2 trial, we believe FCR001, and our Facilitated Allo-HSCT Therapy more broadly, has pipeline-in-a product potential and utility in numerous therapeutic areas. These initial areas of focus extend beyond kidney transplantation and include severe autoimmune disease in our planned trial targeting scleroderma and IND-enabling studies targeting severe non-malignant blood, immune and metabolic disorders. We retain global development and commercial rights for FCR001 in all indications.



* Open INDs permit us to move directly into these Phase 2 trials based on existing FCR001 safety data.

Our Therapeutic Approach: Facilitated Allo-HSCT to Induce Allogeneic Tolerance

The goal of our proprietary, investigational Facilitated Allo-HSCT Therapy is to induce allogeneic tolerance for the treatment of multiple therapeutic conditions with significant unmet need. While the principle of inducing allogeneic tolerance has been understood for decades, its clinical application in humans via allo-HSCT has proven elusive due to two key challenges: (i) minimizing the risks of graft rejection and/or GvHD, irrespective of the degree of matching of the donor's and recipient's HLA antigens and (ii) identifying a better-tolerated, nonmyeloablative conditioning regimen (as opposed to a fully myeloablative conditioning regimen) that nonetheless enables durable engraftment of donor cells into the recipient. We believe that our Facilitated Allo-HSCT Therapy has the potential to address these two challenges and could represent a major advance in unlocking potential clinical applications for induced tolerance in the following ways:

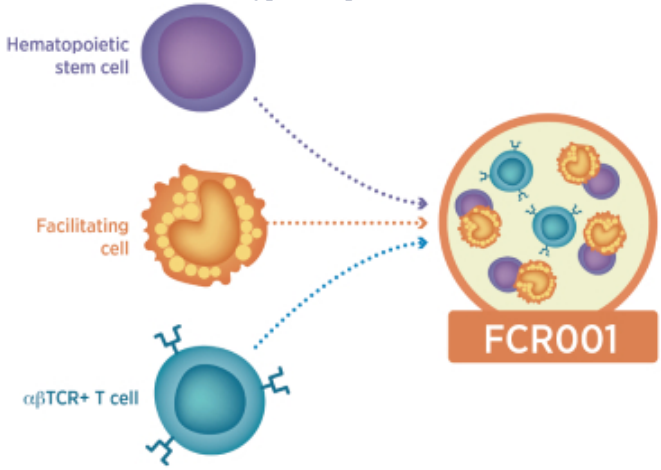
- **Reprogram—Solid Organ Transplantation—**By reprogramming the immune system to tolerate the donated organ without the need for chronic immunosuppression, we believe that our Facilitated Allo-HSCT Therapy has the potential to prevent immune-mediated organ rejection and thereby reduce or eliminate the co-morbidities, toxicities, costs and suboptimal patient survival rates and quality of life associated with lifelong immunosuppression.
- **Restore—Severe Autoimmune Disease—**By restoring tolerance to self-antigens in patients with severe autoimmune diseases, we believe that our Facilitated Allo-HSCT Therapy has the potential to induce durable remission without the need for chronic immunosuppression.
- **Replace—Severe Non-Malignant Blood, Immune and Metabolic Disorders—**By replacing defective or deficient HSCs, we believe that our Facilitated Allo-HSCT Therapy has the potential to correct a range of non-malignant blood, immune and metabolic disorders that have been shown to be potentially curable with allo-HSCT, but with a less toxic conditioning regimen, reduced or no need for HLA-matching, and reduced risk of GvHD compared to standard allo-HSCT.

Our lead product candidate, FCR001, which is central to our Facilitated Allo-HSCT Therapy, is a proprietary, one-time, investigational cell therapy derived from donor-mobilized peripheral blood cells, which

are processed to contain an optimized number of the donor's HSCs, Facilitating Cells (FCs), and Alpha Beta T-cell Receptor Cells (aßTCR+ T-cells). As depicted in the figure below, these three distinct cell types and the combination of these cell populations are critical for the safety and efficacy of FCR001. Specifically:

- ***HSCs*** are progenitor cells that are used to rebuild the hematopoietic and immune system of the recipient. As a result of their engraftment, the recipient's new immune system will reflect the donor's genotype and, thus, can potentially recognize the donor cells and tissues as "self" without the need for chronic immunosuppression.
- ***FCs*** are defined by the cell surface expression of the CD8 protein and by the lack of a functional T-cell receptor (**TCR**) (CD8+/TCR-). FCs are a mixed cell population that we believe to be responsible for fast and efficient engraftment of donor HSCs to promote chimerism. In addition, in preclinical studies, FCs have been observed to be associated with a reduced risk of GvHD relative to standard allo-HSCT. Consistent with these data, we have observed a very low incidence of GvHD in our Phase 2 trial of FCR001, despite a high degree of HLA mismatch between most donors and recipients.
- a***ßTCR+ T-cells*** are known to support donor HSC engraftment in recipients who receive allo-HSCT from an HLA-mismatched donor with nonmyeloablative conditioning, but they are also known to increase the risk of acute GvHD in the recipient. FCR001 incorporates an optimized number of aßTCR+ T-cells that are intended to promote engraftment of the donor's HSCs in the recipient while minimizing the risk of acute GvHD.

Active Cell Type Composition of FCR001



Manufacturing

Our manufacturing strategy is designed to meet the high quality and demand needs of clinical supply and commercial launch of any approved product. We manufacture FCR001 in less than a day at our GMP cell processing facility, employing robust, reproducible, proprietary methods, which remain substantially unchanged as we have progressed FCR001 from Phase 2 to Phase 3. We do not outsource any key aspect of our cell processing. Unlike gene therapies or chimeric antigen receptor T-cell (**CAR-T**) therapies, our manufacturing process does not employ viral vectors, nor do we perform any transductions or *ex vivo* cell expansions.

Our History and Team

Our experienced executive management team has over 100 years of experience developing and investing in innovative cell therapies and biopharmaceutical products. Our founder and Chief Scientific Officer,

Dr. Suzanne T. Ildstad, has published over 230 peer-reviewed papers, is a named inventor or co-inventor on 35 patents, and has dedicated herself to inducing durable immune tolerance for nearly thirty years.

We have raised $190.0 million in aggregate gross proceeds since November 2018 through two private financings. Our investors include Blackstone Life Sciences, Surveyor Capital (a Citadel company), Viking Global Investors, Longitude Capital, Qiming Venture Partners USA, Cormorant Asset Management, Invus, BlackRock, Eventide, Logos Capital, Aisling Capital, and Pamoja Capital, as well as one other large-but-unnamed investment fund. Between 2002 and 2018, we received substantial non-dilutive funding from grants, as well as from a prior strategic collaboration with Novartis AG.

Our Strengths

We aim to remove solid organ transplantation recipients' need for chronic immunosuppression and treat patients who suffer from severe autoimmune diseases and certain severe non-malignant blood, immune and metabolic disorders. We believe we can achieve this by leveraging our core strengths:

- Registration-stage lead program with long-term, compelling Phase 2 data indicating the potential to induce durable immune tolerance to a transplanted organ;
- Near-term surrogate marker, which was highly predictive of long-term tolerance in our Phase 2 trial;
- Significant pipeline-in-a-product opportunity for FCR001, with potential across multiple therapeutic areas;
- Fully in-house, robust and efficiently scalable manufacturing and testing;
- Significant first mover advantage in solid organ transplants with long-term durability data, a proprietary process and broad IP protection;
- Unencumbered worldwide rights to FCR001 and all of our other programs; and
- Talented and experienced team with deep and relevant experience.

Our Strategy

Our goal is to transform the standard of care in solid organ transplantation, severe autoimmune disease, and certain severe non-malignant blood, immune and metabolic disorders, all with a single therapeutic approach. We plan to do this through our proprietary investigational therapy, FCR001, the cornerstone of our novel Facilitated Allo-HSCT Therapy. Our strategy is comprised of the following key elements:

- Establish Talaris as a leader in developing, manufacturing, and ultimately commercializing cell therapies to address multiple areas of high unmet need;
- Advance FCR001 through clinical development, registration, and commercialization in LDKT;
- Extend FCR001 clinical development to severe autoimmune diseases;
- Further extend FCR001 clinical development to certain severe non-malignant blood, immune or metabolic disorders;
- Explore the potential to extend our therapeutic approach to deceased donor organ transplantation;
- Further scale our in-house manufacturing and analytical capabilities and supply chain logistics; and
- Commercialize FCR001 independently in North America, if approved, and explore other markets through strategic collaborations.

Risks Associated with our Business

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully in the section of this prospectus entitled "Risk Factors." You should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- We have incurred net losses in every period since our inception and anticipate that we will incur significant net losses for the foreseeable future.
- We have not yet completed any registrational trials and have no history of commercializing products, and we face significant challenges and expense as we build our capabilities.
- We are heavily dependent on the success of FCR001, our lead product candidate.
- Our current and any future product candidates, or the 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 may not successfully identify, acquire, develop or commercialize any indications for FCR001 or other product candidates.
- We currently operate our own manufacturing facility and intend to further scale our manufacturing and processing approaches to appropriately address our anticipated commercial needs, 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.
- FCR001 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.
- We face substantial competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We are dependent on a limited number of suppliers and, in some instances, a sole supplier, for some of our components and materials used in our product candidates.
- We depend substantially on intellectual property licensed from the University of Louisville, and termination of this license could result in the loss of significant rights, which would materially harm our business.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- We will need substantial additional financing to develop our products and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization 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 timely and satisfactorily carry out their contractual duties, our development programs may be delayed or subject to increased costs.
- If our efforts to protect the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

- Our ability to commercialize any product candidate successfully will depend, in part, on the extent to which coverage and adequate reimbursement for such product and related treatments will be available from government health administration authorities, private health insurers and other organizations.
- Our business has been adversely affected by the ongoing COVID-19 pandemic, and could be further adversely affected by the effects of this and other 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.

Corporate History

We were initially organized as a Delaware limited liability company on February 15, 2002, under the name Regenerex LLC. On October 30, 2018, we converted to a Delaware corporation under the name of "Regenerex, Inc." and on March 6, 2019, we changed our name to "Talaris Therapeutics, Inc." Our principal corporate office is located at 570 S. Preston St, Louisville, KY 40202, and our telephone number is (502) 398-9250. Our website address is www.talaristx.com. We do not incorporate the information on or accessible through our website into this prospectus, and you should not consider any information on, or that can be accessed through, our website as part of this prospectus.

We own various U.S. federal trademark applications and unregistered trademarks, including our company name. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the JOBS Act). As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure about our executive compensation arrangements;
- no non-binding advisory votes on executive compensation or golden parachute arrangements;
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on financial statements.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in non-convertible debt during the previous three years; or

(iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from other public companies in which you hold stock. Additionally, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption and, therefore, while we are an emerging growth company we will not be subject to new or revised accounting standards at the same time that they become applicable to other public companies that are not emerging growth companies. As a result of these elections, the information that we provide in this prospectus may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that (i) our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or (ii) our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

THE OFFERING

Common stock offered	8,825,000 shares.
Underwriters' option to purchase additional shares	We have granted a 30-day option to the underwriters to purchase up to an aggregate of 1,323,750 additional shares of common stock from us at the public offering price, less underwriting discounts and commissions on the same terms as set forth in this prospectus.
Common stock to be outstanding immediately after this offering	40,086,910 shares (41,410,660 shares if the underwriters exercise their option to purchase additional shares in full).
Non-voting common stock to be outstanding after this offering	1,150,000 shares.
Total common stock and non-voting common stock to be outstanding after this offering	41,236,910 shares (or 42,560,660 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately $136.7 million, or $157.6 million if the underwriters exercise in full their option to purchase additional shares, based on the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, for the following: (i) further development of 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) continued 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) development of expanded CMC operations to facilitate scale-up and commercialization of FCR001; (iv) development of our preclinical programs towards IND filings and/or into clinical trials; and (v) the remainder for working capital and other general corporate purposes. See "Use of Proceeds" for additional information.

Risk factors	You should carefully read the "Risk Factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Nasdaq Global Market symbol	"TALS"

The number of shares of our common stock and non-voting common stock to be outstanding after this offering is based on 32,411,910 shares of our common stock and non-voting common stock outstanding as of December 31, 2020, including 932,279 shares of non-vested restricted common stock, which are not considered outstanding for accounting purposes, and after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 24,392,498 shares of our common stock (of which 1,150,000 will be shares of non-voting common stock) immediately prior to the completion of this offering, and excludes:

- 2,670,419 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2020 under our Second Amended and Restated 2018 Equity Incentive Plan (2018 Plan) at a weighted average exercise price of $4.16 per share;
- 74,766 shares of common stock issuable upon the exercise of stock options outstanding, which were granted outside our 2018 Plan, as of December 31, 2020 at an exercise price of $5.35 per share;
- 1,143,820 shares of common stock reserved for future issuance as of December 31, 2020 under the 2018 Plan, which ceased to be available for issuance at the time that our 2021 Stock Option and Incentive Plan (2021 Stock Plan) became effective;
- 65,186 shares of common stock contingently issuable to a licensor in connection with this offering;
- 852,971 shares of common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan (2021 ESPP), which became effective in connection with this offering; and
- 3,015,907 shares of our common stock that became available for future issuance under our 2021 Stock Plan, which became effective in connection with this offering.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- the conversion of all outstanding shares of our preferred stock into an aggregate of 24,392,498 shares of common stock (of which 1,150,000 will be shares of non-voting common stock) upon the closing of this offering;
- no exercise of the outstanding options described above;
- no exercise by the underwriters of their option to purchase up to 1,323,750 additional shares of common stock in this offering;
- a one-for-5.35 reverse split of our voting and non-voting common stock effected on April 30, 2021 and a proportional adjustment to the existing conversion ratios for the Company's convertible preferred stock effective as of April 30, 2021; and
- the filing of our third amended and restated certificate of incorporation (amended and restated certificate of incorporation) in connection with the closing of this offering and the effectiveness of our second amended and restated bylaws (amended and restated bylaws), which became effective upon the effectiveness of the registration statement of which this prospectus is a part.

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statements of operations data for the years ended December 31, 2020 and December 31, 2019 and the balance sheet data as of December 31, 2020 from our audited financial statements appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in any future periods.

	Year ended December 31, 2020	Year ended December 31, 2019
	(in thousands, except share and per share amounts)	
Statements of Operations Data:		
Operating expenses:		
Research and development	$ 15,278	$ 13,369
General and administrative	7,406	5,009
Total operating expenses	22,684	18,378
Loss from operations	(22,684)	(18,378)
Interest and other income (expense), net	(23)	223
Net loss	$ (22,707)	$ (18,155)
Unrealized loss on marketable securities	(13)	—
Total other comprehensive loss	(13)	—
Total comprehensive loss	$ (22,720)	$ (18,155)
Net loss attributable to common stockholders	$ (22,707)	$ (18,155)
Net loss per common share, basic and diluted	$ (3.40)	$ (2.84)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	6,685,066	6,383,261
Pro forma net loss per common share, basic and diluted	$ (1.07)	
Pro forma weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	21,192,565	

(1) See Note 14 to our financial statements appearing at the end of this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of December 31, 2020		
	Actual	Pro forma(1)	Pro forma as adjusted(2)
		(in thousands)	
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	$149,488	$ 149,488	$ 286,186
Working capital(3)	147,347	147,347	284,045
Total assets	152,778	152,778	289,476
Convertible preferred stock	186,151	—	—
Total stockholders' equity (deficit)	(38,147)	148,005	284,703

(1) The pro forma balance sheet data gives effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 24,392,498 shares of common stock (of which 1,150,000 will be shares of non-voting common stock) prior to the completion of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation.

(2) The pro forma as adjusted balance sheet data gives effect to (i) the pro forma adjustments set forth in footnote (1) above and (ii) the issuance and sale of 8,825,000 shares of our common stock in this offering at the initial public offering price of $17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as current assets less current liabilities.

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 prospectus, including our financial statements and the related notes thereto and the section of this prospectus 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.

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 losses were $22.7 million and $18.2 million for the years ended December 31, 2020 and December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $43.0 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 U.S. Food and Drug Administration (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.

Even if we consummate this offering, we will need substantial additional funding, and 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 our amended and restated exclusive license agreement with the University of Louisville Research Foundation, Inc. (ULRF) or the ULRF license, 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 December 31, 2020, we had cash, cash equivalents and marketable securities of approximately $149.8 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 the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements at least into 2025. 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 additional 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 and the Clinical Development, Regulatory Review and Approval of Our Product Candidates

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 the 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 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.

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 European Medicines Agency (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 living donor kidney transplantation (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.

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 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 Stated. 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 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 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. 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 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 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 and 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.

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, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

In 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, foreign and domestic inspections by the FDA have largely been on hold with prioritized domestic inspections resuming in July 2020. FDA may not be able to continue its current pace for reviews of applications for medical products and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. 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, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 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. Moreover, later audits of our earlier clinical data, such as from our Phase 2 clinical trial, may reveal inaccuracies or deviations impacting the integrity of those data. 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, 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 favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, 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, and the results 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 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.

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 LDTK.

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. Graft vs. host disease (GvHD) also accounts for approximately 10% of deaths following allogeneic HSCT. 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 form the marketplace;

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

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

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 non-malignant 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.

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 NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

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 living donor kidney transplantation. 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.

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. 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.

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 coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. 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 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 fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would 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 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. 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 Affordable Care Act), 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. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor,

including commercial insurers or patients; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

In addition to the above, on November 20, 2020, OIG finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. These rules (with exceptions) were scheduled to became effective January 19, 2021, but their effective date has been delayed by the Biden administration until January 1, 2023. We continue to evaluate what effect, if any, these rules will have on our business.

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.

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, US 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, will require 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.

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. Further, the United Kingdom's decision to leave the E.U., often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In addition, various jurisdictions around the world continue to propose new laws that regulate the privacy and/or security of certain types of personal data. 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, the GDPR includes restrictions on cross-border data transfers. A recent decision by the Court of Justice of the European Union (the "Schrems II" ruling), however, has invalidated the E.U.-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. Companies to import personal information from Europe, and raised questions about whether the European Commission's Standard Contractual Clauses (SCCs), one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from Europe to the United States or most other countries. Similarly, the Swiss Federal Data Protection and Information Commissioner recently opined that the Swiss-U.S. Privacy Shield is inadequate for transfers of data from Switzerland to the U.S. The United Kingdom, whose data protection laws are similar to those of the European Union, may similarly determine that the E.U.-U.S. Privacy Shield is not a valid mechanism for lawfully transferring personal information from the U.K. to the United States. The European Commission recently proposed updates to the SCCs, and additional regulatory guidance has been released that seeks to impose additional obligations on companies seeking to rely on the SCCs. Given that, at present, there are few, if any, viable alternatives to the E.U.-U.S. Privacy Shield and the SCCs, any transfers by us or our vendors of personal data from Europe may not comply with European data protection law, which may increase our exposure to the GDPR's heightened sanctions for violations of its cross-border data transfer restrictions and may prohibit our transfer of E.U. personal data outside of the E.U. (including clinical trial data), and may adversely impact our operations, product development and ability to provide our products.

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.

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.

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 Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of our product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which any product candidate is approved;
- acceptance by physicians and patients of the product candidate as a safe and effective treatment;
- the administrative and logistical burden of treating patients, including the availability and accessibility of healthcare provider sites for administering infusions to patients;
- the adoption of novel cellular therapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the safety of our product candidates seen in a broader patient group, including their use outside the approved indications;
- any contraindications or restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our product candidates;
- the cost of our therapy in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from, and our ability to negotiate pricing with, third-party payors, providers and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product candidate successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.

The pricing and reimbursement of our product candidates, if approved, must be adequate to support the necessary commercial infrastructure. If we are unable to obtain adequate levels of reimbursement, our ability to successfully market and sell any such product candidates will be adversely affected. In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford expensive treatments, such as our therapies. Sales of our product

candidates will depend substantially on the extent to which the costs of our product candidates will be covered and paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other payors.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Additionally, the process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval, and ultimately our ability to successfully commercialize any product candidate for which we obtain regulatory approval. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

We are initially targeting rare diseases with small patient populations. In order for products that are designed to treat smaller patient populations to be commercially viable, the reimbursement for such products must be higher, on a relative basis, to account for the lack of volume. Accordingly, we will need to implement a coverage and reimbursement strategy for any approved product candidate with a smaller patient population that accounts for the smaller potential market size. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate. We are also initially developing products that are designed to be used one time. We expect the cost of one-time cell therapy products, such as those we are developing, to be substantial, when and if they achieve market approval. We believe a value-based price for our one-time therapies should encompass both short- and long-term clinical, health economic, and humanistic value. Recently approved one-time cell therapies can command prices that may expose payors to higher upfront costs than annual costs for existing therapies administered chronically. Accordingly, healthcare providers may face challenges securing reimbursement from payors for one-time therapies that necessitate higher upfront or near-term payments even if the long-term treatment cost with the one-time therapy is less expensive than the long-term cost for existing treatments. Ultimately, payors may not be willing to pay high prices for a one-time therapy.

In the United States, solid organ transplants and hematopoietic stem cell transplants are performed in tertiary hospitals, particularly high volume centers of excellence situated in major metropolitan areas. Most of these hospitals are part of large regional health systems and are likely to be the main adopters of FCR001 and our other Facilitated Allo-HSCT products. To ensure optimal adoption of our products at these hospitals, we will need to secure implementation of our novel treatment protocols at the facility, and in some cases, systemic level. Moreover, adoption at the hospital and health system level will depend heavily upon hospital administrators' confidence they can be adequately reimbursed by payors for our product and any incremental costs they incur to administer our products.

Solid organ transplant and hematopoietic stem cell transplant (HSCT) procedures are currently reimbursed at capitated case rates for both commercial payors and Medicare (DRG) in the US. Whereas it takes time for

CMS to approve a new DRG, we anticipate seeking outlier payments (typically billed under CPT Category III Codes—a set of temporary (T) codes assigned to emerging technologies, services, and procedures) plus a New Technology Add-on Payment (NTAP) to bridge any funding gaps between current transplant DRGs and the incremental cost for FCR001—akin to what was done for CAR-T therapies. As with CAR-T therapies, we anticipate that a new DRG will likely need to be issued to provide full reimbursement of our Facilitated Allo-HSCT Therapy to providers. If a new DRG is not granted within three years of the approval of FCR001 in the United States, this could compromise our or hospitals' ability to obtain adequate reimbursement for FCR001, which in turn could negatively affect commercial adoption of our therapy. We also recognize that as one-time cell therapies become an increasingly prominent component of medical practice for a range of conditions, that manufacturers, hospitals, health systems and public and private payors may refine their pricing and reimbursement models to balance short-term costs with long-term potential systemic savings from such therapies. For example, some products have risk-sharing models in which the total cost is amortized over multiple installments that are contingent upon annual confirmation of continued benefit. We believe that a therapy such as FCR001 may be reimbursed under such models, given that there are objective measures of continued benefit (e.g., continued lack of need for immunosuppression evidenced by absence of signs of organ rejection). However, some payors, most notably Medicare, do not currently have reimbursement mechanisms in place for multi-year, risk-sharing pricing models. The lack of such mechanisms could pose constraints to the total treatment cost for our products.

There may be significant delays in obtaining coverage and reimbursement for newly approved therapies, and coverage may be more limited than the purposes for which the therapy is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any therapy will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for our therapies, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of our therapy and the clinical setting in which it is used, and may be incorporated into existing payments for other services. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such products. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Net prices for our therapies may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors.

Further, third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. It is difficult to predict what the CMS will decide with respect to reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these new products. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise the capital needed to commercialize products and our overall financial condition.

Current and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, 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 successfully sell any product candidates for which we obtain regulatory approval. In particular, in March 2010, the Affordable Care Act was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research and established a new Medicare Part D coverage gap discount program.

Since its enactment, there have been executive, judicial and Congressional challenges to numerous elements of the Affordable Care Act. For example, the former President signed Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld a District Court ruling that the individual mandate was unconstitutional and remanded the case back to the Texas District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when a decision will be made or how the Supreme Court will rule. Although the U.S. Supreme Court has yet ruled on the constitutionality of the Affordable Care Act, on February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Further, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs 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 Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

Any other executive, legislative or judicial action to "repeal and replace" all or part of the Affordable Care Act may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the Affordable Care Act or the implementation of new health care legislation, could result in significant changes to the health care system which may adversely affect our business in unpredictable ways.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. COVID-19 pandemic relief legislation suspended these reductions from May 1, 2020 through December 31, 2021. In addition, in January 2013, the American Taxpayer Relief Act of 2012 (ATRA) was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In addition, there has been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs (SCODs). The court ruled this change was not an “adjustment” which was within the Secretary’s discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court’s decision and found that the changes were within the Secretary’s authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. While a number of these and other proposed measures will require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, former President Trump signed several Executive Orders aimed at lowering drug pricing that seek to implement several of the former administration’s proposals. On November 20 2020, CMS also issued an Interim Final Rule implementing the Most Favored Nation (MFN) Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. For example, on December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. Additionally, on November 20, 2020, HHS finalized 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 the implementation of which have also been delayed until January 1, 2023. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

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. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product candidates, if any, may be. In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

Additionally, there is a risk that any granted exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way

that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We are at an early stage of establishing an organization that would eventually be responsible for the sale, marketing and distribution of our therapy, if approved, and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we will have to build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without a sufficiently scaled, appropriately timed and trained internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

Risks Related to Manufacturing

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. 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.

Our manufacturing capabilities could be affected by cost-overruns, resource constraints, unexpected delays, equipment failures, labor shortages or disputes, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, jeopardize our ability to provide our product candidates to patients, and have a material adverse effect on our business, financial condition, results of operations and prospects. For example, two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. 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.

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 (aßTCR+ 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.

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), 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 Therapeutic Approach 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 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, or 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, two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. 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 on account of 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 Our Intellectual Property

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.

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.

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

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

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

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

We may 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 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.

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.

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.

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.

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.

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.

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.

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 (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.

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 Our Business, Growth and Industry

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 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, the performance of our CROs may also be delayed or disrupted by the ongoing COVID-19 pandemic, 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 COVID-19 pandemic. Clinical site initiation and patient enrollment has been and may be further delayed due to prioritization of healthcare

system resources toward the 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 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 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.

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, and we also maintain a corporate office in Wellesley, Massachusetts. Competition for skilled personnel in our 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 of 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 March 31, 2021, we had 82 full-time employees and 24 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.

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.

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, for taxable years beginning after December 31, 2020, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in any future taxable year. In addition, both our current and our future unused U.S. federal net operating losses and tax credits may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (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 this offering or subsequent 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, 2020, we had U.S. federal net operating loss carryforwards of approximately $8.4 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.

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

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines

in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that 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.

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.

Risks Related to This Offering and Ownership of Our Common Stock

There has been no prior public market for our common stock and we do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.

Prior to this offering, there was no public trading market for shares of our common stock. Although our common stock has been approved for listing on The Nasdaq Stock Market, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock was determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

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 following this offering 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 prospectus, 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. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. 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.

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 82.1% of our fully diluted voting stock as of March 31, 2021, and, assuming the sale by us of 8,825,000 shares of common stock in this offering, and not accounting for any shares purchased in this offering by certain of our existing stockholders (or their affiliates), we anticipate that same group will hold approximately 63.7% of our outstanding voting stock following this offering (assuming no exercise of the underwriters' option to purchase additional shares). 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, even after this offering, 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.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price will be substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $10.10 per share, based on the initial public offering price of $17.00 per share. Further, investors purchasing common stock in this offering will contribute approximately 44% of the total amount invested by stockholders since our inception, but will own only approximately 21% of the total number of shares of our common stock and non-voting common stock outstanding after this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering, and the exercise of stock options granted to our employees. To the extent that outstanding stock options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section of this prospectus entitled “Dilution.”

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase or maintain the value of your investment.

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.

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 Jumpstart Our Business Startups Act, or 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 (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in this prospectus 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 year in which we complete this offering, 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 this 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 this prospectus and 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.

Participation in this offering by our existing stockholders and/or their affiliated entities may reduce the public float for our common stock.

To the extent our existing stockholders who are our affiliates or their affiliated entities participate in this offering, such purchases would reduce the non-affiliate public float of our common stock after this offering, which is the number of shares of common stock that are not held by our officers, directors and affiliated stockholders. A reduction in the public float could reduce the number of shares of common stock that can be traded at any given time, which could adversely impact the liquidity of our common stock and depress the price at which you may be able to sell shares of common stock purchased in this offering.

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 will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which will require, among other things, that we file with the Securities and Exchange Commission (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 (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 this 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.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Upon the closing of this offering, we will have outstanding a total of 40,086,910 shares of common stock and 1,150,000 shares of non-voting common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. In connection with this offering, our officers, directors and substantially all of our stockholders have agreed to be subject to a contractual lock-up with the underwriters, which will expire 180 days after the date of this prospectus.

The lock-up agreements contain important exceptions that govern their applicability. Morgan Stanley & Co. LLC, SVB Leerink LLC and Evercore Group, L.L.C., however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2021 Stock Plan and our 2021 ESPP, which became effective on the date immediately prior to the date on which the registration statement of which this prospectus forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended (Securities Act). If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 24,392,498 shares of our common stock (of which 1,150,000 will be shares of non-voting common stock) will be entitled to rights with respect to the registration of their shares under the Securities Act (or, in the case of the non-voting common stock, the voting common stock to be received upon

conversion of the non-voting common stock), subject to the 180-day lock-up agreements described above. See "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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 to become effective in connection with the completion of this offering. Immediately following this offering, Citadel Multi-Strategy Equities Master Fund Ltd. will hold an aggregate of 1,150,000 shares of our non-voting common stock. Based on the shareholdings of this entity as of immediately prior to this offering, at any time following completion of this offering, upon written notice, 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. See "Description of Capital Stock—Common Stock and Non-Voting Common Stock." Consequently, if this holder of our non-voting common stock following this offering 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.

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, which is to become effective in connection with the closing of this offering, and our amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus is a part, will contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and

- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover 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 involving our company. These provisions could also discourage proxy contests and make it more difficult for you 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, that became effective upon the effectiveness of the registration statement of which this prospectus forms part, 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 that became effective upon the effectiveness of the registration statement of which this prospectus forms part 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 (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 (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.

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. In connection with this offering, we intend to begin 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.

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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if 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.

After the completion of this offering, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, including the sections entitled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and “Business,” contains express or implied forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the initiation timing, progress, results and cost of manufacturing and conducting clinical trials of FCR001, as well as our research and development programs and our current and future preclinical and clinical studies, 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 current and future programs;
- our ability to identify research priorities and apply a risk-mitigated strategy to efficiently discover and develop additional product candidates, if any, including by applying learnings from one program to other programs and from one indication to our other indications;
- our ability to initiate, recruit and enroll patients in and conduct our clinical trials at the pace that we project;
- our ability to scale-up our manufacturing and processing approaches to appropriately address our anticipated commercial needs, if FCR001 is approved, which will require significant resources;
- our ability to maintain and further develop the specific shipping, storage, handling and administration of FCR001 at the clinical sites, including cold-chain logistics,
- the ability and willingness of our third-party vendors to continue to supply raw materials, supplies and other components that we use for processing and analyzing FCR001, and to supply the future research and development components of any future product candidates;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our ability to commercialize our products, if approved;
- the pricing and reimbursement of our product candidates, if approved;
- the implementation of our business model, and strategic plans for our business, product candidates, and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and our Facilitated Allo-HSCT Therapy;
- estimates of our future expenses, revenues and capital requirements and our needs for additional financing;
- future agreements with third parties in connection with the development and commercialization of 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;
- our financial performance;

- the rate and degree of market acceptance of our product candidates;
- regulatory developments in the United States and foreign countries;
- our ability to produce our products or product candidates with advantages in turnaround times or manufacturing cost;
- the success of competing therapies that are or may become available;
- our ability to attract and retain key scientific, cell manufacturing, quality or management personnel, particularly in the necessary geographic areas;
- the impact of laws and regulations;
- our use of the proceeds from this offering;
- developments relating to our competitors and our industry;
- the effect of the COVID-19 pandemic, including variants of the virus, mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to a negative impact on enrollment in our ongoing clinical trial as well as any other impacts on our existing and future clinical trials or our preclinical studies; and
- other risks and uncertainties, including those listed under the caption “Risk Factors.”

In some cases, forward-looking statements can be identified by terminology such as “may,” “should,” “expects,” “intends,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential,” “continue,” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section entitled “Risk Factors” and elsewhere in this prospectus. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this prospectus and the documents that we reference in this prospectus and have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

USE OF PROCEEDS

We estimate that our net proceeds from the sale of shares of our common stock in this offering will be approximately $136.7 million, or $157.6 million if the underwriters exercise in full their option to purchase additional shares, based on the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to create a public market for our common stock and thereby facilitate future access to the public equity markets, increase our visibility in the marketplace and obtain additional capital. We currently intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, for the following:

- Approximately $130.0 million for the further development of 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;
- Approximately $40.0 million for the continued 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;
- Approximately $30.0 million for the development of expanded CMC operations to facilitate scale-up and commercialization of FCR001;
- Approximately $25.0 million to fund the development of our preclinical programs towards IND filings and/or into clinical trials; and
- the remainder for working capital and other general corporate purposes.

Based on our current plans, we believe that our existing cash, cash equivalents and marketable securities, together with the net proceeds from this offering, will be sufficient to enable us to fund our operating expenses and capital expenditure requirements at least into 2025. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. We do not have any committed external source of funds.

Our expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above and we expect that we will require additional funds in order to fully accomplish the specified uses of the proceeds of this offering. We may also use a portion of the net proceeds to in-license, acquire, or invest in complementary businesses or technologies to continue to build our pipeline, research and development capabilities and our intellectual property position, although we currently have no agreements, commitments, or understandings with respect to any such transaction.

Due to the many inherent uncertainties in the development of our product candidates, the amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our research and development, the timing of patient enrollment and evolving regulatory requirements, the timing and success of preclinical studies, our ongoing clinical studies or clinical studies we may commence in the future, the timing of regulatory submissions, any strategic alliances that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, and any unforeseen cash needs.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation instruments, including short-term and long-term interest-bearing instruments, investment-grade securities, and direct or guaranteed obligations of the U.S. government. We cannot predict whether the proceeds invested will yield a favorable return. Our management will retain broad discretion in the application of the net proceeds we receive from our initial public offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

DIVIDEND POLICY

We currently intend to retain all available funds and any future earnings to fund the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and our capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 24,392,498 shares of common stock (of which 1,150,000 will be shares of non-voting common stock) prior to the completion of this offering and the filing and effectiveness of our amended and restated certificate of incorporation prior to the completion of this offering, in each case as if such events had occurred on December 31, 2020; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of 8,825,000 shares of common stock in this offering at the initial public offering price of $17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our financial statements and the related notes appearing at the end of this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus.

	As of December 31, 2020		
	Actual	Pro forma	Pro forma as adjusted
	(in thousands, except share and per share amounts)		
Cash, cash equivalents and marketable securities	$149,488	$149,488	$286,186
Convertible preferred stock (Series A, A-1 and B), $0.0001 par value; 130,499,993 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	186,151	—	—
Stockholders' equity (deficit):			
Common stock, $0.0001 par value; 36,366,101 shares authorized, 8,019,412 shares issued and outstanding, actual; 150,000,000 shares authorized, 32,411,910 shares issued and outstanding, pro forma; 150,000,000 shares authorized, 41,236,910 shares issued and outstanding, pro forma as adjusted	1	3	4
Additional paid-in capital	4,880	191,029	327,726
Accumulated deficit	(43,014)	(43,014)	(43,014)
Accumulated other comprehensive loss	(13)	(13)	(13)
Total stockholders' equity (deficit)	(38,147)	148,005	284,703
Total capitalization	$148,005	$148,005	$284,703

The number of shares of our common stock and non-voting common stock in the table above is based on 32,411,910 shares of our common stock and non-voting common stock outstanding as of December 31, 2020, including 932,279 shares of unvested restricted common stock (which are not considered outstanding for accounting purposes), and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 24,392,498 shares of our common stock (of which 1,150,000 will be shares of non-voting common stock) immediately prior to the completion of this offering, and excludes:

- 2,670,419 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2020 under our Second Amended and Restated 2018 Equity Incentive Plan (2018 Plan) at a weighted-average exercise price of $4.16 per share;

- 74,766 shares of common stock issuable upon the exercise of stock options outstanding, which were granted outside our 2018 Plan, as of December 31, 2020 at an exercise price of $5.35 per share;
- 1,143,820 shares of common stock reserved for future issuance as of December 31, 2020 under the 2018 Plan, which ceased to be available for issuance at the time that our 2021 Stock Option and Incentive Plan (2021 Stock Plan) became effective;
- 65,186 shares of common stock contingently issuable to a licensor in connection with this offering;
- 3,015,907 shares of our common stock that became available for future issuance under the 2021 Stock Plan, which became effective in connection with this offering; and
- 852,971 shares of our common stock reserved for future issuance under our 2021 Employee Stock Purchase Plan (2021 ESPP), which became effective in connection with this offering.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book deficit as of December 31, 2020 was $(38.1) million, or $(4.76) per share of our common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our total liabilities and the carrying values of our convertible preferred stock, which is not included within stockholders' deficit. As of December 31, 2020, we did not have any intangible assets to exclude from net tangible book deficit. Our historical net tangible book deficit per share represents historical net tangible book deficit divided by the 8,019,412 shares of our common stock outstanding as December 31, 2020, including 932,279 shares of unvested restricted common stock (which are not considered outstanding for accounting purposes).

Our pro forma net tangible book value as of December 31, 2020 would have been $148.0 million, or $4.57 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 24,392,498 shares of common stock (of which 1,150,000 will be shares of non-voting common stock) prior to the completion of this offering and (ii) the filing and effectiveness of our amended and restated certificate of incorporation and amended and restated bylaws prior to the completion of this offering, in each case as if such events had occurred on December 31, 2020. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of December 31, 2020, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of 8,825,000 shares of our common stock in this offering at the initial public offering price of $17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been $284.7 million, or $6.90 per share. This amount represents an immediate increase in pro forma as adjusted net tangible book value per share of $2.33 to our existing stockholders and immediate dilution of $10.10 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering.

Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis (without giving effect to any exercise by the underwriters of their option to purchase additional shares):

Initial public offering price per share		$17.00
Historical net tangible book value (deficit) per share as of December 31, 2020	$(4.76)	
Increase per share attributable to the pro forma adjustments described above	9.33	
Pro forma net tangible book value per share as of December 31, 2020 attributable to the conversion of convertible preferred stock	4.57	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	2.33	
Pro forma as adjusted net tangible book value per share after this offering		6.90
Dilution per share to new investors purchasing common stock in this offering		$10.10

If the underwriters exercise their option to purchase additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be $7.18, representing an immediate increase in pro forma as adjusted net tangible book value per share of $2.61 to existing stockholders and immediate dilution in pro

forma as adjusted net tangible book value per share of $9.82 to new investors purchasing common stock in this offering, based on the initial public offering price of $17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes on the pro forma as adjusted basis described above, the total number of shares of voting common stock and non-voting common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at the initial public offering price of $17.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders	32,411,910	78.6%	$191,680,903	56.1%	$ 5.91
New investors	8,825,000	21.4%	$150,025,000	43.9%	$ 17.00
Total	41,236,910	100.0%	$341,705,903	100.0%	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our voting common stock and non-voting common stock held by existing stockholders would be reduced to 76.2% of the total number of shares of our voting common stock and non-voting common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to 23.8% of the total number of shares of our voting common stock and non-voting common stock outstanding after this offering.

The discussion and tables above are based on 32,411,910 shares of our common stock and non-voting common stock outstanding as of December 31, 2020, including 932,279 shares of unvested restricted common stock (which are not considered outstanding for accounting purposes), and after giving effect to the automatic conversion of all outstanding shares of our convertible preferred stock into an aggregate of 24,392,498 shares of our common stock (of which 1,150,000 will be shares of non-voting common stock) immediately prior to the completion of this offering, and excludes:

- 2,670,419 shares of common stock issuable upon the exercise of stock options outstanding as of December 31, 2020 under our 2018 Plan at a weighted-average exercise price of $4.16 per share;
- 74,766 shares of common stock issuable upon the exercise of stock options outstanding, which were granted outside our 2018 Plan, as of December 31, 2020 at an exercise price of $5.35 per share;
- 1,143,820 shares of common stock reserved for future issuance as of December 31, 2020 under the 2018 Plan, which ceased to be available for issuance at the time that the 2021 Stock Plan becomes effective;
- 65,186 shares of common stock contingently issuable to a licensor in connection with this offering;
- 3,015,907 shares of our common stock that became available for future issuance under the 2021 Stock Plan, which became effective in connection with this offering; and
- 852,971 shares of our common stock reserved for future issuance under our 2021 ESPP, which became effective in connection with this offering.

To the extent that new stock options are issued or any outstanding options are exercised, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes appearing at the end of this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statements of operations data for the years ended December 31, 2020 and December 31, 2019 and the balance sheet data as of December 31, 2020 and 2019 from our audited financial statements appearing at the end of this prospectus. Our historical results are not necessarily indicative of the results that should be expected in any future periods.

	Year ended December 31, 2020	Year ended December 31, 2019
	(in thousands, except share and per share amounts)	
Statements of Operations Data:		
Operating expenses:		
Research and development	$ 15,278	$ 13,369
General and administrative	7,406	5,009
Total operating expenses	22,684	18,378
Loss from operations	(22,684)	(18,378)
Interest and other income (expense), net	(23)	223
Net loss	$ (22,707)	$ (18,155)
Unrealized loss on marketable securities	(13)	—
Total other comprehensive loss	(13)	—
Total comprehensive loss	$ (22,720)	$ (18,155)
Net loss attributable to common stockholders	$ (22,707)	$ (18,155)
Net loss per common share, basic and diluted	$ (3.40)	$ (2.84)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	6,685,066	6,383,261
Pro forma net loss per common share, basic and diluted	$ (1.07)	
Pro forma weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	21,192,565	

(1) See Note 14 to our financial statements appearing at the end of this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the calculation of basic and diluted pro forma net loss per share attributable to common stockholders.

	As of December 31,	
	2020	2019
	(in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	$149,488	$ 38,978
Working capital(1)	147,347	38,503
Total assets	152,778	41,942
Convertible preferred stock	186,151	56,690
Total stockholders' deficit	(38,147)	(17,102)

(1) We define working capital as current assets less current liabilities.

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 prospectus and our financial statements and the related notes appearing elsewhere in this prospectus. This discussion and other parts of this prospectus 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 prospectus.

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 non-malignant blood, immune and metabolic disorders. In the organ transplant setting, which is our initial focus, we believe our proprietary therapeutic approach, which we call **Facilitated Allo-HSCT Therapy**, could prevent organ rejection without the morbidity and mortality that has been associated with the use of lifelong immunosuppression. Beyond the organ transplant setting, our Facilitated Allo-HSCT Therapy also has the potential to treat a range of severe non-malignant blood, immune and metabolic disorders, in each case with potential for similar outcomes to what has previously been observed with HSCT, while mitigating the toxicities, morbidities and extended hospital stay associated with the fully myeloablative conditioning typically required by HSCT. We believe that these indications, individually and collectively, represent a significant unmet need and commercial opportunity.

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

Since our inception, we have devoted substantially all of our resources to developing our lead product candidate, FCR001, building our intellectual property portfolio, business planning, raising capital and providing general and administrative support for these operations. To date, we have principally financed our operations through private placements of convertible preferred stock, together with payments under a former research collaboration with Novartis, Inc. and research grants. Through December 31, 2020, we had received net proceeds of $186.2 million from sales of our convertible preferred stock.

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 losses were $22.7 million and $18.2 million for the years ended December 31, 2020 and December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $43.0 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, upon the completion of this offering, 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.

As of December 31, 2020, we had cash and cash equivalents and marketable securities of $149.5 million. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities as of December 31, 2020, will enable us to fund our operating expenses and capital expenditure requirements at least into 2025. 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. See “Liquidity and Capital Resources.”

Impact of COVID-19 on Our Business

The 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. In addition, the pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could adversely affect our business, operations and ability to raise funds to support our operations.

We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. In response to the direction from state and local governmental authorities, we have limited the access to our facility to those individuals who are not performing critical research and laboratory support activities that must be completed on site, limited the total number of such people that can be present at our facility at any one time and required any employees working in our facility to receive negative COVID-19 tests before entering site. Timely enrollment in planned clinical trials is dependent upon clinical trial sites which have been adversely affected by global health matters, such as COVID-19. For example, screening and enrollment in our ongoing FREEDOM-1 Phase 3 clinical trial in the United States have been adversely impacted by the COVID-19 pandemic. In addition, we and the third-party manufacturers, 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 COVID-19 pandemic.

We cannot be certain what the overall impact of the 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.

License Agreement

In October 2018, the Company 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, 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. As of March 31, 2021, we have paid ULRF $125,000 in milestone payments and $100,000 in annual maintenance fees, for a total of $225,000.

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. On or prior to the Company's first underwritten public offering or any transaction that is treated as a deemed liquidation event, the Company may 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. At December 31, 2020 and December 31, 2019, the Company measured the fair value of the contingent equity consideration and recorded a contingent stock liability of $0.4 million and $0.1 million, respectively, in other liabilities (see Note 3 in accompanying audited financial statements).

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 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 ULRF.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

The following table summarizes our results of operations for the years ended December 31, 2020 and 2019:

	Years ended December 31,		
	2020	2019	Change
	(in thousands)		
Operating expenses			
Research and development	$ 15,278	$ 13,369	$ 1,909
General and administrative	7,406	5,009	2,397
Total operating expenses	22,684	18,378	4,305
Loss from operations	(22,684)	(18,378)	(4,305)
Interest and other income (expense), net	(23)	223	(246)
Net loss	$ (22,707)	$ (18,155)	$(4,552)

Research and development expenses

	Years ended December 31,		
	2020	2019	Change
	(in thousands)		
Direct research and development expenses by program:			
FREEDOM-1 program	$ 3,886	$ 6,049	$(2,163)
Other pre-clinical and clinical programs	454	—	454
Indirect research and development expenses:			
Personnel related (including stock-based compensation)	8,572	5,074	3,498
Facilities and other operating costs	2,366	2,246	120
Total research and development expenses	$ 15,278	$ 13,369	$ 1,909

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 $15.3 million for the year ended December 31, 2020, compared to $13.4 million for the year ended December 31, 2019. The increase of $1.9 million was primarily due to:

- An increase of $3.5 million in personnel costs related to the need for additional staff to conduct our FREEDOM-1 Phase 3 clinical trial, progress start-up activities in our FREEDOM-3 Phase 2 clinical trial and to advance other pre-clinical activities.
- An increase of $0.4 million in other pre-clinical and clinical program expense related to start-up activities for our FREEDOM-3 Phase 2 clinical trial; and

- An increase of $0.1 million in other unallocated costs related to consulting and other services in support of ongoing and planned clinical trials.

The increase in research and development expenses was offset by a decrease of $2.1 million in the direct program costs of FREEDOM-1 as the majority of start-up costs for this Phase 3 clinical trial were incurred in 2019.

General and Administrative Expenses

The following table summarizes our general and administrative expenses to support our business activities for the years ended December 31, 2020 and 2019:

	Years ended December 31,		
	2020	2019	Change
	(in thousands)		
Personnel related (including stock-based compensation)	$ 3,031	$ 2,208	$ 823
Professional and consulting fees	1,981	1,101	880
Facility-related and other	2,394	1,700	694
Total general and administrative expenses	$ 7,406	$ 5,009	$2,397

General and administrative expenses were $7.4 million for the year ended December 31, 2020 compared to $5.0 million for the year ended December 31, 2019. The increase in general and administrative costs of $2.4 million was primarily due to:

- An increase of $0.8 million in personnel costs primarily due to the hiring of additional personnel in our general and administrative functions as we continued to expand our operations to support the organization.
- An increase of $0.9 million fees primarily due to increased legal and accounting fees in association with our Series A-1 financing and Series B financing during 2020, as well as increased accounting and consulting fees in association with our IPO preparation; and
- An increase of $0.7 million in facility-related and other costs primarily due to an expanded lease agreement for additional space in our Louisville facility in 2020 and other expenditures to support our expanded operations.

Other Income (Expense), Net

Other income, net in the year ended December 31, 2020 was comprised of $0.4 million in interest income from our marketable securities and operating cash balance, $(0.1) million of net amortization expense on our marketable securities and $(0.3) million in expense related to a fair value adjustment of our contingent stock liability. Other income, net in the year ended December 31, 2019 was comprised of $0.2 million of interest income.

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. Through December 31, 2020, we had received net proceeds of $186.2 million from sales of our convertible preferred stock.

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 December 31, 2020, we had cash and cash equivalents of $17.6 million and marketable securities of $131.9 million.

Cash Flows

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

	Years ended December 31,		
	2020	2019	Change
		(in thousands)	
Net cash used in operating activities	$ (19,212)	$ (17,660)	$ (1,552)
Net cash used in investing activities	(133,300)	(562)	(132,738)
Net cash provided by financing activities	131,123	36,204	94,919
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (21,389)	$ 17,982	$ (39,371)

Cash Flow from Operating Activities

During the year ended December 31, 2020, operating activities used $19.2 million of cash, due to our net loss of $22.7 million, partially offset by non-cash charges of $1.9 million and net cash provided by changes in our operating assets and liabilities of $1.6 million. Non-cash charges primarily consisted of $1.0 million of stock-based compensation expense, $0.6 million of depreciation on fixed assets and amortization of marketable securities and $0.3 million of expense related to the fair value adjustment of our contingent stock liability. Net cash provided by changes in our operating assets and liabilities primarily consisted of a $1.0 million increase in accounts payable and accrued expenses related to timing and a decrease in current assets of $0.6 million driven by a decrease in our prepaid balances with contract research organizations.

During the year ended December 31, 2019, operating activities used $17.7 million of cash, due to our net loss of $18.2 million and $0.1 million of net cash used from changes in our operating assets and liabilities, partially offset by non-cash charges of $0.6 million. Non-cash charges primarily consisted of $0.4 million of depreciation expense and $0.2 million of stock-based compensation expense.

Cash Flow from Investing Activities

During the year ended December 31, 2020, investing activities used $133.3 million of cash, due to purchases of marketable securities of $158.2 million and purchases of property and equipment of $1.3 million, partially offset by maturities of marketable securities of $26.2 million.

During the year ended December 31, 2019, investing activities used $0.6 million of cash, consisting solely of purchases of property and equipment.

Cash Flow from Financing Activities

During the year ended December 31, 2020, net cash provided by financing activities was $131.1 million, primarily consisting of proceeds from our issuances of Series B preferred stock in September 2020 of $114.5 million, net of issuance costs, issuances of Series A-1 preferred stock in August 2020 of $15.0 million, net of issuance costs, early exercise of stock options of $1.0 million and issuances of common stock from exercise of stock options of $0.6 million.

During the year ended December 31, 2019, net cash provided by financing activities was $36.2 million, primarily consisting of proceeds from our issuances of Series A-1 preferred stock in December 2019 of

$19.3 million, net of issuance costs, and issuances of Series A preferred stock in December 2019 of $16.9 million, net of issuance costs.

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, upon the completion of this offering, 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 the anticipated net proceeds from this offering, together with our existing cash and cash equivalents and marketable securities as of December 31, 2020, will enable us to fund our operating expenses and capital expenditure requirements at least into 2025. 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 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 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

The following table summarizes our contractual obligations as of December 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
	(in thousands)				
Operating lease commitments(1)	1,425	515	910	—	—
Total	$1,425	$ 515	$910	$ —	$ —

(1) Represents our future minimum lease obligation under our non-cancelable operating leases for our manufacturing facility in Louisville, KY, our corporate offices in Wellesley, MA and additional corporate space in Louisville, KY.

Apart from the contracts with payment commitments that we have reflected in the table, 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 financial statements 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 financial statements appearing at the end of this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Contract Costs and Accruals

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

- vendors in connection with clinical development activities; and
- CROs and investigative sites in connection with pre-clinical, non-clinical, and human clinical trials

We base the expense recorded related to external research and development on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple CROs that supply, conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

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.

Determination of the Fair Value of Common Stock

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been 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.

These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. We account for equity-based compensation in accordance with ASC 718, *Compensation-Stock Compensation* (ASC 718). In accordance with ASC 718, compensation cost is measured at estimated fair value and is included as compensation expense over the vesting period during which service is provided in exchange for the award. Our common stock valuation was prepared using the option-pricing method (OPM), which used a market approach to estimate our enterprise value.

The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value if the funds available for distribution to stockholders exceed the value of the liquidation preferences at the time of a liquidity event, such as a strategic sale or merger. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock liquidation preference is paid. The OPM uses the Black-Scholes option pricing model to price the call options. This model defines the fair value of securities as functions of the current fair value of a company and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

The PWERM is a scenario-based analysis that estimates the value per share of common stock based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes considered by the Company, as well as the economic and control rights of each share class. The OPM, PWERM and/or the hybrid methods were used for our November 2018, October 2019, August 2020 and October 2020 valuations.

The assumptions used to determine the fair values of stock options granted to employees and directors during the years ended December 31, 2020 and December 31, 2019, are presented as follows:

	December 31,	
	2020	2019
Fair value of common stock	$1.44-5.72	$1.12
Dividend yield	—%	—%
Volatility	72.8%-80.6%	72.4%-72.8%
Risk-free interest rate	0.31%-1.46%	1.43%-2.69%
Expected term (years)	6.25	6.25

The assumptions underlying these valuations were highly complex and subjective and represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be determined based on the quoted market price of our common stock.

Grant of Stock-Based Awards

The following table sets forth by grant date the number of shares subject to options granted between January 1, 2019 and December 31, 2020, the per share exercise price of the options, the fair value of common stock per share on each grant date, and the per share estimated fair value of the options:

Grant date	Number of shares subject options granted	Per share exercise price of options	Fair value per common share on grant date	Black-Scholes value per share on grant date
November 2018	74,766	$ 5.35	$ 1.12	$ 0.21
December 2018—October 2019	1,584,884	$ 0.90	$ 1.12	$ 0.80
February 2020—July 2020	1,005,011	$ 0.96	$ 1.44	$ 1.07
August 2020	273,275	$ 3.90	$ 3.90	$ 2.51
October 2020—December 2020	1,661,523	$ 5.72	$ 5.72	$ 3.96

The Company utilizes a third-party valuation firm to assist in determining the grant date fair market value of its common stock. In connection with the initial audit of the Company's 2019 financial statements, the fair market value of our common stock was re-valued as of November 1, 2018 and February 7, 2020, solely for financial reporting purposes. This revaluation resulted in recognition of additional stock compensation expense. The fair value of common stock as of November 1, 2018 was determined to be $1.12 as compared to the initial $0.90 third-party fair valuation determination. The exercise price for stock options granted from November 1, 2018 through October 10, 2019 was derived from the initial valuation in November 2018. The fair value of common stock as of February 7, 2020 was determined to be $1.44 as compared to the initial $0.96 third-party fair valuation determination. The exercise price for stock options granted from February 7, 2020 through August 19, 2020 was derived from the initial valuation in February 2020.

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: (1) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) 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 plus the proposed aggregate amount of gross proceeds to us as a result of this offering 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 after this offering 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 end of this prospectus.

Quantitative and Qualitative Disclosures About Market Risks

Our primary exposure to market risk relates to changes in interest rates. As of December 31, 2020 and 2019, we had cash and cash equivalents of $17.6 million and $39.0 million, respectively. As of December 31, 2020, we had marketable securities of $131.9 million. We had no marketable securities as of December 31, 2019. Our exposure to interest rate sensitivity is affected by changes in the general level of U.S. interest rates. If market interest rates were to increase immediately and uniformly by 100 basis points, or one percentage point, the net fair value of our interest sensitive marketable securities would not experience a material change in fair market value.

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

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2020 or 2019.

BUSINESS

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 non-malignant 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 non-malignant 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.

Our lead product candidate, **FCR001**, which is central to our Facilitated Allo-HSCT Therapy, is a novel allogeneic cell therapy comprised of stem and immune cells that are procured from a healthy donor, who is also the organ donor in the case of organ transplantation. FCR001 is rapidly processed in our GMP facility using our proprietary manufacturing methods. Then, at the time of transplant, FCR001 is administered to the recipient following nonmyeloablative conditioning, which is designed to be less toxic than myeloablative conditioning. A fully myeloablative conditioning regimen consists of a combination of agents and high doses of total body irradiation that destroy hematopoietic stem cells **(HSCs)** in the bone marrow and results in profound depletion of HSC-derived cells within one to three weeks following administration that is irreversible, and in most instances is fatal unless rescued by a stem cell transplant. The nonmyeloablative conditioning for FCR001 entails lower doses of chemotherapy and total body irradiation, causes less depletion of blood cells and does not require stem cell support for the recipient to resume the production of blood cells and platelets. We do not outsource any key aspect of our cell processing. We are developing FCR001 as a pipeline-in-a-product with the potential to address the therapeutic areas described above.

We are currently enrolling patients in FREEDOM-1, a randomized, controlled, open-label Phase 3 registration trial in the United States of FCR001 in 120 adult living donor kidney transplant (**LDKT**) recipients. The goal of this trial is to evaluate the potential of FCR001, when administered the day after the kidney transplant, to induce durable, drug-free immune tolerance in the recipient of the transplanted kidney. Inducing durable immune tolerance to a transplanted organ without the morbidities associated with lifelong immunosuppression is a goal that has been broadly referred to in the transplant field as the "*Holy Grail*" of solid organ transplant. The primary endpoint of FREEDOM-1 is the demonstration that the lower end of our confidence interval of FCR001 patients free from chronic immunosuppression and without biopsy-proven acute rejection (**BPAR**) at 24 months post-transplant. The secondary endpoint is to evaluate the change in renal function as measured by estimated glomerular filtration rate (**eGFR**), which estimates how much blood passes through the filters in the kidney that remove waste from the blood, from post-transplant baseline (month one) to month 24 in FCR001 recipients.

We have robust, long-term Phase 2 data supporting our lead indication in LDKT. The primary endpoint of our Phase 2 trial was to determine whether the administration of FCR001 can induce durable tolerance to the donated kidney and substantially reduce or eliminate the requirement for immunosuppression within 12 months following transplant. In our Phase 2 trial, 26 of 37 LDKT patients treated with FCR001 (70%) were able to completely discontinue their chronic immunosuppression approximately one year after receiving their transplant. After mid-course optimizations to the Phase 2 protocol, 14 of the last 17 patients (82%) in the trial were able to discontinue their chronic immunosuppression by approximately one year post-transplant. Every transplant recipient who was weaned off immunosuppression has remained off chronic immunosuppression, without any organ rejection, for the duration of their follow-up. As of January 31, 2021, we have followed these patients for a

median of over six years post-transplant, and the longest for over 11 years post-transplant. These results were achieved despite significant degrees of immune system human leukocyte antigen (**HLA**) mismatch between the donors and recipients, and the degree of immune mismatch between the donor and recipient did not appear to impact the safety or efficacy of our therapy candidate.

We have identified a near-term surrogate marker, chimerism, that we believe to be highly predictive of the ability of an organ transplant recipient to durably discontinue chronic immunosuppression at one year post-transplant without rejecting the transplanted organ. Chimerism refers to a state whereby the recipient's and donor's blood and immune cells co-exist in the recipient, creating a reciprocal state of immune tolerance called allogeneic tolerance. We use a simple blood test to measure and regularly monitor the degree of donor chimerism in the recipient, which has to date shown a close association in our research with long-term immune tolerance in patients who have received FCR001. In our Phase 2 trial of FCR001, we observed that 26 of 27 recipients (96%) who achieved donor chimerism at six months post-transplant were successfully weaned off chronic immunosuppression over approximately the next six months, including recipients who were highly HLA-unmatched and/or unrelated to their donors. In addition, donor chimerism at three months post-transplant, which we observed in 26 of 29 recipients (90%), was also highly predictive of successful weaning off chronic immunosuppression at approximately one year post-transplant.

We continue to monitor the patients in our Phase 2 trial for long term safety and durability of effect. Through January 31, 2021, we have accumulated approximately 235 patient-years of exposure to FCR001 in LDKT, and the safety profile in our patients is generally consistent with that expected if a patient were to separately receive both a standard kidney transplant and an allo-HSCT with nonmyeloablative conditioning. Specifically, through January 31, 2021, there were three deaths and two cases of graft versus host disease (**GvHD**), which is a condition that occurs when donated stem cells attack the recipient. The most commonly reported serious adverse events were fever, deep vein thrombosis, including among several patients who had predisposing factors such as central venous catheter placements or Factor V deficiency, diarrhea, pneumonia and febrile neutropenia (or low white blood cell counts with a high fever). Preliminary data indicates that patients who were able to be weaned off immunosuppression with FCR001 had preserved kidney function and third-party data suggests a markedly lower reliance on cardiovascular medications at four years post-transplant compared to traditional transplants with chronic immunosuppression over a similar time frame. Based on the data generated from our Phase 2 trial, FDA has granted Regenerative Medicine Advanced Therapy (**RMAT**) and Orphan Drug Designation for FCR001 for LDKT.

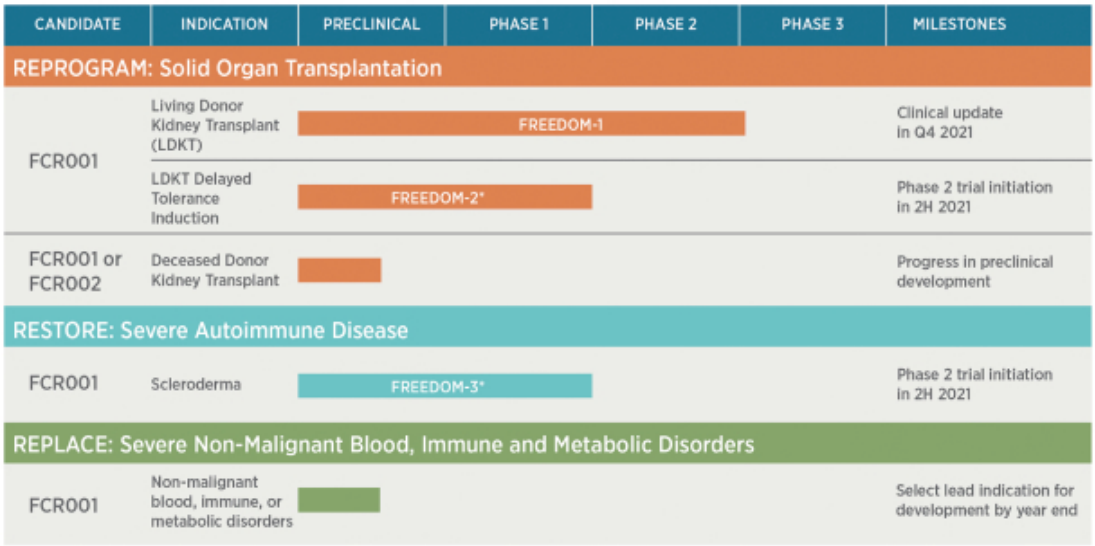
Under our open investigational new drug application (**IND**), the FDA has cleared us, based in part upon the data to date from our ongoing Phase 2 trial, to proceed with an updated protocol for our Phase 2 FREEDOM-2 trial, which we plan to initiate in the second half of 2021. In FREEDOM-2, we will evaluate the potential of FCR001 to induce durable immune tolerance in patients who have previously received a kidney from a living donor, which is a process called delayed tolerance. In this trial, FCR001 will be administered between three and twelve months after the initial kidney transplant. Positive results in this trial would be the first step to potentially extending the use of FCR001 to a portion of the prevalent LDKT population and could also support extending our Facilitated Allo-HSCT Therapy to deceased donor transplant procedures. Every year in the United States, there are approximately four times as many deceased donor solid organ transplants as living donor transplants. We are conducting preclinical research to evaluate whether we can procure the same types of stem and immune cells from a recently deceased donor as from a living donor. If our preclinical studies are successful, we intend to assess the ability of FCR001, or a product candidate similar to FCR001 (**FCR002**), to induce durable allogeneic tolerance in a recipient of an organ from a deceased donor.

Additionally, the FDA has cleared our IND, based in part upon the data to date from our ongoing Phase 2 trial, to proceed with our Phase 2 FREEDOM-3 trial, which we plan to initiate in the second half of 2021. In FREEDOM-3, we will evaluate the safety and efficacy of FCR001 in adults with a severe form of scleroderma, a debilitating autoimmune disease. In our Phase 2 LDKT trial, all seven LDKT patients who required a kidney transplant as a result of a kidney-related autoimmune disease, and who achieved durable chimerism and could be withdrawn from chronic immunosuppression at one year, have not experienced recurrence of their prior kidney-

related autoimmune disease. We believe that this observation, as well as the current use of HSCT for severe scleroderma, supports the potential of our therapy in autoimmune diseases. We believe that positive data in the FREEDOM-3 trial in severe scleroderma patients could support the potential applicability of FCR001 to other severe, systemic autoimmune diseases.

There are also a number of severe non-malignant blood, immune and metabolic disorders for which allo-HSCT has already been observed to be potentially curative, but its use to date for these indications has been limited by two important considerations: (i) it necessitates matching the patient with a highly HLA-matched stem cell donor and (ii) it subjects the patient to the toxicities, morbidities and an extended hospital stay associated with fully myeloablative conditioning. The conditioning regimen is a key component of HSCT procedures that aims to provide sufficient suppression of the recipient's immune system to prevent rejection of the transplanted donor stem cells, and to provide sufficient space in the recipient's bone marrow to permit engraftment and maturation. Moreover, in certain disease states, the conditioning regimen also plays a role in eradicating immune or blood cells that drive the underlying disease that prompts the need for an HSCT. A fully myeloablative conditioning regimen consists of a combination of agents (such as busulfan, cyclophosphamide, and high doses of total body irradiation) that destroy HSCs in the bone marrow and results in profound depletion of HSC-derived cells within one to three weeks following administration that is irreversible, and in most instances is fatal unless rescued by a stem cell transplant. Non-myeloablative conditioning regimens, which are designed to be less toxic than myeloablative regimens (due to lower doses of chemotherapy and total body irradiation), cause minimal depletion of blood cells and do not require stem cell transplant for the recipient to resume production of HSC-derived cells. Since our Phase 2 data suggest that our Facilitated Allo-HSCT Therapy can promote durable incorporation of the donated transplanted stem cells into the recipient where they will grow and reproduce, which is a process known as engraftment, and diverse immune reconstitution regardless of degree of HLA match and with a less toxic nonmyeloablative (as opposed to myeloablative) conditioning regimen, with a low incidence of GvHD, we intend to explore the potential of our Facilitated Allo-HSCT Therapy in one or more such disorders. We expect to announce the first of these initiatives by the end of 2021.

The pipeline-in-a-product potential of FCR001, and our Facilitated Allo-HSCT Therapy more broadly, is summarized in the graphic below:



* Open INDs permit us to move directly into these Phase 2 trials based on existing FCR001 safety data.

We own unencumbered, worldwide rights to all of our product candidates and technologies.

Our manufacturing strategy is designed to meet the high quality and demand needs of clinical supply and commercial launch of any approved product. We manufacture FCR001 in less than a day at our GMP cell processing facility, employing robust, reproducible, proprietary methods which remain substantially unchanged as we have progressed FCR001 from Phase 2 to Phase 3. We do not outsource any key aspect of our cell processing. Unlike gene therapies or chimeric antigen receptor T-cell (**CAR-T**) therapies, our manufacturing process does not employ viral vectors, nor do we perform any transductions or *ex vivo* cell expansions.

Our executive management team has over 100 years of experience developing and investing in innovative cell therapies and biopharmaceutical products. Our founder and Chief Scientific Officer, Dr. Suzanne T. Ildstad, has published over 230 peer-reviewed papers, is a named inventor or co-inventor on over 35 patents, and has dedicated herself to inducing durable immune tolerance for nearly 30 years.

We have raised $190.0 million in aggregate gross proceeds since November 2018 through two private financings. Our investors include Blackstone Life Sciences, Surveyor Capital (a Citadel company), Viking Global Investors, Longitude Capital, Qiming Venture Partners USA, Cormorant Asset Management, Invus, BlackRock, Eventide, Logos Capital, Aisling Capital, and Pamoja Capital, as well as one other large-but-unnamed investment fund. Between 2002 and 2018, we received substantial non-dilutive funding from grants, as well as from a prior strategic collaboration with Novartis AG.

Our Strengths

We aim to remove solid organ transplantation recipients' need for chronic immunosuppression and treat patients who suffer from severe autoimmune diseases and certain severe non-malignant blood, immune and metabolic disorders. Our competitive strengths include the following:

- **Registration-stage lead program with long-term, compelling Phase 2 data indicating the potential to induce durable immune tolerance to a transplanted organ.** In our Phase 2 trial of 37 adult living donor kidney transplant patients treated with our investigational therapy, FCR001, 26 of 37 (70%) of patients were able to discontinue their use of chronic immunosuppression approximately one year after receiving their transplant. After mid-course optimizations to the Phase 2 protocol, 14 of the last 17 patients (82%) in the trial were able to discontinue their chronic immunosuppression by approximately one year post-transplant. Every patient in our trial who was weaned off their transplant immunosuppression has remained off immunosuppression for the duration of their follow-up. As of January 31, 2021, we have followed these patients for a median of over six years, and the longest for more than 11 years. We believe these data indicate the potential of FCR001 to enable the majority of transplant patients to durably remain off chronic immunosuppression without rejecting the transplanted organ.
- **Near-term surrogate marker, which was highly predictive of long-term tolerance in our Phase 2 trial.** We have identified a near-term surrogate marker, chimerism, which, through a simple blood test, allows us to routinely monitor and, thus far, predict long-term immune tolerance in patients who received FCR001. In our Phase 2 trial of FCR001, we observed that 26 of 27 recipients (96%) who achieved chimerism at six months post-transplant were able to be weaned off their chronic immunosuppression over approximately the next six months, including recipients who were highly HLA-unmatched or unrelated to their donors. Donor chimerism at three months post-transplant, which we observed in 26 of 29 recipients (90%), was also highly predictive of this outcome. We intend to continue to assess donor chimerism as a potential surrogate marker for long term immune tolerance in our ongoing Phase 3 trial of FCR001.
- **Significant pipeline-in-a-product opportunity for FCR001, with potential across multiple therapeutic areas.** Beyond the organ transplant setting, we believe that FCR001 also has the potential to define a new standard of care for the treatment of patients with severe autoimmune diseases and severe non-malignant blood, immune or metabolic disorders where standard hematopoietic stem cell transplant

(**HSCT**) has already been observed to be potentially curative. We believe that our Facilitated Allo-HSCT Therapy has the potential to achieve similar outcomes in such patients as have been observed with standard HSCT, but with considerably greater degrees of HLA mismatch than was previously thought to be possible or safe for allogeneic HSCT (**allo-HSCT**), and with lesser toxicities, co-morbidities, and costs compared to the myeloablative conditioning that is generally needed for HSCT in such settings. In our Phase 2 LDKT trial, all seven patients who required kidney transplant as a result of kidney-related autoimmune disease and who were successfully tolerized with FCR001, have not experienced recurrence of their prior kidney-related autoimmune diseases. We have followed these patients from four to ten years post-transplant. Moreover, we observed a very low rate of graft versus host disease (**GvHD**) in our Phase 2 patients despite significant degrees of HLA-mismatch between the donors and recipients, and we have optimized our Phase 3 protocol in ways that we believe further reduce the risk of GvHD. We believe that our Facilitated Allo-HSCT Therapy has the potential to enable the broader use of allo-HSCT in indications where it could be curative, but, at present, is not widely used due risks associated with fully myeloablative conditioning, as well as concerns over GvHD.

- **Fully in-house, robust and efficiently scalable manufacturing and testing.** We have developed a robust and reliable one-day manufacturing process for FCR001 that does not involve complex and time-consuming cell expansion or gene modification using viral vectors. Unlike many organizations that outsource their cell processing activities, our in-house manufacturing capabilities have allowed us to better control our manufacturing processes and to develop significant know-how regarding all aspects of our processes and analytics. Our process for making FCR001 has remained substantially unchanged as we have progressed from Phase 2 to Phase 3, and we have developed and qualified our own in-house potency assays. We believe our current manufacturing processes to be scalable to address our future commercial needs in North America without substantial modifications, potentially with a single, centrally-located facility. Moreover, we expect to use substantially the same manufacturing process, testing and starting material for all of our currently planned programs and indications, with the exception of our deceased donor transplant program.
- **Significant first mover advantage in solid organ transplants with long-term durability data, a proprietary process and broad IP protection.** Chronic immunosuppression is a very significant concern and burden for transplant and autoimmune disease patients. The ability to durably wean such patients off their chronic immunosuppression would confer a significant benefit to their health and quality of life (**QoL**). As of January 31, 2021, we have followed our Phase 2 patients for a median of over six years, and the longest for more than 11 years, demonstrating 100% durability in all patients who were successfully weaned off their chronic immunosuppression for the duration of their follow-up. We will continue to follow these patients for up to 15 years from the time of their transplant, to monitor the long-term safety and durability of our therapy. Through January 31, 2021, we have accumulated approximately 235 patient-years of exposure to FCR001 in LDKT. We believe these long-term data represent a significant first mover advantage compared to any third party seeking to demonstrate comparable results to ours. We have also established an extensive intellectual property portfolio, including issued claims directed at FCR001 composition of matter and pending claims directed at our potency assays. We believe that our intellectual property portfolio, as well as our substantial know-how and trade secrets associated with our proprietary manufacturing process, create significant additional barriers to entry.
- **Unencumbered worldwide rights to FCR001 and all of our other programs.** We own all rights to develop and commercialize FCR001 and all of our other programs in all indications and territories worldwide. We hold exclusive rights to all of our intellectual property for all indications.
- **Talented and experienced team with deep and relevant experience.** Our executive management team has over 100 years of experience developing and investing in innovative cell therapies and biopharmaceutical products. Our founder, Dr. Suzanne T. Ildstad, has over 230 peer reviewed manuscripts, is a named inventor or co-inventor on over 35 patents, and has dedicated herself to inducing durable immune tolerance in the organ transplant setting for nearly 30 years.

Our Strategy

Our goal is to transform the standard of care in solid organ transplantation, severe autoimmune disease, and certain severe non-malignant blood, immune and metabolic disorders, all with a single therapeutic approach. We plan to do this through our proprietary investigational therapy, FCR001, the cornerstone of our novel Facilitated Allo-HSCT Therapy. Our strategy is comprised of the following key elements:

- **Establish Talaris as a leader in developing, manufacturing, and ultimately commercializing cell therapies to address multiple areas of high unmet need.** Our Facilitated Allo-HSCT Therapy combines nonmyeloablative conditioning and optimized stem cell transplant protocols with our investigational therapy, FCR001. FCR001 consists of a unique and proprietary composition of donor stem and immune cells, which are processed via our proprietary manufacturing methods. We believe that FCR001 and our proprietary therapeutic approach have the potential to transform the standard of care for a range of severe non-malignant blood, immune and metabolic disorders.
- **Advance FCR001 through clinical development, registration, and commercialization in LDKT.** Our lead product candidate, FCR001, is a single-dose, investigational cell therapy that is currently in an ongoing Phase 3 registration trial known as FREEDOM-1, for LDKT. The goal of this trial, in which FCR001 is administered the day after the kidney transplant, is to assess the potential of our therapy to induce durable, drug-free immune tolerance in the transplant recipient to their donated kidney. In the second half of 2021, we also expect to initiate FREEDOM-2, a Phase 2 trial to evaluate the potential for FCR001 to induce durable immune tolerance to a donated kidney in patients who have previously received a kidney from a living donor, which we refer to as “delayed tolerance.”
- **Extend FCR001 clinical development to severe autoimmune diseases.** We intend to investigate the potential of FCR001 to treat certain severe, systemic autoimmune diseases in which HSCT has already been observed to be potentially curative, albeit with significant risks. In the second half of 2021, we expect to initiate FREEDOM-3, a Phase 2 trial that will evaluate the safety and efficacy of FCR001 in patients with a severe form of scleroderma. Scleroderma is a complex and heterogeneous systemic autoimmune disease affecting multiple tissues and organs. We believe that positive proof of concept data from FREEDOM-3 could support the potential of our Facilitated Allo-HSCT Therapy to be disease-modifying or even curative in scleroderma as well as certain other severe, systemic autoimmune diseases.
- **Further extend FCR001 clinical development to certain severe non-malignant blood, immune or metabolic disorders.** We believe that our Facilitated Allo-HSCT Therapy has the potential to benefit patients in other severe non-malignant settings where allo-HSCT has previously been associated with clinical benefit and/or curative potential, but where the use of allo-HSCT has been limited due to the challenge of identifying highly HLA-matched donors and the significant toxicities, co-morbidities, and lengthy hospitalization associated with myeloablative conditioning. We expect to announce our first initiative in this therapeutic area by the end of 2021.
- **Explore the potential to extend our therapeutic approach to deceased donor organ transplantation.** Annually in the United States, there are more than four times as many deceased donor transplants as living donor transplants. We are conducting preclinical research to explore whether we can successfully procure and process cells from deceased donors to produce FCR001 or a product candidate similar to FCR001, which we would refer to as **FCR002**. If successful, this could extend the potential of our Facilitated Allo-HSCT Therapy to benefit recipients of organs from deceased donors, significantly expanding our commercial opportunity in kidney transplant and other solid organ transplant patients.
- **Further scale our in-house manufacturing and analytical capabilities and supply chain logistics.** We have developed a robust and reproducible proprietary manufacturing process and streamlined logistics to produce FCR001 in-house at our centrally located and dedicated cell processing facility. Our current facility is sufficient for all of our currently contemplated clinical supply needs and we

believe that, if FCR001 is approved, we are well positioned to serve our initial commercial markets with our existing and planned infrastructure. We intend to further scale our manufacturing and processing approaches to appropriately address our anticipated commercial needs, which will require significant resources.

- **Commercialize FCR001 independently in North America, if approved, and explore other markets through strategic collaborations.** We have global development and commercialization rights to FCR001 in all indications and geographies. Given the high concentration of Clinical Centers of Excellence performing allo-HSCT and solid organ transplant in North America, we plan to advance our Facilitated Allo-HSCT Therapy independently through clinical development and commercialization in these geographies in our three main areas of therapeutic interest. We intend to explore expanding into other high-value markets, notably EU and Asia, either alone or in collaboration with global or regional partners. We may also explore collaborations with partners in areas outside of our core areas of therapeutic interest.

Overview of Immune Intolerant Indications and Current Treatment Approaches

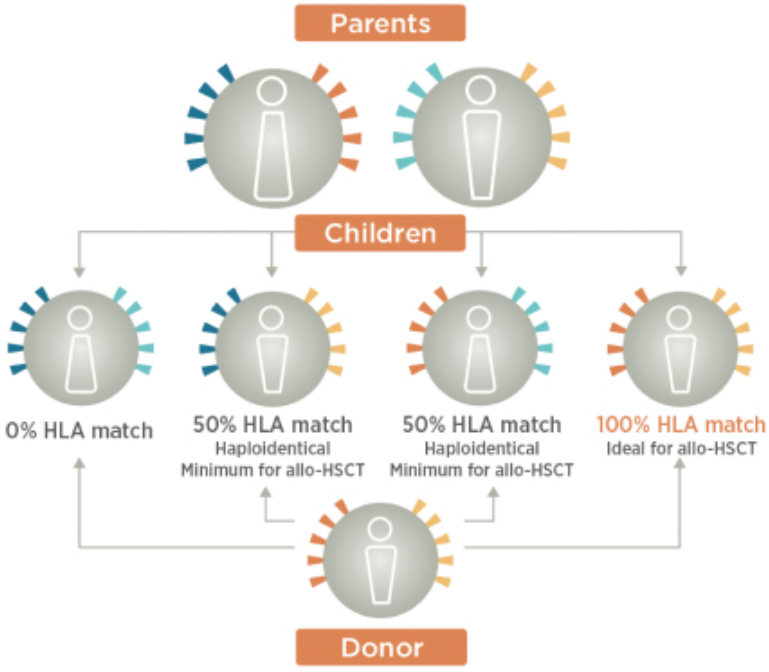
Immune Tolerance and HLA Inheritance

The human immune system is composed of cells that mature from hematopoietic stem cells (**HSCs**). HSCs are immature cells found primarily in the bone marrow that can develop into all types of blood and immune cells that protect individuals against infection, tumors, and other pathogens. In healthy individuals, the immune system distinguishes “self” antigens from “non-self” foreign antigens (e.g., transplanted organs, infectious agents or cancerous cells) and selectively mounts a protective attack against “non-self” foreign antigens while avoiding an attack on “self” antigens. The immune system’s natural process for not mounting an immune response to antigens it deems as “self” is referred to as **immune tolerance**. An autoimmune disease occurs when the immune system mistakenly recognizes some aspect of “self” as “non-self” and attacks those cells or tissues.

The immune system distinguishes “self” versus “non-self” predominantly via the major histocompatibility complex (**MHC**). The MHC is a group of proteins expressed on the surface of most cells that function to present “self” or “non-self” antigens to lymphocytes, which mediate the immune response against antigens that are recognized as “non-self.” In humans, the MHC is composed of highly genetically diverse MHC proteins called human leukocyte antigens (**HLAs)**. As depicted in the figure below, human cells express combinations of multiple HLA proteins that collectively define an individual’s unique “tissue type” or a distinct molecular “self” signature.

The genes that encode HLAs are inherited in sets called haplotypes. An individual inherits one haplotype from each parent; as a result, their tissue type is 50% matched, or haploidentical to each parent's tissue type. As shown in the figure below, if two children inherit the same HLA haplotypes from their parents, they are fully HLA matched. Siblings have a one in four chance of having a complete HLA match in their tissue types. Even if 100% HLA-matched, siblings are not genetically identical unless they are identical twins.

Illustration of HLA Matching



Although the immune system plays a vital role in eliminating pathogens and damaged cells, it poses significant challenges in two distinct areas where immune-mediated attack of antigens deemed non-self is detrimental: (1) allogeneic transplantation of solid organs, such as kidneys, or of HSCs; and (2) autoimmune diseases.

Allogeneic Transplantation of Solid Organs

In solid organ transplantation, practitioners generally seek a tissue-typing match of six HLA proteins between donors and recipients to lower the risk of the immune system recognizing the donated organ as "non-self", which can trigger immune-mediated rejection of the donated organ by the recipient's immune system, a process called allograft rejection. The greater the HLA match, the lower the risk of rejection because the recipient's immune system is more likely to recognize the foreign cells as similar to "self." However, with the exception of identical twin donor/recipient pairs, even recipients with a 6 out of 6 HLA match must take lifelong immunosuppression drugs to prevent life-threatening organ rejection. Organ rejection can occur immediately (hyperacute), within months (acute) or gradually over years (chronic) following transplant.

Normally, an organ transplant recipient's immune system sees the donated organ as foreign and will attack it, which is a process called rejection. To prevent this process, anti-rejection medicines are used to suppress the transplant recipient's immune system, and are accordingly termed immunosuppressants. Solid organ transplant recipients require

a regimen of chronic immunosuppression that entails daily treatment with these medications for as long as the recipient's graft continues to function, which can span several decades. A standard immunosuppression regimen typically includes one or more high dose immunosuppressant drugs administered in the hospital at the time of transplant, called induction therapy, followed by lifelong, daily maintenance treatment, typically with tacrolimus (Prograf ®, Envarsus XR ®, generics), mycophenolate mofetil (**MMF**: CellCept ®, Myfortic ®, generics), and frequently also includes a corticosteroid (usually prednisone). Other maintenance therapies used in lieu of tacrolimus include everolimus, sirolimus, and belatacept. Although immunosuppressants can be effective at preventing organ rejection, they have many drawbacks, including but not limited to the following:

- **Immunosuppressant medications do not induce tolerance to transplanted organs and require chronic dosing.** These medicines broadly impair the recipient's immune system to reduce the risk of rejecting the organ, but do not train the recipient's immune system to recognize the "non-self" antigens on the organ as "self." Thus, recipients must take immunosuppressants for as long as their donated organ is functioning.
- **Chronic immunosuppressant treatment can damage kidneys, ultimately leading to loss of the transplanted organ.** Ironically, long-term treatment with immunosuppressant medications such as tacrolimus can be toxic to, and can cause premature loss of, kidneys. Kidneys are the most commonly transplanted organs for which transplant recipients take immunosuppressants to prevent rejection. The half-life of a transplanted kidney is between 15.5 and 20.9 years, with one-third of LDKTs and approximately half of deceased donor kidney transplants failing within 10 years. Individuals whose transplants fail typically require hemodialysis, at an average Medicare fee-for-service cost in the United States of approximately $90,000 per year. Hemodialysis imposes a substantial negative impact on the patient's QoL and is associated with significant morbidity and mortality. If a patient whose transplant has failed is fortunate enough to locate another organ donor, they must undergo a repeat transplant. All of these factors lead to significant burdens individually on patients and systemically to our healthcare system. Total hospital charges for a solid organ transplant in the United States average $442,500. This figure does not include any costs outside of the 30-day window following the transplant.
- **Chronic immunosuppressant treatment is associated with an increased risk of cancer.** Several studies have demonstrated that the degree and duration of immunosuppression influence the risk for post-transplant malignancies. Most notably, in a study of over 175,000 solid organ transplant recipients from 1987 to 2008, more than 30 types of cancer were identified in over 10,650 cases, which correlated with a twofold increased incidence relative to the general population. Cancers with a fivefold or greater increase compared with the general population included Kaposi's sarcoma, skin cancers, non-Hodgkin's lymphoma, and cancers of the liver, anus, vulva and lip. Cancer accounts for nearly 25% of overall mortality in kidney transplant patients.
- **Chronic immunosuppressant treatment is associated with significant co-morbidities that prompt need for many other medications.** Patients on chronic immunosuppression medication typically need to take numerous medicines—often 20 or more pills per day—to manage the numerous negative side effects and significant co-morbidities that chronic immunosuppressant medicines cause, notably:
  - **Cardiovascular complications.** Cardiovascular death is the leading cause of mortality in kidney transplant recipients. Chronic use of immunosuppressant medications can lead to hypertension, hyperlipidemia, and hypertriglyceridemia, all of which are risk factors for cardiovascular morbidity and mortality and accordingly prompt the need for medical management along with lifestyle modifications.
  - **Infection**. Viral, bacterial, and fungal infections collectively are among the leading causes of post-transplant mortality after cardiovascular death. Transplants recipients on chronic immunosuppression must often take numerous prophylactic anti-infectives and adapt their lifestyles to avoid exposure to infection.
  - **Metabolic abnormalities.** Approximately 12% of kidney transplant recipients develop post-transplant diabetes mellitus (**PTDM**) within the first five years post-transplant. Both corticosteroids and tacrolimus contribute to this complication, which requires medication to manage glycemic control. PTDM is associated with an increased risk of cardiovascular events, failure of the transplanted organ, and death.

- **Neurologic disorders.** Patients treated with tacrolimus over extended periods can experience a range of troubling neurologic adverse events including impaired cognition, tremors, neuropathies, depression, and sleep disorders.

- **The burden and cost of immunosuppressants can lead to non-compliance, which can adversely affect outcomes.** Reimbursement of immunosuppressant drugs, labs and associated medications for comorbidities varies greatly from patient to patient. The high cost (averaging nearly $25,000 in the first year and ranging from approximately $5,000 to $10,000 annually lifelong for tacrolimus and MMF alone) and decreased QoL associated with chronic immunosuppression and other medications to manage its complications often leads transplant recipients to stop taking them, or to take them inconsistently, thus increasing their risk of organ rejection.

In light of the above, we believe that reprogramming a transplant recipient's immune system, with a one-time therapy, to durably tolerate the donated organ regardless of HLA match could potentially have significant benefits for patients and substantial cost savings for the healthcare system more broadly.

Allo-HSCT

Allo-HSCT has been used to replace diseased immune, blood or stem cells in patients with severe immune, blood or metabolic disorders. In allo-HSCT, an HLA-matched, healthy donor's HSCs are first procured, then the patient's own HSCs (and their associated immune and blood systems) are eliminated by high dose chemotherapy and radiation in a process known as myeloablative conditioning. The donor's HSCs are then transplanted to the patient. If the donor's HSCs engraft in the recipient's bone marrow, and are not rejected in the months following, then they will differentiate into donor-derived immune and blood cells.

In allo-HSCT, less-than-perfect HLA matching can increase the potential for GvHD. GvHD occurs when immune cells that are produced by donor-derived stem cells that have engrafted in the recipient attack the recipient's body as "non-self." GvHD, which can be acute (within the first 100 days following transplant) or chronic (beyond 100 days), can cause potentially life-threatening damage to the liver, skin, mucosal tissues, and gastrointestinal tract. Current medical practice for HLA matching in allo-HSCT is more stringent than for solid organ transplantation. Specifically, in solid organ transplant, HLA matching is based on a panel of six HLA proteins, whereas in HSC transplant, HLA matching is based on a more stringent panel of ten HLA proteins. Thus, in allo-HSCT, a ten out of ten match of HLA proteins is strongly preferred, with a minimum requirement for at least a haploidentical match of five out of ten. If individuals in need of allo-HSCT cannot find a suitable donor match, they cannot benefit from the curative potential of this procedure because the risk of GvHD is unacceptably high. As a result, although allo-HSCT also has the potential to restore self-tolerance in patients with autoimmune disease, it is seldom used for autoimmune disease because of the challenge of finding a highly HLA-matched donor and associated concerns over the risk of GvHD.

Although there is no currently approved, standard regimen to prevent GvHD, patients may receive peri-procedural treatment with cyclophosphamide, corticosteroids and other therapies. GvHD can develop in up to 50% of individuals receiving allo-HSCT, depending on the conditioning regimen, underlying disease, and degree of HLA mismatch between donor and recipient. Treatment of acute or chronic GvHD depends on the extent of tissue and organ involvement, which is rated from Grade 1 (mild) to Grade 4 (severe), with corticosteroids generally serving as the typical first-line treatment. Nearly half of patients with acute GvHD are refractory to first-line steroid treatment and may receive treatment with second line therapies such as ruxolitinib. However, ruxolitinib can have limited efficacy, and its side effects include anemia, thrombocytopenia, neutropenia, infections, and edema. Thus, there is a significant need for an approach to allo-HSCT that could enable reciprocal tolerance between the donor's and recipient's tissues and immune cells, irrespective of the degree of HLA match, thereby lowering the risk of GvHD in the allo-HSCT recipient.

Autoimmune Diseases

In healthy individuals, the immune system produces cells that are potentially capable of attacking "self", but such cells are either eliminated or silenced by regulatory mechanisms within the body. However, if these mechanisms fail, or if an infection introduces a foreign antigen that mimics a self-antigen, the immune system can mount an attack on an individual's own cells, tissues, or organs, either locally or systemically. This phenomenon is termed autoimmune disease, and reflects the absence of immune tolerance to some aspect of self. There are more than 80 recognized types of autoimmune diseases.

The discovery and understanding of several key molecular pathways and mediators of pathological inflammation have led to the approval of several immunomodulatory therapies (e.g., anti-cytokines, co-stimulatory blockers and interferons) that improve symptoms and delay progression of debilitating autoimmune diseases such as rheumatoid arthritis and multiple sclerosis. However, these therapies require chronic, repeated administration to maintain significant benefit, and can be associated with side effects and toxicities similar to other immunosuppressive therapies. No therapies approved to date have been shown to be curative of autoimmune disease or to effectively restore durable immune tolerance to self-antigens.

HSCT is not an approved treatment for autoimmune disorders, but it has been observed to have curative potential for certain severe autoimmune diseases—notably scleroderma, multiple sclerosis and Crohn's disease—in clinical trials conducted by third parties, albeit with the significant limitations described above. To date, autologous HSCT has been preferred to allo-HSCT in these trials because the latter carries a significant risk of GvHD, as well as a greater risk that the donated stem cells will fail to engraft in the recipient.

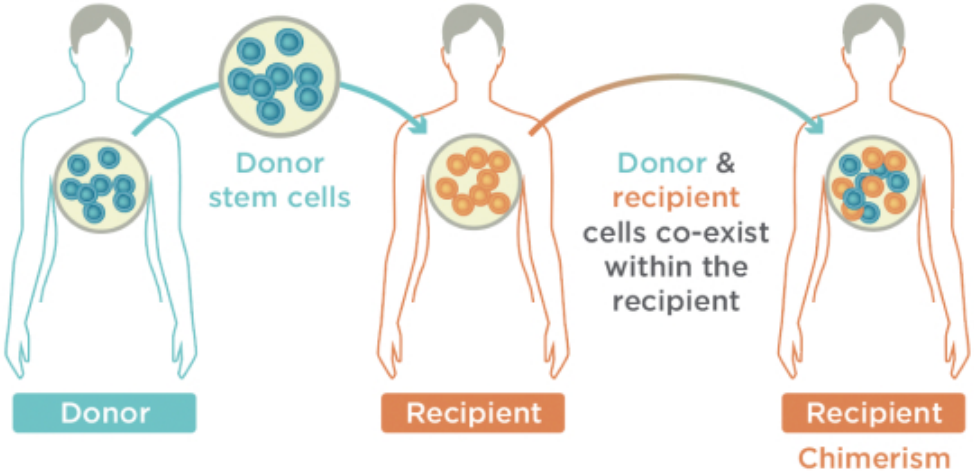
In **autologous HSCT**, a patient's HSCs are first procured and then the patient's entire immune system, including the autoreactive cells, is eliminated by myeloablative conditioning. The previously procured stem cells are then transplanted back into the patient, where they engraft and then differentiate into mature immune cells. The underlying principle is that these newly created immune cells have the potential to reset the patient's immune system, and enable disease remission.

Autologous HSCT has two major limitations. First, the acute toxicity of myeloablative conditioning, notably to the heart, lungs, and kidneys, necessitates a long and costly hospitalization—on average 20 days with billed charges of over $250,000—and restricts its use solely to the patients who can tolerate its intensity. Moreover, there are important long-term complications of myeloablative conditioning, including significantly increased risk of infections and hematological malignancies. Second, since these patients likely have a genetic predisposition towards autoimmune diseases, there is a higher risk of recurrence, which should be lower if stem cells were transplanted from a healthy allogeneic donor. Our Facilitated Allo-HSCT Therapy has the potential to mitigate both of these key limitations. As a result, we believe there is an opportunity with our Facilitated Allo-HSCT Therapy to improve and safely expand the practice of HSCT to a greater number of patients and induce durable remissions in severe autoimmune diseases.

Chimerism and Inducible Allogeneic Tolerance

As depicted in the figure below, **chimerism** refers to a state in which both the donor's HSCs and the recipient's HSCs co-exist in the recipient's bone marrow. These co-existing HSCs in turn produce blood and immune cells of both donor and recipient origin. We believe chimerism is the most robust means of inducing durable allogeneic tolerance.

The Concept of Chimerism



Allogeneic tolerance refers to a chimeric state in which the recipient's preexisting immune system and the donor's transplanted immune system (which co-exist in the recipient following our Facilitated Allo-HSCT Therapy) mutually recognize the other's cells and tissues as "self", thereby evading immune-mediated rejection and GvHD. We believe allogeneic tolerance can be achieved by transplanting a healthy donor's HSCs so that they coexist with the recipient's HSCs in the recipient's bone marrow, thereby creating a "dual hematopoietic system" (part-donor and part-recipient) in the recipient. The dual hematopoietic system in turn produces cells that constitute coexisting immune- and blood systems. If the donor's T-cells constitute more than 50% of the detectable T-cells in the recipient's blood for six months or longer after the transplant, our Phase 2 data have shown that this is highly predictive of the recipient having achieved durable chimerism, and thus durable allogeneic tolerance.

We believe inducible allogeneic tolerance has therapeutic potential in three broad categories of clinical applications: (1) solid organ transplantation; (2) severe autoimmune disease; and (3) severe non-malignant blood, immune and metabolic disorders that have been shown to be potentially curable via allo-HSCT.

Our Therapeutic Approach: Facilitated Allo-HSCT to Induce Allogeneic Tolerance

The goal of our proprietary, investigational Facilitated Allo-HSCT Therapy is to induce allogeneic tolerance for the treatment of multiple therapeutic conditions with significant unmet need. While the principle of inducing allogeneic tolerance has been understood for decades, its clinical application in humans via allo-HSCT has proven elusive due to two key challenges: (1) minimizing the risks of graft rejection and/or GvHD, irrespective of the degree of matching of the donor's and recipient's HLA antigens and (2) identifying a better-tolerated, nonmyeloablative conditioning regimen (as opposed to a fully myeloablative conditioning regimen) that nonetheless enables durable engraftment of donor cells into the recipient. We believe that our Facilitated Allo-

HSCT Therapy has the potential to address these two challenges and could represent a major advance in unlocking potential clinical applications for induced tolerance in the following ways:

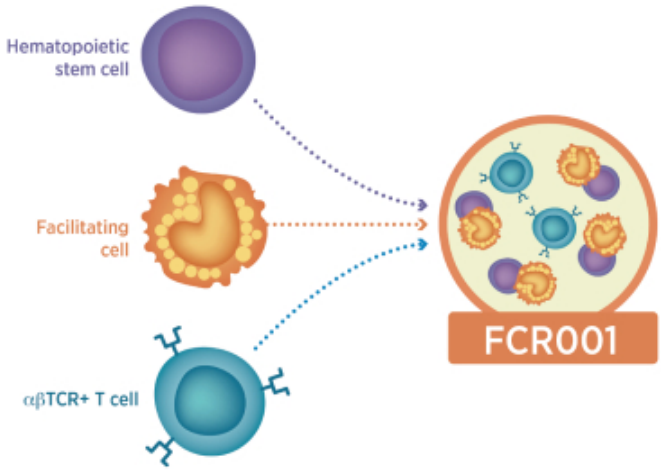
- **Reprogram—Solid Organ Transplantation—**By reprogramming the immune system to tolerate the donated organ without the need for chronic immunosuppression, we believe that our Facilitated Allo-HSCT Therapy has the potential to prevent immune-mediated organ rejection and thereby reduce or eliminate the co-morbidities, toxicities, costs and suboptimal patient survival rates and QoL associated with lifelong immunosuppression.
- **Restore—Severe Autoimmune Disease—**By restoring tolerance to self-antigens in patients with severe autoimmune diseases, we believe that our Facilitated Allo-HSCT Therapy has the potential to induce durable remission without the need for chronic immunosuppression.
- **Replace—Severe Non-Malignant Blood, Immune and Metabolic Disorders—**By replacing defective or deficient HSCs, we believe that our Facilitated Allo-HSCT Therapy has the potential to correct a range of severe non-malignant blood, immune and metabolic disorders that have been shown to be potentially curable with allo-HSCT, but with a less toxic conditioning regimen, reduced or no need for HLA-matching, and reduced risk of GvHD compared to standard allo-HSCT.

Our lead product candidate, FCR001, which is central to our Facilitated Allo-HSCT Therapy, is a proprietary, one-time, investigational cell therapy derived from donor-mobilized peripheral blood cells, which are processed to contain an optimized number of the donor's HSCs, FCs, and aßTCR+ T-cells. As depicted in the figure below, these three distinct cell types and the combination of these cell populations are critical for the safety and efficacy of FCR001. Specifically:

- ***HSCs*** are progenitor cells that are used to rebuild the hematopoietic and immune system of the recipient. As a result of their engraftment, the recipient's new immune system will reflect the donor's genotype and, thus, can potentially recognize the donor cells and tissues as "self" without the need for chronic immunosuppression.
- ***Facilitating Cells* (FCs)** are defined by the cell surface expression of the CD8 protein and by the lack of a functional T-cell receptor (**TCR**) ($CD8^+/TCR^-$). FCs are a mixed cell population that we believe to be responsible for fast and efficient engraftment of donor HSCs to promote chimerism. In addition, in preclinical studies, FCs have been observed to be associated with a reduced risk of GvHD relative to standard allo-HSCT. Consistent with these data, we have observed a very low incidence of GvHD in our Phase 2 trial of FCR001, despite a high degree of HLA mismatch between most donors and recipients.

- a***ßTCR+ T-cells*** are known to support donor HSC engraftment in recipients who receive allo-HSCT from an HLA-mismatched donor with nonmyeloablative conditioning, but they are also known to increase the risk of acute GvHD in the recipient. FCR001 incorporates an optimized number of aßTCR+ T-cells that are intended to promote engraftment of the donor's HSCs in the recipient while minimizing the risk of acute GvHD.

Active Cell Type Composition of FCR001

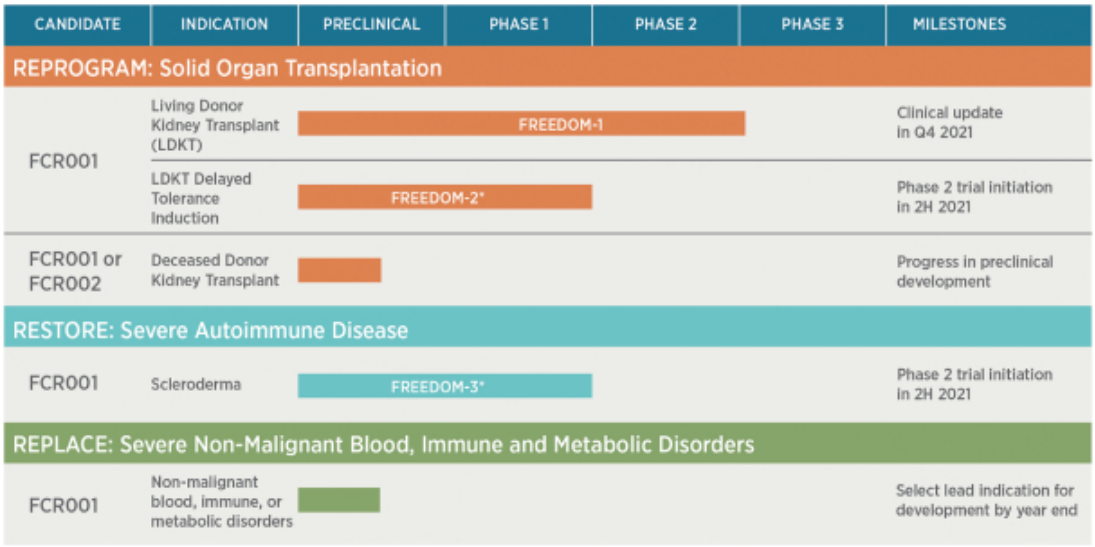


The FCR001 manufacturing process is designed to limit the number of aßTCR+ T-cells to a desired number in the cell therapy product candidate while optimizing the yield of HSCs and FCs obtained after apheresis of the donor. See "*Preclinical Studies: Facilitating Cell Mechanism of Action*," below, for a summary of some of the key preclinical data supporting the mechanism of action of FCR001.

Our Pipeline

Based on the clinical evidence we have observed in our Phase 2 trial, we believe FCR001, and our Facilitated Allo-HSCT Therapy more broadly, can potentially be applied to numerous therapeutic areas. We are advancing a pipeline of three clinical and two preclinical programs across three therapeutic categories: (1) solid organ transplantation, (2) severe autoimmune disease, and (3) severe non-malignant blood, immune and metabolic disorders that have been observed to be potentially curable via allo-HSCT. These initial areas of focus extend beyond kidney transplantation and include severe autoimmune disease in our planned trial targeting scleroderma and IND-enabling studies targeting several non-malignant blood, immune and metabolic disorders. We retain global development and commercial rights for FCR001 in all indications.

FCR001: Pipeline-in-a-Product Opportunity



* Open INDs permit us to move directly into these Phase 2 trials based on existing FCR001 safety data.

Our lead indication for FCR001 is living donor kidney transplant (**LDKT**). We are currently evaluating FCR001 in FREEDOM-1, a randomized, controlled, open-label, multi-center Phase 3 trial in the United States. This registration trial is designed to assess the safety and efficacy of FCR001 in first-time LDKT recipients, where FCR001 is administered the day after the kidney transplant. The goal of the FREEDOM-1 trial is to assess the potential of FCR001 to induce durable immune tolerance to the transplanted kidney without the need for chronic immunosuppression to prevent graft rejection. Based on the data generated from our Phase 2 trial, FCR001 has been granted Regenerative Medicine Advanced Therapy (**RMAT**) and Orphan Drug designations by the U.S. Food and Drug Administration (**FDA**) in this indication. We anticipate providing an initial clinical update on FREEDOM-1 in the fourth quarter of 2021.

In the second half of 2021, we plan to initiate FREEDOM-2, a Phase 2 trial to evaluate the potential for FCR001 to induce durable immune tolerance in patients who have previously received a kidney from a living donor, which is a process called delayed tolerance. In this trial, FCR001 will be administered between three and twelve months after the initial kidney transplant. Demonstrating that FCR001 can induce durable tolerance to a transplanted kidney, even if FCR001 is administered up to one year after the original LDKT, could enable broader clinical application of our Facilitated Allo-HSCT Therapy both to a portion of the prevalent LDKT population as well as potentially to the deceased donor solid organ transplant setting. We are also currently conducting preclinical

research to explore whether we can manufacture FCR001 (or FCR002, if deemed a separate product candidate) from bone marrow procured from deceased organ donors. If these preclinical studies are successful, we plan to initiate IND-enabling studies of FCR001 or FCR002 in deceased donor kidney transplants.

Also in the second half of 2021, we plan to initiate our first clinical trial in autoimmune diseases, FREEDOM-3, a Phase 2 trial exploring the safety and clinical activity of FCR001 in patients with a severe form of scleroderma. We believe that positive proof of concept data in this trial could support the potential applicability of FCR001 to other severe, systemic autoimmune diseases.

We also plan to prioritize FCR001 for one or more severe non-malignant blood, immune or metabolic disorders for advancement into IND-enabling studies by the end of 2021.

Our Programs

Reprogram: Solid Organ Transplantation

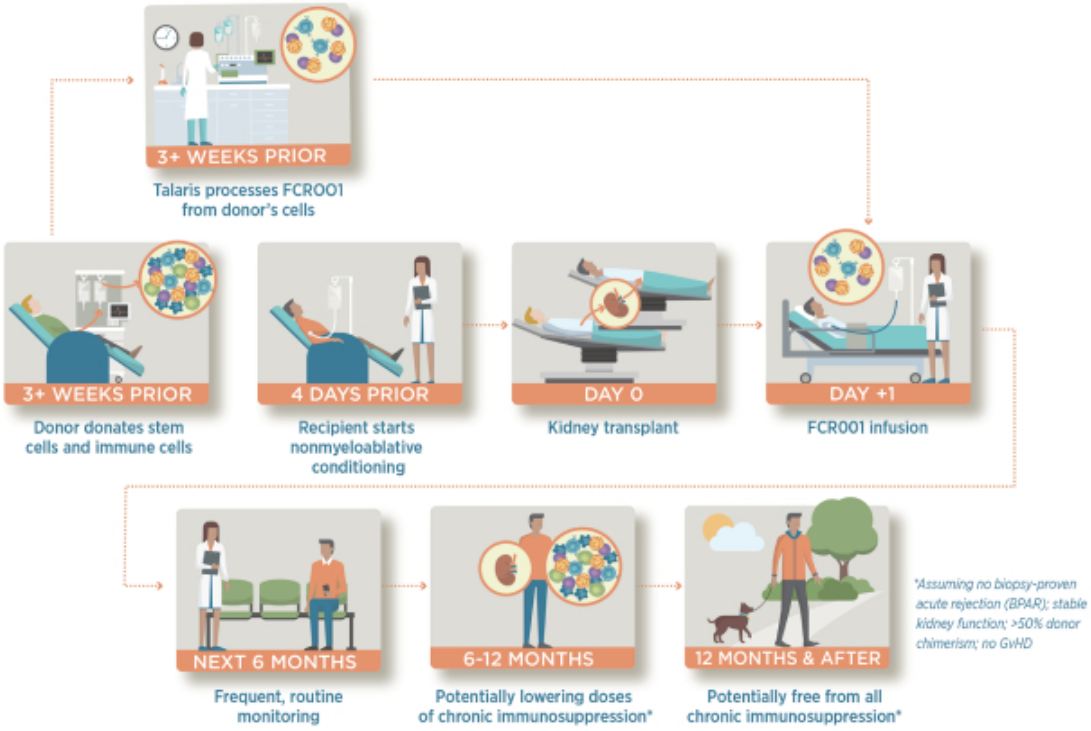
We believe that our Facilitated Allo-HSCT Therapy has the potential to reprogram the immune system of recipients of solid organ transplants to recognize the donated organ as "self," thereby avoiding organ rejection without the degree of toxicities, risks, co-morbidities, and burden of compliance associated with chronic immunosuppression. In the United States, there were 39,719 transplants of solid organs performed in 2019, up from 36,350 in 2018. These life-saving procedures entail procuring organs from either living donors (in the case of kidney and partial liver) or deceased donors (in the case of kidney, liver, heart, lung, pancreas and intestine) and surgically implanting them into appropriately matched recipients with end-stage organ failure. In 2019 (the most recent year before the COVID-19 pandemic temporarily reduced the number of transplants, such as LDKT, which are considered elective procedures), there were 7,397 transplants performed from living donors, of which 6,687 were kidney and 524 were partial liver. In addition, there were 32,322 transplants from deceased donors in 2019, as follows: 16,534 kidney, 8,372 liver, 3,552 heart, 2,714 lung, and 1,150 other organs, including heart/lung, kidney/pancreas, pancreas, and intestine.

Demand for solid organ transplants significantly exceeds the supply. As of January 2021, there were more than 108,100 people in the United States on the waiting list for a transplant, of whom more than 91,400 were awaiting a kidney—with a median wait of 4.1 years. We believe that inducing durable tolerance to a transplanted organ without the need for chronic immunosuppression has the potential to prolong the viability of kidney transplants and ultimately other solid organ transplants, thereby reducing the need for the approximately 10% of organ transplants annually that are repeat transplants. Reducing the number of repeat transplants following failure of their initial transplant should, in turn, enable more patients on the waiting list to receive an initial transplant, and save significant associated healthcare costs.

Our Initial Focus: First-Time Living Donor Kidney Transplant

Long-term outcomes in LDKT are suboptimal due to the complications associated with taking lifelong chronic immunosuppression medications. We believe FCR001 has the potential to induce durable allogeneic tolerance in LDKT recipients to their transplanted organ, thereby permitting the LDKT recipient to discontinue all chronic immunosuppression within approximately twelve months of their transplant, without rejecting the transplanted organ. FCR001 is a single-dose, personalized investigational therapy that is made from stem and immune cells procured from the kidney donor, that are processed at our GMP facility to specifications that are optimized for the transplant recipient. FCR001 is infused into the transplant recipient within a day of the LDKT. The patient journey and our therapeutic approach in our Phase 2 and Phase 3 LDKT trials, including our vein-to-vein process from donor to recipient, is illustrated in the figure below.

The Patient Journey and Our Therapeutic Approach in Our Current LDKT Clinical Trials



Our approach begins with the procurement of a donor's stem and immune cells through a standard mobilization and apheresis procedure. At least three weeks prior to the scheduled LDKT, the kidney donor receives medication over a five-day period to mobilize their stem cells and immune cells and allow these cells to circulate out of the bone marrow and into the bloodstream. The mobilized cells that comprise FCR001 are then collected from the donor using our specified apheresis protocol.

The donated cells are shipped to our GMP cell processing facility in Louisville, Kentucky (which is also the location of UPS' WorldPort hub), where our proprietary process removes a calculated amount of the donor's aßTCR+ T-cells and relatively enriches the product for the donor's HSCs and FCs. The minimum doses of donor-derived HSCs and FCs in our FCR001 investigational therapy are customized for each patient, as is the target dose range of aßTCR+ T-cells. The final product is cryopreserved, and after clearing quality control specifications and processing, shipped to the transplant center, where it is stored until the transplant date.

Separately, commencing four days prior to the transplant, the recipient will receive nonmyeloablative conditioning to facilitate engraftment of the HSCs contained in FCR001. Our nonmyeloablative conditioning regimen consists of low total doses of fludarabine and cyclophosphamide and a one-time, low dose of total body irradiation (**TBI**), resulting in a less toxic regimen than fully myeloablative conditioning. Our nonmyeloablative conditioning regimen enables the patient to be managed primarily in an outpatient setting, with a relatively short hospital stay, whereas fully myeloablative conditioning typically requires inpatient management for 20 to 30 days. As the nonmyeloablative conditioning regimen employed as part of our Facilitated Allo-HSCT Therapy is mainly immunosuppressive and much less toxic to the recipient's stem cells than myeloablative conditioning, the patient's immune system is generally expected to recover on its own even if the donated HSCs do not engraft.

Three days prior to the LDKT, the recipient will begin a standard chronic immunosuppressive therapy of tacrolimus and MMF, to help prevent both graft rejection and GvHD after transplantation. On Day 1 post-LDKT, the recipient will receive a single intravenous infusion of FCR001 at their bedside. On Day 3 post-transplant, the recipient will receive a single dose of cyclophosphamide and Mesna to suppress the immune system and reduce undesired side effects of certain chemotherapy drugs.

Over the course of the next six months, the transplant recipient will remain on standard immunosuppressive therapy (i.e. tacrolimus and MMF) and will return to the clinic for routine monitoring. At approximately month six post-transplant, if the recipient demonstrates durable donor chimerism (defined as at least 50% donor T-cell chimerism) there is no evidence of rejection or GvHD, and kidney function remains stable, then MMF can be discontinued. Thereafter, tacrolimus can be tapered starting at month nine, and if the recepient continues to fulfill the preceding conditions, tacrolimus can be discontinued at approximately month 12 post-transplant.

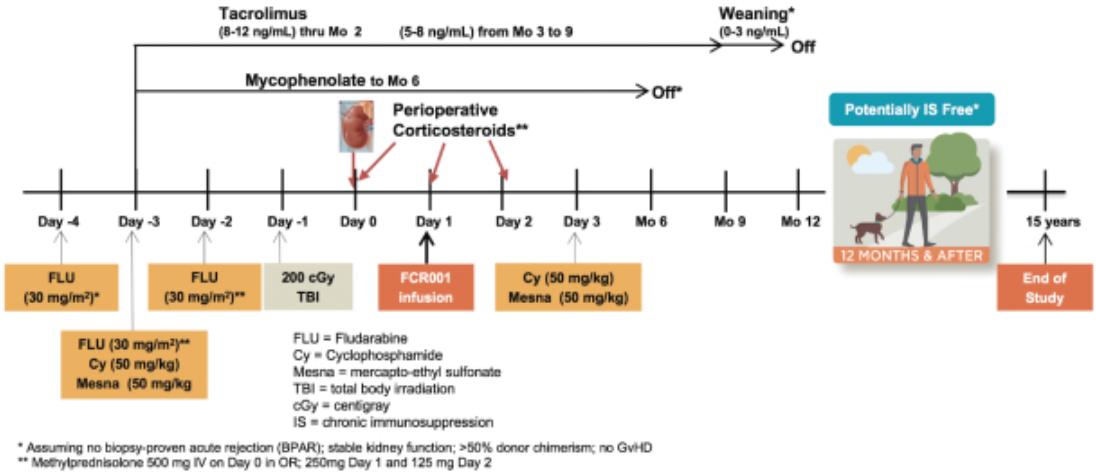
Overview of Our Phase 2 Trial

We conducted an our open-label, single-arm Phase 2 trial to investigate whether administration of FCR001 along with nonmyeloablative conditioning can induce durable immune tolerance to a donated kidney in adult LDKT recipients. Although this trial is no longer actively enrolling patients, this trial will continue to monitor the FCR001-dosed patients for up to 15 years from the time of their transplant and thereby provide long-term follow-up safety and durability data.

Thirty-seven patients were dosed between 2009 and 2016 at Northwestern Medical Center (n=36) and Duke University Hospital (n=1). The first four patients dosed at Northwestern Medical Center were treated under a compassionate use exemption, but we consider these patients to be part of our Phase 2 trial because they were treated with the same FCR001 product and under substantially the same protocol as the subsequent 33 patients. Eligible donor and recipient pairs were adults between the ages of 18 to 65 who met trial eligibility criteria. All levels of immune HLA mismatching between donor and recipients were allowed.

The primary endpoint of the trial was to determine whether the administration of FCR001 can induce durable tolerance to the donated kidney and substantially reduce or eliminate the requirement for immunosuppression within 12 months following transplant.

Phase 2 LDKT study design

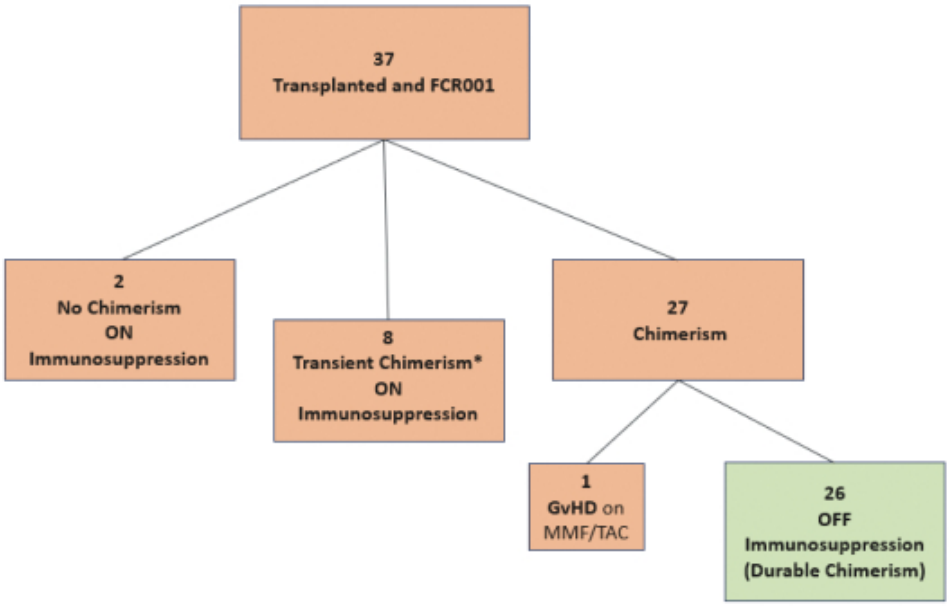


As of January 31, 2021, the median follow-up of the 37 patients who received LDKT and FCR001 was over six years, with the longest follow-up being over 11 years. Moreover, as of such time, 33 recipients have at least 36 months of follow-up, and 21 patients have had at least 60 months of follow-up. As of January 31, 2021, we have accumulated a total of approximately 235 patient-years of exposure to FCR001 in LDKT.

Our Phase 2 Results—Clinical Activity

As depicted in the flowchart below, 37 patients received LDKT as well as our investigational therapy, FCR001, plus nonmyeloablative conditioning. As of January 31, 2021, the results were as follows:

Phase 2 Clinical Trial Results as of January 31, 2021



* Chimerism lost between months 2 and 5 post-transplant.

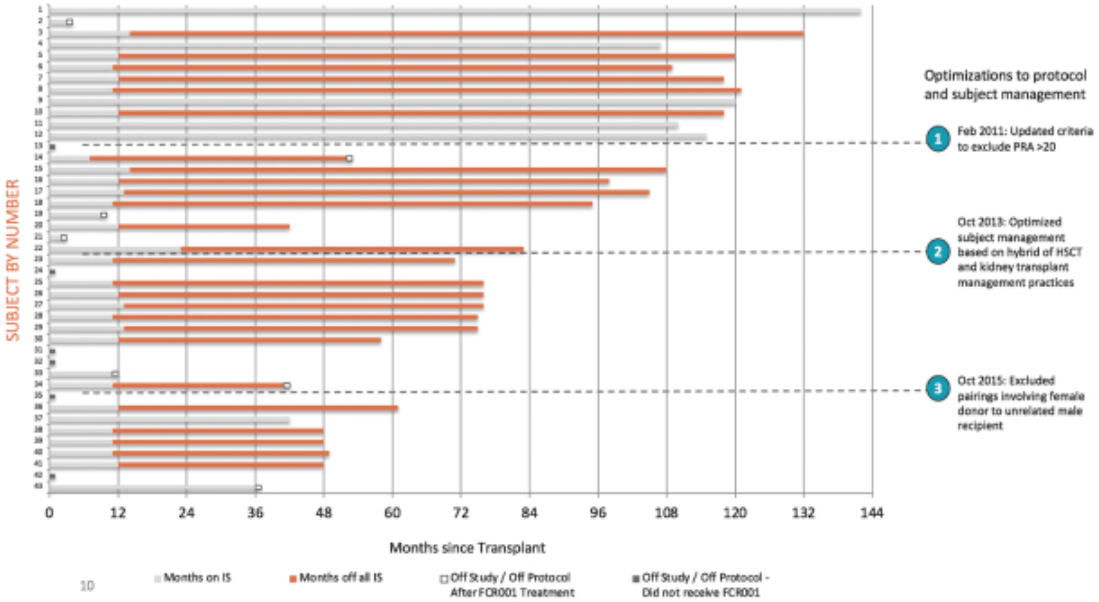
In our Phase 2 trial, nearly every patient (26 of 27) who demonstrated chimerism at six months post-transplant was able to be completely weaned off all chronic immunosuppression by approximately twelve months post-transplant, and every patient (n = 26) who was weaned off all chronic immunosuppression at twelve months post-transplant has subsequently been able to stay off chronic immunosuppression, without organ rejection during their follow-up. As detailed below, two patients that remained off chronic immunosuppression died at years 3.5 and 4 post-transplant due to pneumococcal sepsis and lung cancer, respectively. We have followed these 26 patients for a median of six years, and the longest for up to 11 years since their transplant.

Induction of Durable Chimerism and Withdrawal of Immunosuppression

Of the 37 patients who received FCR001, 26 (70%) achieved durable donor chimerism (defined for purposes of the Phase 2 trial as whole blood or T-cell donor chimerism greater than 40% at six months post-transplant) and were successfully weaned from their chronic immunosuppression without developing acute rejection or donor specific antibodies. After mid-course optimizations to the Phase 2 protocol were implemented in late 2013, 14 of the last 17 patients (82%) in the trial achieved durable chimerism and could be withdrawn

from chronic immunosuppression at approximately one year post-transplant. The chart below shows the duration and disposition of each patient who participated in our Phase 2 trial, as well as the three main timepoints at which our trial protocol was optimized. Each row in the chart below is indicative of a patient enrolled in our trial. While a total of 43 patients were originally enrolled in our Phase 2 trial, only 37 patients were ultimately dosed with FCR001.

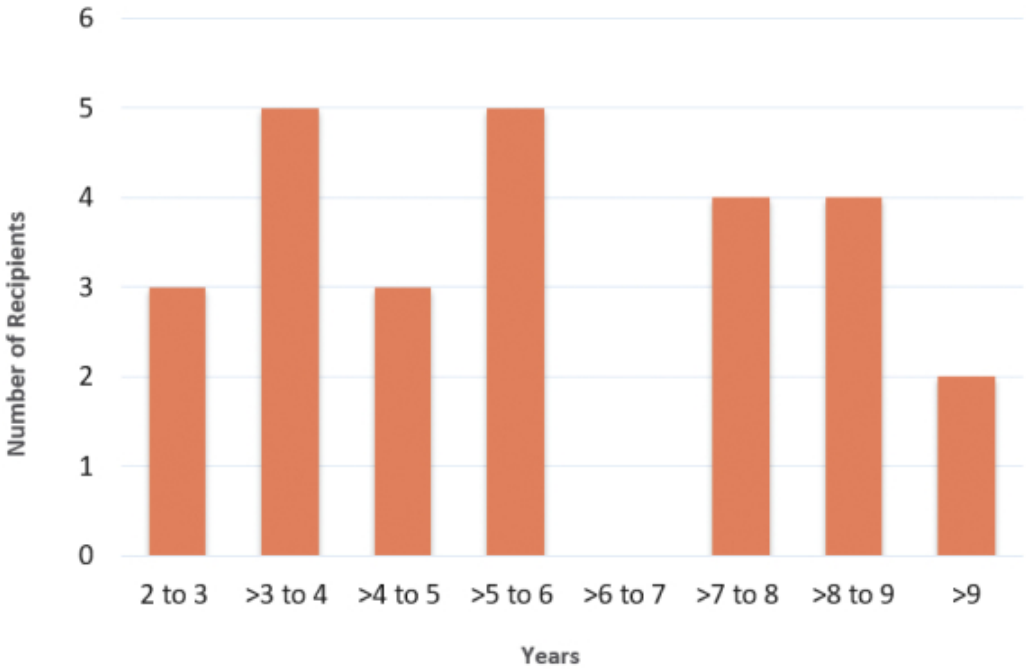
Phase 2 LDKT Trial: Summary of Patient Dispositions and Duration of Follow-Up



As depicted in the chart above, during approximately the first half of the Phase 2 trial, we identified certain factors that may have contributed to the failure of the donor's HSCs to durably engraft in some of our FCR001 recipients. These factors include suboptimal HSC/FC cell counts, failure to administer a post-transplant dose of cyclophosphamide per protocol, the presence of infection at the time of the transplant, a lack of adherence to best clinical practices for management of allo-HSCT patients, and a Panel Reactive Antibody (**PRA**) greater than 20%. A high PRA indicates that a patient has a disproportionate response to HLA antigens, and a PRA of greater than 20% (which is observed in approximately 10% of LDKT recipients) is a known risk factor for organ rejection in solid organ transplant. Based on these observations, we incorporated certain dosing and protocol refinements into our Phase 2 trial through late 2013. From that timepoint onward (denoted by the (2) in the figure above), 14 of the last 17 patients (82%) dosed in our trial achieved durable donor chimerism and were able to be weaned off their chronic immunosuppression without rejecting the transplanted organ. Based on two observed cases of GvHD in 2014 and 2015, each of which involved a female donor to unrelated male recipient (a known risk factor for GvHD in allo-HSCT), in October 2015 we further refined our Phase 2 protocol to exclude female donors to unrelated male recipients (denoted by the (3) in the figure above). Once this protocol change was implemented in our Phase 2 trial, we did not observe any further cases of GvHD in the last seven patients who received FCR001.

The chart below shows the distribution of the duration off immunosuppression of the 26 patients in our Phase 2 trial who are off all chronic immunosuppression without having rejected their transplanted kidney, including two patients whose follow-up stopped at years 3.5 and 4 post-transplant due to their death.

Distribution of 26 Patients Durably Free of Chronic Immunosuppression

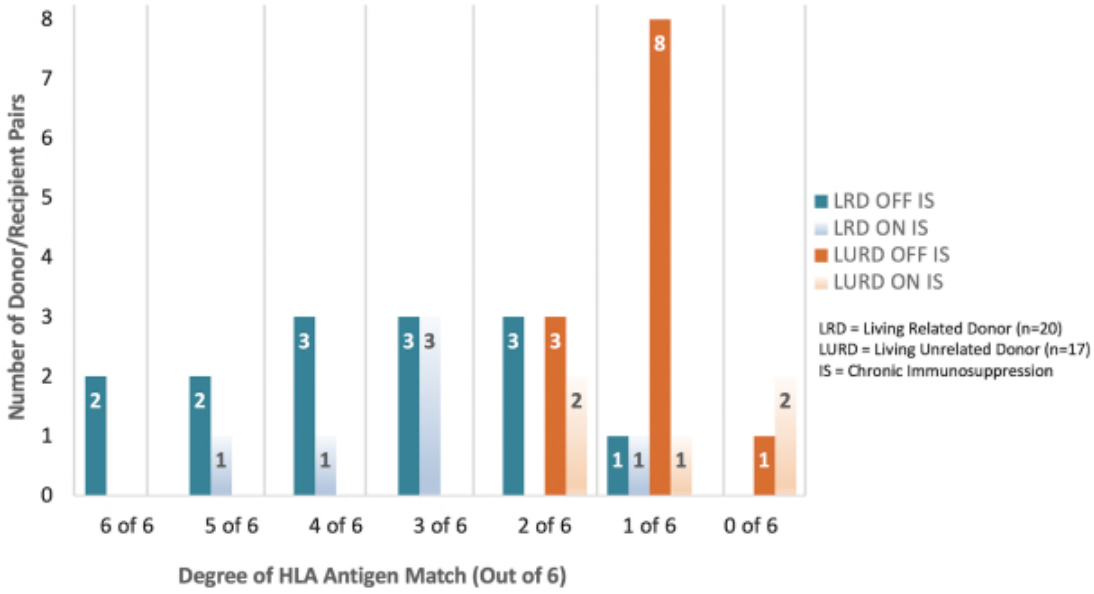


The above data represent the time interval between the date each patient discontinued immunosuppression and that patient's last study follow up visit that occurred prior to January 31, 2021.

Withdrawal of Chronic Immunosuppression Irrespective of HLA Mismatch

In our Phase 2 trial, the ability to discontinue chronic immunosuppression was observed across all levels of donor and recipient HLA matching, with 19 out of 26 recipients (73%) who were able to durably discontinue their chronic immunosuppression having an HLA match of three or less to their donor. We did not observe any correlation between the degree of HLA mismatch and any of durable chimerism, safety, or GvHD. We believe that the induction of durable allogeneic tolerance (as demonstrated by successful discontinuation of chronic immunosuppression) in a number of patients with poor HLA matching demonstrates FCR001's potential to overcome a major obstacle in solid organ transplantation and allo-HSCT. The figure below summarizes the distribution of all 37 FCR001-dosed patients in terms of the degree of HLA matching in each of living related donors and living unrelated donors. Results were comparable across all degrees of HLA matching, and whether the donor was related or unrelated. Of patients who received very low-matched (zero to two HLA match) kidneys from unrelated donors, 12 of 17 were durably weaned off their chronic immunosuppression.

HLA Matching and Relatedness—Patient Status



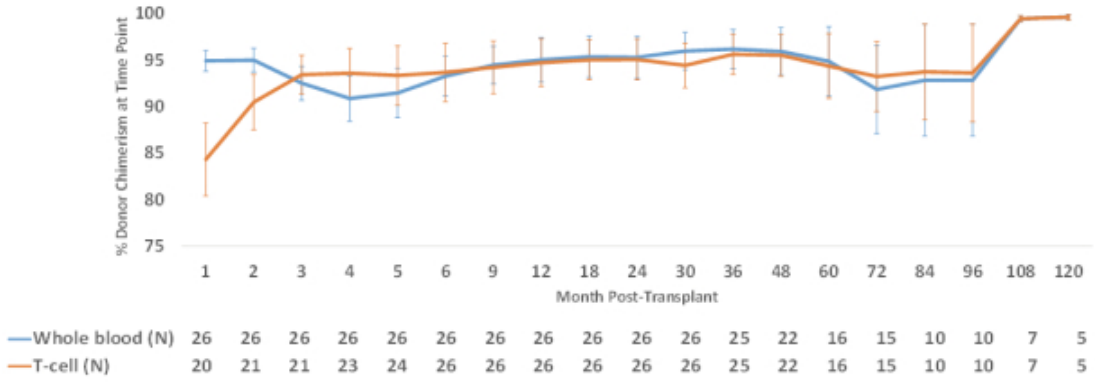
Chimerism as Predictor of Ability to Withdraw Chronic Immunosuppression at One Year Post-Transplant

Hematopoietic chimerism has recently emerged as a promising, near-term, surrogate marker for predicting allogeneic tolerance induction. In our Phase 2 trial, we observed that high levels (>50%) of donor chimerism at three and six months post-transplant correlated strongly with the ability to discontinue chronic immunosuppression approximately one year after transplant, without subsequent graft rejection. Durable whole-blood and T-cell donor chimerism was observed in 27 patients, of whom 26 were successfully weaned from chronic immunosuppression at approximately one year, with one durably chimeric subject dying due to complications from GvHD shortly before the one-year time point.

All 26 patients in our Phase 2 trial who could be withdrawn from chronic immunosuppression at approximately one year post-transplant attained high and durable levels of whole blood chimerism and/or T-cell chimerism. Of these 26 patients, 22 developed very high level (>90%) donor whole blood chimerism beginning the first month post-transplant, and 24 out of 26 patients had >90% chimerism at one year post transplant. As of January 31, 2021, all 26 patients had retained durable chimerism for the duration of their follow-up.

As depicted in the graph below, the mean percentage whole blood and T-cell donor chimerism levels for FCR001-treated patients weaned off their chronic immunosuppression at approximately one year post-transplant reached approximately 95% as early as one month post-transplant and remained at this level for as long as ten years.

Percentage of Donor Chimerism in FCR001-Treated Patients Who Are Off Chronic Immunosuppression



Values are mean +/- standard error.

N indicates the number of FCR001 treated patients weaned off IS at approximately one year post-transplant for whom % whole blood and T-cell donor chimerism were measured at that time point

We believe that these collective observations support our belief that the establishment of high levels of donor chimerism is an early and consistent predictor of the ability to durably withdraw an LDKT recipient from chronic immunosuppression without rejecting the transplanted organ.

Of the ten FCR001-dosed transplant recipients in our Phase 2 trial who did not achieve durable chimerism, eight were transiently chimeric and two never engrafted. Transiently chimeric patients typically lost donor chimerism within the first two to five months post-transplant.

While none of the 26 patients in our Phase 2 trial who developed durable chimerism experienced biopsy-proven acute rejection (**BPAR**), seven of the ten patients who did not achieve durable chimerism did develop BPAR. BPAR was successfully treated in five of these seven patients, but severe infections in two patients required them to be removed from all immunosuppression, which resulted in graft loss. This is consistent with how severe infections would be treated in a standard of care solid organ transplant setting. At the time of their BPAR episodes, all but one patient was being maintained on lower-than-normal levels of immunosuppression, which would have significantly increased the risk of BPAR. In four of these seven patients, immunosuppression therapy was lowered to monotherapy (tacrolimus in three cases and sirolimus in one case), at the investigator's discretion, and/or lowered to a dose level below what would be permitted in our Phase 3 trial. Our Phase 3 protocol requires that standard of care immunosuppression therapy be maintained for all patients who do not maintain durable donor chimerism at and beyond month six post-transplant unless lowering of immunosuppression is otherwise determined to be medically necessary (e.g. due to a serious infection).

Overall Five-Year Kidney Graft Survival

As of January 31, 2021, five-year survival of the donated kidney was 34 out of 37 patients (92%) in our Phase 2 trial, compared to five-year kidney graft survival of 86% in patients tracked by the United Network for Organ Sharing (**UNOS**). The three cases of kidney graft loss in our Phase 2 trial occurred in patients who did not establish durable chimerism and were unable to discontinue chronic immunosuppression. As noted earlier, we revised our Phase 2 protocol (and maintained these revisions in our Phase 3 protocol) to address certain factors

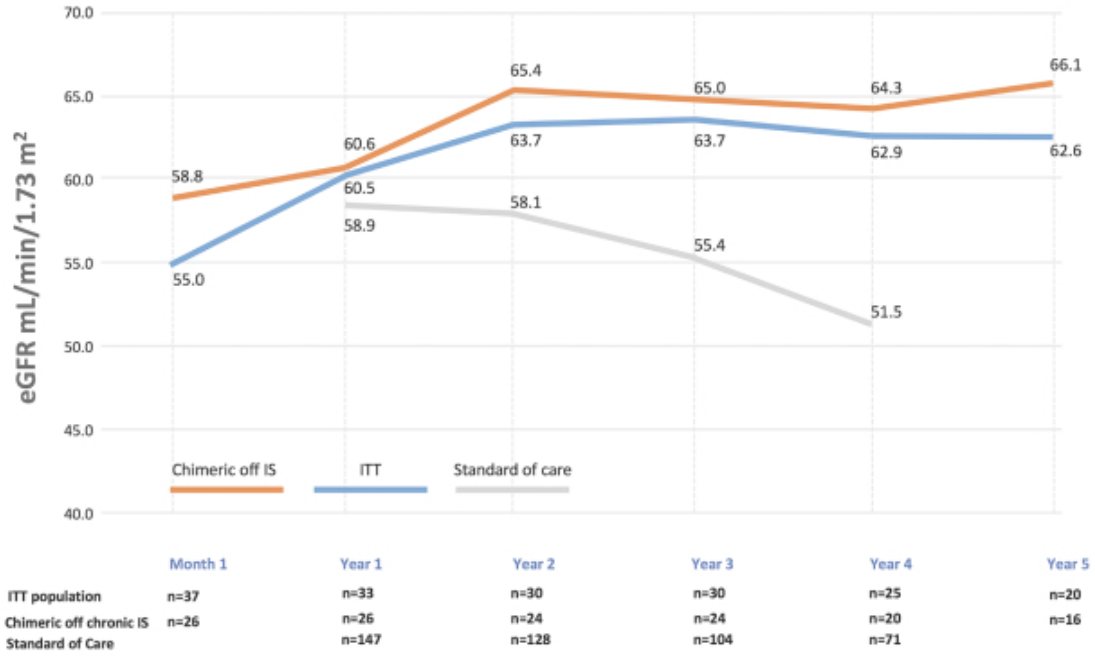
that we believe may have played a role in these three graft losses, including incorporating into our Phase 2 protocol best clinical practices for management of allo-HSCT patients to minimize infections and excluding patients with a history of infection.

Observation of Renal Function

As shown in the graph below, average renal function in our Phase 2 patients, as measured by estimated glomerular filtration rate (**eGFR**) by Modification of Diet in Renal Disease, was observed to be preserved over time, both for the durably chimeric patients off chronic immunosuppression after approximately one year as well as for all FCR001 patients on an intent-to-treat basis (**ITT**). No abnormal histologic findings or instances of BPAR were observed on any protocol biopsies in durably chimeric patients off chronic immunosuppression.

Separately and apart from our Phase 2 trial protocol, the lead investigator at Northwestern Medical Center for our Phase 2 trial evaluated both longer-term kidney function and cardiovascular medication usage, as described further below, at up to five years post-transplant in FCR001-treated patients. These patients were compared to a cohort of standard of care LDKT patients who the investigator determined would have met all of our Phase 2 trial enrollment criteria and were transplanted at Northwestern between 2009 and 2012 (the first three years of our Phase 2 trial). In a retrospective analysis through year four post-transplant of these standard of care LDKT patients, mean eGFR of this cohort was observed to decline over time as depicted by the gray line in the graphic below.

Mean eGFR* Over Time Post-Transplant



**MDRD-4 (Modification of Diet in Renal Disease) equation*

Average renal function calculation excludes graft losses occurring prior to any given time point. Over time, sample size decreased due to 3 deaths, 3 graft losses, patients not yet out to the time point, or eGFR values missing. Note that ITT analysis excludes the five patients who were enrolled in the Phase 2 trial but did not actually receive FCR001.

Due to the retrospective nature of the analysis, which is not included in our database, data from the standard of care cohort (depicted by the gray line) does not include baseline eGFR data or year 5 data.

Cardiovascular Medication Usage

The evaluation of cardiovascular medication usage conducted by the lead investigator at Northwestern Medical Center for our Phase 2 trial as described above resulted in the findings summarized as follows. As shown in the table below, at four years post-transplant, cardiovascular medication usage of FCR001 patients who were durably chimeric and off chronic immunosuppression compared favorably with that of the retrospectively gathered standard of care cohort of 132 transplant recipients who received their LDKT at the same site and during the same timeframe as the first half of our Phase 2 trial.

Comparison of Cardiovascular Medication Usage in Durably Chimeric FCR001 Patients vs. Historical Standard of Care Cohort, at Four Years Post-Transplant

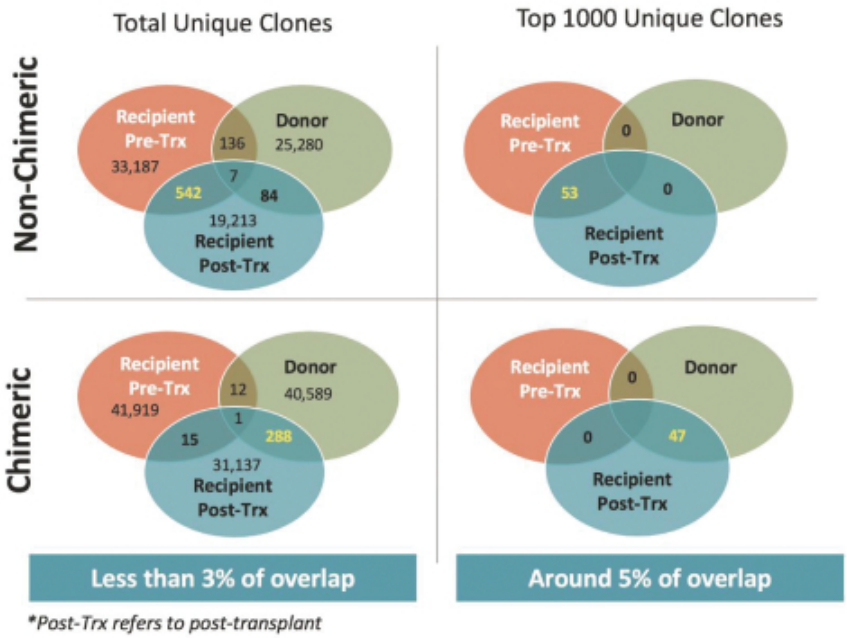
	Durably chimeric FCR001 patients off immunosuppression (n=26)	Standard of care patients (n=132)
Anti-hypertension medications	18%	83%
Anti-hyperlipidemia medications	9%	43%

Baseline data not available

Evidence of Immunocompetence in FCR001-Treated Patients

One measure of successful immune system reconstitution is having a highly diverse repertoire of T cell receptor (**TCR**) clones, meaning a wide range of TCR clones, each capable of recognizing and targeting different foreign antigens. To examine TCR clone diversity in our LDKT patients, we randomly selected nine patients from our Phase 2 trial, of which five had achieved full chimerism and four did not, and analyzed blood samples 24 months after LDKT. We observed that, even though the clone diversity in TCR repertoire was somewhat reduced in all nine post-transplant recipients, the repertoire in these patients was diverse enough to suggest recovery of immune competence. As shown in the figure below, at least 97% and 95% of the total and top 1000 TCR clones, respectively, observed in a representative sample of these post-transplant recipients were not present in either donor or recipient pre-transplant. This suggests that a significant number of unique TCR clones (that were not previously present in either the donor or the recipient) were generated post-transplant, which is evidence of a competent immune system. Within the pool of shared sequences observed in the remaining 3% of clones, full chimerism correlated with a shift towards homology with the donor, meaning that the TCR clones were primarily derived from the donor HSCs, rather than from residual recipient HSCs, while loss of chimerism correlated more closely with the TCR clonal diversity in the recipient following autologous recovery of T-cells.

Unique TCR Clones in Post-Transplant Recipients



In another study, reported in Science Translational Medicine (2012), Dr. Ildstad and certain collaborators analyzed lineage reconstitution in the first eight recipients of FCR001 in our Phase 2 trial. In that study, Dr. Ildstad and certain collaborators observed evidence of reconstitution of immune and blood cell components (e.g. T-cells, B-cells, natural killer (**NK**) cells, monocytes, granulocytes) in those FCR001 recipients. In addition, in a separate analysis reported in Transplantation (2015), Dr. Ildstad and certain collaborators analyzed blood reconstitution in the first 20 recipients of FCR001 in our Phase 2 trial (with follow up on the durably chimeric patients between eight and 48 months post-discontinuation of chronic immunosuppression). In five of the 12 patients who achieved durable chimerism, donor-derived red blood cell production was observed. We believe that these observations support the potential of our Facilitated Allo-HSCT Therapy to address certain severe non-malignant blood, immune or metabolic disorders that have previously been successfully treated with standard allo-HSCT.

Our Phase 2 Results—Safety

Through January 31, 2021, we have accumulated a total of approximately 235 patient-years of exposure to FCR001 in LDKT, and the safety profile observed in our patients was generally consistent with that expected if a patient were to separately receive both a standard kidney transplant and an allo-HSCT with nonmyeloablative conditioning. Moreover, as noted above, preliminary data indicates that patients who were able to be weaned off immunosuppression with FCR001 had preserved kidney function and third-party data suggests a markedly lower reliance on cardiovascular medications at four years post-transplant compared to traditional transplants with chronic immunosuppression over a similar time frame. Most adverse events occurred during the first 12 months post-transplant when the patients were on conventional immunosuppression, and no events of infusion toxicity following FCR001 administration were observed. We summarize the safety findings in greater detail below.

The most commonly reported adverse events were diarrhea, BK viruria/viremia, fever, cough, and nausea. The most commonly reported serious adverse events were fever, deep vein thrombosis, including among several patients who had predisposing factors such as central venous catheter placements or Factor V deficiency, diarrhea, pneumonia and febrile neutropenia. The most commonly reported infections were BK viruria/viremia, nasopharyngitis, cellulitis, upper respiratory tract infection, and urinary tract infection. BK urine/blood were

monitored frequently per protocol and no cases of BK nephropathy were observed. Cytomegalovirus (**CMV**) viremia was also observed at a rate consistent with what would be expected in a kidney transplant and allogeneic stem cell transplant population. There was not an increase in CMV incidence in donor/recipient pairs at higher risk of CMV incidence or activation. There were two cases of tissue invasive CMV disease (colitis), both of which occurred in the two FCR001 patients that experienced GvHD.

Five-year patient survival in our Phase 2 trial is comparable to that of LDKT patients as reported in the UNOS database, being approximately 92% in each case. Out of the 37 patients in our Phase 2 trial who received FCR001, there were three patient deaths. The first death, of a patient who had durable chimerism through month 11 post-transplant, occurred eleven months post-transplant and was attributed to complications arising from progressive, treatment-resistant, Grade III GvHD with recurrent CMV colitis. There was a meaningful delay between onset of symptoms and when this patient presented to the transplant center for evaluation and treatment. The second death, of a durably chimeric patient approximately four years after transplant and approximately three years after the patient had discontinued chronic immunosuppression, was attributed to non-small cell carcinoma of the lung. This patient had a more than 40-year history of heavy smoking and refused treatment for his cancer. The third death, of a durably chimeric patient approximately 3.5 years post-transplant and approximately 2.5 years after the patient had discontinued chronic immunosuppression, was attributed to pneumococcus sepsis and human metapneumovirus infection. This patient was non-compliant with the trial's revaccination protocol (which is standard of care following allo-HSCT) and fell ill while traveling abroad.

There were two cases of GvHD, both in the setting of a female donor to an unrelated male recipient. This donor/recipient combination is known to have a higher risk of GvHD in allo-HSCT. The first case of GvHD occurred at 135 days post-transplantation and was fatal, as described above. The HLA match between this recipient and his donor was two out of six. The second case (Grade II acute GvHD) occurred at approximately two months post-transplant, almost immediately after the patient's immunosuppression medication was changed from tacrolimus to sirolimus due to tacrolimus-induced toxicity. The patient's acute GvHD resolved following treatment with corticosteroids. This patient was weaned off chronic immunosuppression and subsequently developed Grade I-II ocular/musculoskeletal chronic GvHD, which is currently well-managed. The HLA match between this recipient and his donor was one out of six. There were no other reports of acute or chronic GvHD. While other female-donor-to-unrelated-male-recipient pairs in our Phase 2 trial did not experience GvHD, we nonetheless excluded female donor to unrelated male recipients from the last seven patients in our Phase 2 trial, and no further instances of GvHD were observed. We are continuing to exclude these donor-recipient pairs from our FREEDOM-1 Phase 3 protocol.

Six patients in our Phase 2 trial were diagnosed with skin cancers (squamous cell and basal cell), all of which were successfully treated. Skin cancers account for 40% to 50% of malignancies in solid organ transplant, and solid organ transplant recipients are 65- to 250-fold more likely to develop squamous cell cancers and ten- to 16-fold more likely to develop basal cell skin cancers compared to the general population. One patient who was not durably chimeric and remained on chronic immunosuppression developed acute lymphocytic leukemia approximately seven years post-transplant and is in remission following chemotherapy. Approximately six years after transplant, this patient had received rituximab to treat an episode of acute, antibody-mediated rejection approximately nine months before this diagnosis. One patient was diagnosed approximately seventeen months post-transplant with papillary thyroid carcinoma, which was successfully surgically removed, and, as described above, one patient, a lifelong smoker, was diagnosed 4.5 years post-transplant with non-small cell carcinoma of the lung, which was ultimately fatal.

Adverse events reported by stem cell donors consisted of headache, fatigue, skeletal muscular pain, and nausea, and occurred around the timing of their granulocyte colony-stimulating factor administration for stem cell mobilization and apheresis. These adverse events were generally mild, fairly transient, and responded to nonsteroidal anti-inflammatory drugs or similar pain medications. There were no serious adverse events reported by any stem cell donors.

Our Phase 2 Results—Quality of Life (QoL)

Several clinical and real-world studies highlight that treatment with chronic immunosuppression significantly impairs patient-reported QoL in solid organ transplant recipients. To study the potential influence of withdrawal from chronic immunosuppression on transplant recipients' patient-reported QoL, 13 FCR001-treated patients from our Phase 2 LDKT trial who were successfully withdrawn from chronic immunosuppression at approximately one year post-transplant were compared with 12 patients who would have met inclusion criteria for the FCR001 tolerance protocol but were transplanted under standard of care therapy. Patients were administered three validated QoL self-administered questionnaires: the End Stage Renal Disease Symptom Checklist—Transplantation Module (**ESRD-TM**); the Short Form 36 (**SF-36**) questionnaire, the most frequently used patient reported outcomes instrument in clinical trials today; and the EuroQol 5 Dimension (**EQ-5D-5L**) questionnaire. Investigators and statisticians were blinded to the treatment group. The patient demographics were similar between the two groups. FCR001-treated patients and the standard of care patients were surveyed an average of 50 and 75 months after their organ transplant, respectively.

In general, FCR001 treated patients reported better QoL than standard of care treated patients in all dimensions. In the ESRD-TM, standard of care patients reported statistically significantly greater cardiac and renal dysfunction and significantly greater levels of side effects from corticosteroids than FCR001 patients. The General Health Component of the SF-36 showed a statistically significant decrease in self-reported health among the standard of care patients compared to the FCR001 patients. In the EQ-5D-5L, standard of care patients reported a statistically significantly higher rate of pain and discomfort problems than FCR001 patients. A number of other categories in each of the three questionnaires showed positive trends in favor of FCR001 patients, but the findings were not statistically significant due to the small sample size. In addition to the dimensions of the SF-36 and ESRD-TM where FCR001 treated patients had a statistically significant benefit versus standard of care, patients treated with FCR001 had numerically favorable ratings on all other dimensions that did not reach statistical significance. Moreover, on the EQ-5D5L, in addition to the statistically significant benefit on pain/discomfort ratings, FCR001 treated patients had numerically favorable ratings versus standard of care on the dimensions of usual activity, anxiety/depression, and mobility. Both FCR001 and standard of care treated patients rated no problems on the dimension of self-care.

In summary, the three quality of life instruments used in this trial were in agreement that standard of care patients reported diminished mental health in the form of greater psychological stress, decreased overall mental health, and greater anxiety/depression scores compared to the FCR001-treated patients who had been able to discontinue their chronic immunosuppression. The three instruments also provided similar results in the areas of reported pain and discomfort as well as cognitive impairment, which again were notably higher in the standard of care patients compared to the FCR001-treated patients. Collectively, these preliminary results suggest that when our investigational FCR001 therapy enabled the discontinuation of all chronic immunosuppression medications, this outcome may be associated with significantly improved QoL in those FCR001-treated patients as compared to the QoL of standard of care patients who remained on chronic immunosuppression. Our FREEDOM-1 trial will further evaluate the potential QoL impact of FCR001 versus standard of care using the ESRD-TM and SF-36 questionnaires.

Our Phase 3 FREEDOM-1 Trial

Based on promising data from our Phase 2 LDKT trial, we have initiated FREEDOM-1, a 5-year multicenter, open-label, randomized, controlled, Phase 3 trial assessing the safety and efficacy of FCR001 in first-time, adult LDKT. We expect the trial to take place across 15 to 18 sites in the United States, of which ten were activated as of January 31, 2021. A total of 120 LDKT recipients will be randomized 2-to-1 into the following two arms: (1) *the interventional arm*, where 80 patients will receive LDKT and FCR001 accompanied by nonmyeloablative conditioning, and will receive standard of care chronic immunosuppression that can potentially be eliminated by 12 months post-transplant, and (2) *the control arm*, where 40 patients will receive a LDKT plus standard of care chronic immunosuppression. The primary objective is to evaluate the proportion of FCR001 recipients who are free from chronic immunosuppression, without BPAR, at 24 months post-transplant.

The secondary objective is to evaluate the change in mean renal function (eGFR by Modification of Diet in Renal Disease) from month one post-transplant to month 24 in FCR001 recipients. Because LDKT recipients on standard of care treatments do not discontinue immunosuppression without rejecting the transplanted organ, neither the primary endpoint nor the secondary endpoint of FREEDOM-1 involves a statistical comparison between the interventional arm and the control arm. Instead, the primary endpoint of FREEDOM-1 is the demonstration that the lower end of our confidence interval of FCR001 patients free from chronic immunosuppression and without BPAR at two years post-transplant is above 30%. The secondary endpoint of FREEDOM-1 is the demonstration that the lower end of our confidence interval for the mean renal function (as measured by eGFR) of the FCR001 patients is above a five-point decline in eGFR.

Our Phase 3 protocol incorporates several learnings from our Phase 2 trial in order to optimize the likelihood of achieving donor stem cell engraftment and durable chimerism and minimize the risks of graft rejection or GvHD. As depicted in the figure above entitled "*Phase 2 LDKT Trial: Summary of Patient Dispositions and Duration of Follow-Up,"* and the accompanying discussion, during our Phase 2 trial, we identified a number of factors that we believe negatively affected outcomes, and we adjusted our minimum cell doses and trial protocols accordingly. For example, we observed that highly sensitized patients were more likely to reject their stem cell graft. As a result, we are excluding certain types of highly sensitized patients from our Phase 3 protocol. Characteristics of highly sensitized patients include, but are not limited to, patients with a PRA greater than 20% and patients who have had recent blood product transfusions. We are also excluding female-donor-to-unrelated-male-recipient pairings, as this pairing is known to increase the risk of GvHD in allo-HSCT, as well as transplant recipients who have had significant recent infections.

Further, we require adherence to our full nonmyeloablative conditioning regimen (including administration of the post-transplant dose of cyclophosphamide), and we require that our centers adhere to best clinical practices for allo-HSCT, including enhanced surveillance for, and proactive management of, GvHD; infectious disease prophylaxis and treatment with drugs that are not myelosuppressive; standard revaccination protocols; and avoiding medications that may induce cytopenia. We will also require all FCR001-dosed patients who are not durably chimeric and weaned off their chronic immunosuppression to be maintained at all times on standard of care maintenance immunosuppression unless it is medically necessary to reduce immunosuppression, such as in cases of severe infection.

Delayed Tolerance in LDKT: FREEDOM-2

In our FREEDOM-2 trial, we intend to assess whether FCR001 can induce durable immune tolerance to the transplanted organ when it is administered, together with nonmyeloablative conditioning to LDKT recipients up to one year following their kidney transplant. The design of the FREEDOM-2 trial is virtually identical to the FREEDOM-1 trial, except that FCR001 will be administered three- to twelve months post-LDKT in FREEDOM-2, whereas it will be administered the day after the LDKT in FREEDOM-1. In both cases, nonmyeloablative conditioning will be administered commencing five days prior to the administration of FCR001. Positive results in FREEDOM-2 could potentially enable us to also address some portion of the prevalent LDKT population, rather than the incident LDKT population that is addressed by FREEDOM-1.

FREEDOM-2 is a five-year, multi-center, single-arm, open-label trial to assess the safety, preliminary efficacy, and overall benefit of FCR001 cell therapy in previously transplanted recipients of a kidney from a living donor. We filed an original IND and protocol for this trial in 2011, in which two patients were dosed on an exploratory basis. We have recently revitalized and amended this protocol to incorporate numerous learnings from our Phase 2 LDKT trial, including increasing our minimal cell doses, exclusion of highly sensitized patients, and adherence to best allo-HSCT practices and use of appropriate prophylactic medications for HSCT. Similar to FREEDOM-1, the primary objective of FREEDOM-2 is to evaluate the proportion of FCR001 recipients who are free from chronic immunosuppression, without BPAR, at 24 months post-FCR001 infusion. The secondary objective is to evaluate the change in renal function from baseline (day one, prior to FCR001 infusion) to month 24 in FCR001 recipients. The amended protocol has not yet been reactivated to enroll patients. We expect to reinitiate the FREEDOM-2 trial in the second half of 2021.

As noted above, in 2012, we enrolled two patients in an earlier version of our delayed tolerance protocol. Both patients continue to have stable renal function and are being managed as standard of care kidney transplant patients, even though neither achieved durable chimerism. As noted above, we have revitalized and amended this protocol to incorporate numerous learnings from our Phase 2 LDKT trial. Because neither of these patients was treated in accordance with the current protocol, nor received our optimized cell doses, these patients will not count towards the formal analysis of our FREEDOM-2 trial.

Although FREEDOM-2 initially contemplates administering FCR001 no more than one year after LDKT, we have the flexibility to amend the trial protocol to extend the period of time between LDKT and FCR001 administration if we see positive initial results from our FREEDOM-2 trial.

We believe that positive proof of concept in FREEDOM-2 could open to the door to broader clinical application of our Facilitated Allo-HSCT Therapy to deceased donor kidney and other solid organ transplantation settings. In the deceased donor setting, there is an inherent delay between the time that a deceased donor's solid organ is transplanted to a recipient, and when a product made from cells procured from the deceased donor could be processed and then subsequently administered to the transplant recipient. Demonstration in FREEDOM-2 of the feasibility of delayed tolerance induction would lend support to the potential of our Facilitated Allo-HSCT Therapy to induce durable immune tolerance in a recipient of a deceased donor's organ up to twelve months after their original organ transplant.

Deceased Donor Program

We believe that it may be possible to induce allogeneic tolerance in a recipient using HSCs procured and processed from a deceased donor. We are conducting preclinical research to explore whether we can successfully procure and process cells from deceased donors to produce either FCR001 or a similar product to FCR001, which we would designate FCR002.

Deceased donor kidney transplants represent a substantial portion of the kidney transplant recipient population, accounting for more than 70% of annual kidney transplants in the United States. If our Facilitated Allo-HSCT Therapy is shown to be capable of inducing durable immune tolerance in the deceased donor kidney transplant setting, then we also believe our therapeutic approach could be applied to the transplant of other solid organs from deceased donors. Collectively, the incident deceased solid organ transplant population is more than four times greater than the living donor transplant population.

Restore: Severe Autoimmune Disease

We believe that our Facilitated Allo-HSCT Therapy has the potential to restore self-tolerance in patients suffering from severe autoimmune diseases by eradicating diseased autoreactive cells and regenerating a new and healthy repertoire of immune cells, thereby halting the autoreactive cells' attack on one's own body.

We believe that our Phase 2 LDKT trial has already provided some proof of concept that our Facilitated Allo-HSCT Therapy could be used to treat severe autoimmune disease. Typically, 20% to 60% of kidney transplant patients whose end-stage renal disease is caused by a kidney-related autoimmune disease experience post-transplant recurrence of their kidney-related autoimmune disorder. Ten patients in our Phase 2 trial of FCR001 had an underlying, kidney-related autoimmune disease that led to their need for a LDKT. As shown in the table below, seven of these ten patients achieved durable donor chimerism and were able to be weaned off all chronic immunosuppression approximately one year post-transplant. As of January 31, 2021, none of these seven successfully tolerized patients has experienced recurrence of their prior kidney-related autoimmune disorder, with follow-up from four to ten years post-transplant. By contrast, recurrence of the prior kidney-related autoimmune disease was reported in two of the three other patients who experienced either transient or no chimerism.

Durable Chimerism vis-à-vis Disease Recurrence in our Phase 2 Trial

	Durable Chimerism		Disease Recurrence	
Condition	Durable Chimerism	Disease Recurrence	Transient or no Chimerism	Disease Recurrence
IGA Nephropathy	4	0	2	1
Focal Segmental Glomerulosclerosis	2	0	0	0
Membranous Glomerulonephritis	1	0	1	1
Total	7	0	3	2

We believe that this preliminary finding highlights the importance of achieving durable chimerism in order to induce durable allogeneic tolerance, as well as the potential of FCR001 to induce durable allogeneic tolerance in patients with an autoimmune disease.

Over the past 25 years, data from randomized trials and real-world experience gathered from more than 3,300 patients by the European Society for Blood and Marrow Transplantation Autoimmune Disease Working Party has shown that individuals suffering from a range of severe, refractory forms of rheumatologic, neurologic, and hematological autoimmune diseases appear to have benefitted from HSCT, primarily autologous HSCT. We believe that those data, together with our preliminary findings showing the potential of FCR001 to induce allogeneic tolerance in patients with a prior kidney-related autoimmune disease, support development of FCR001 for severe autoimmune disease. We initially have prioritized development of FCR001 in a severe form of scleroderma, also known as systemic sclerosis (**SSc**), given the high unmet need in this indication and third party data supporting the potential benefit of HSCT for SSc.

Background of Scleroderma or SSc

SSc is a rare, clinically heterogenous, progressive, multisystem, chronic autoimmune disorder that primarily affects the connective tissues. It has a prevalence of approximately 70,000 to 80,000 individuals in the United States, about 80% of whom are women aged 30 to 50. SSc is characterized by progressive fibrosis of the skin and visceral organs, vasculopathy, and the presence of autoantibodies against various cellular antigens. The etiology of this disorder is largely unknown, but research suggests it is due to both genetic and environmental factors that lead to dysregulation of the innate and adaptive immune systems, dysfunctional inflammatory responses, and connective tissue repair injury in susceptible individuals.

We estimate that approximately 40% of systemic sclerosis patients are diagnosed with the most severe form of SSc, diffuse cutaneous SSc (**dcSSc**). dcSSc has a poor prognosis, with a disease-related mortality of 5% to 10% per year. dcSSc may progress rapidly, affecting areas throughout the body. Progression from Raynaud's phenomenon—a condition that causes decreased blood flow to the fingers and toes—to skin thickening typically occurs within one year and can cause profound impairments to quality of life and morbidities, including disfigurement, difficulty opening the mouth, loss of facial expression, and joint contractures. Internal organ vasculopathy and fibrosis typically begin within five years of diagnosis. Commonly affected organs can include the gastrointestinal tract, heart, lungs and kidneys. Interstitial lung disease and pulmonary hypertension together account for nearly 50% of SSc deaths, followed by renal and cardiac complications.

The mortality rate in dcSSc is highest during the first five years of disease onset, when disease progression is most rapid. Patients with rapidly progressing dcSSc have an especially poor prognosis, with survival rates at five and ten years as low as 60% and 30%, respectively. There are no disease modifying therapies for dcSSc. Nintedanib and tocilizumab are the only FDA-approved therapies indicated for SSc but are only labeled to address interstitial lung disease in these patients. Other treatment options are only focused on symptom management and their costs can be substantial, especially in patients with advanced disease. A study published prior to the introduction of nintedanib—which costs nearly $140,000 annually—estimated that five-year direct healthcare costs in the United States for SSc patients with interstitial lung disease or pulmonary hypertension exceed $190,000 and $250,000, respectively.

Recently, however, HSCT has emerged as a promising and potentially disease-modifying treatment for patients with dcSSc at risk for organ failure.

HSCT as Potential Treatment for dcSSc

SSc is thought to be mediated by autoreactive T-cells and B-cells targeting self-antigens, eventually leading to organ damage. HSCT aims to reconstitute the hematopoietic system using either the patient's own (autologous) or healthy donor (allogeneic) stem cells to re-establish a naïve, self-tolerant immune system to both allo-antigens and auto-antigens. The combination of lymphotoxic chemotherapy (e.g., cyclophosphamide and anti-thymocyte globulin) with or without TBI leads to a profound and long-lasting lymphopenia with persistently reduced levels of pathogenic autoantibodies. Aside from this nonspecific immunosuppression, there is growing evidence that HSCT can restore tolerance by establishing a diversified T-cell receptor repertoire and by increasing numbers of regulatory T-cells.

Autologous HSCT is increasingly being explored as a treatment option for patients with dcSSc and internal organ involvement. Cumulative data from three randomized, controlled trials conducted by third parties have observed the benefit of autologous HSCT therapy in dcSSc as assessed by multiple important outcome measures including clinical improvement, overall and event-free survival, and disease relapse. Further, based on these findings, the European League Against Rheumatism and the American Society for Blood and Marrow Transplantation both now recommend HSCT for patients with rapidly progressive dcSSc at risk for organ failure. Data to date indicate that autologous HSCT may require a myeloablative regimen to be most effective. Higher rates of relapse have been observed when less intensive conditioning regimens have been used. Nevertheless, disease recurrence still was observed in autologous HSCT patients, presumably in part because the patient's own diseased stem cells are being reinfused in the patient.

Allogeneic HSCT offers a promising alternative therapy to autologous HSCT for patients diagnosed with dcSSc. The advantage of allo-HSCT is its ability to replace the immune system with cells from healthy donors that lack the genetic predisposition for a return to autoimmunity, and with the potential of inducing tolerance to both auto-antigens and allo-antigens. Despite these benefits, allo-HSCT is not commonly used to treat dcSSc patients due to concerns over a potentially higher risk of transplant-related mortality (**TRM**) and GvHD, which affects between 20% to 70% of recipients. The risk of TRM and GvHD depends on the type of transplant, the degree of donor-recipient HLA compatibility, and the prophylaxis regimen.

Compared to autologous HSCT, standard allo-HSCT has the potential to offer patients with dcSSc additional benefit of lower rates of disease recurrence or potentially a cure. However, with current approaches, this procedure is accompanied by the significant risk of acute and chronic GvHD and a higher TRM. We believe that our Facilitated Allo-HSCT Therapy, which combines administration of FCR001 with a nonmyeloablative conditioning regimen, could offer a less toxic alternative to autologous HSCT (which generally requires a fully myeloablative conditioning regimen), and has the potential to enable broader use of allo-HSCT with a lower GvHD risk for patients with dcSSc and potentially other severe autoimmune diseases.

Our Phase 2 Trial in dcSSc: FREEDOM-3

FREEDOM-3 is a two-year treatment and three-year follow-up, multi-center, single-arm, open-label proof-of-concept Phase 2 trial assessing the safety and efficacy of FCR001 in adults with dcSSc at risk for organ failure. The design of the FREEDOM-3 trial is substantially similar to that of the FREEDOM-2 trial, except without the kidney transplant. We plan to enroll up to 18 adults diagnosed with dcSSc within five years of first non-Raynaud's symptom, who have not adequately responded to at least one immunosuppressive agent and have significant cutaneous and pulmonary and/or renal involvement. The primary endpoint in this trial will be safety assessed by AE/SAEs, GvHD, AEs of special interest, neutrophil and platelet recovery time, safety lab assessments, autologous rescue infusion use and donor-specific antibodies. Secondary and exploratory endpoints will include T-cell chimerism over time, overall event-free survival and various efficacy markers (e.g., CRISS, a

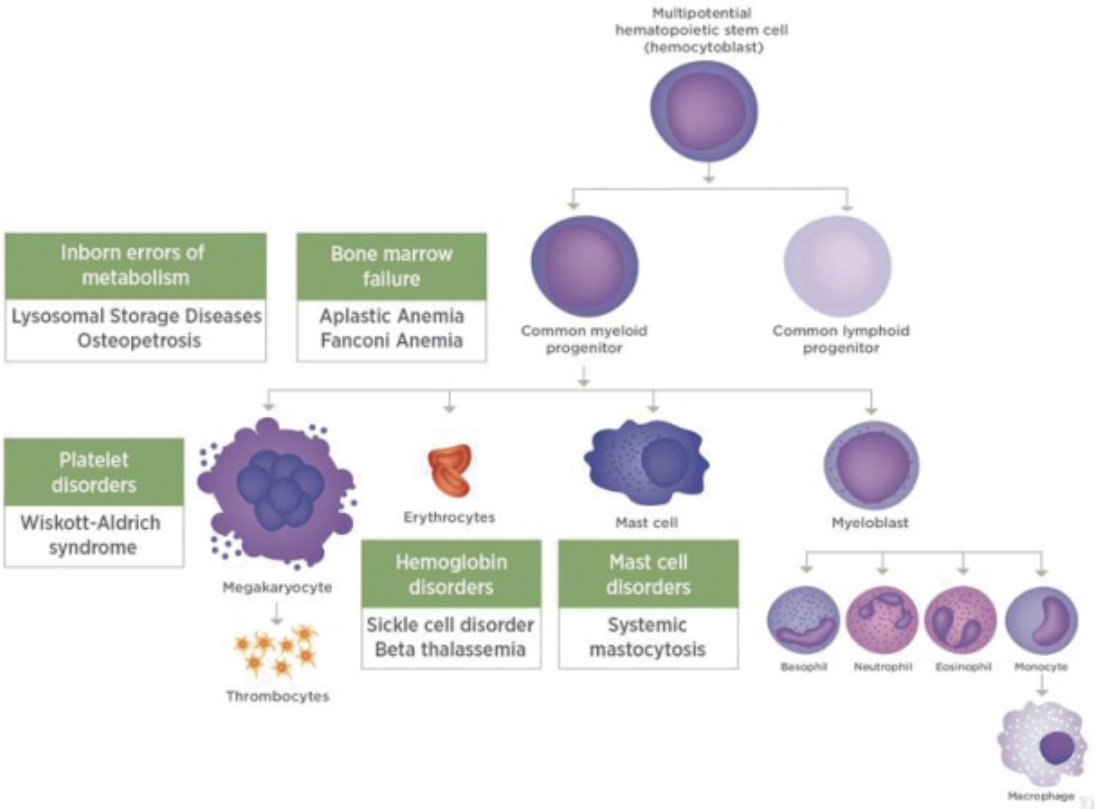
relatively new composite response index for dcSSc which has recently been validated in later stage clinical studies; DMARD use; and skin manifestation changes by Modified Rodnan skin score). We expect to initiate this trial in the second half of 2021.

Replace: Potential of FCR001 to Treat Certain Other Severe Non-Malignant Disorders

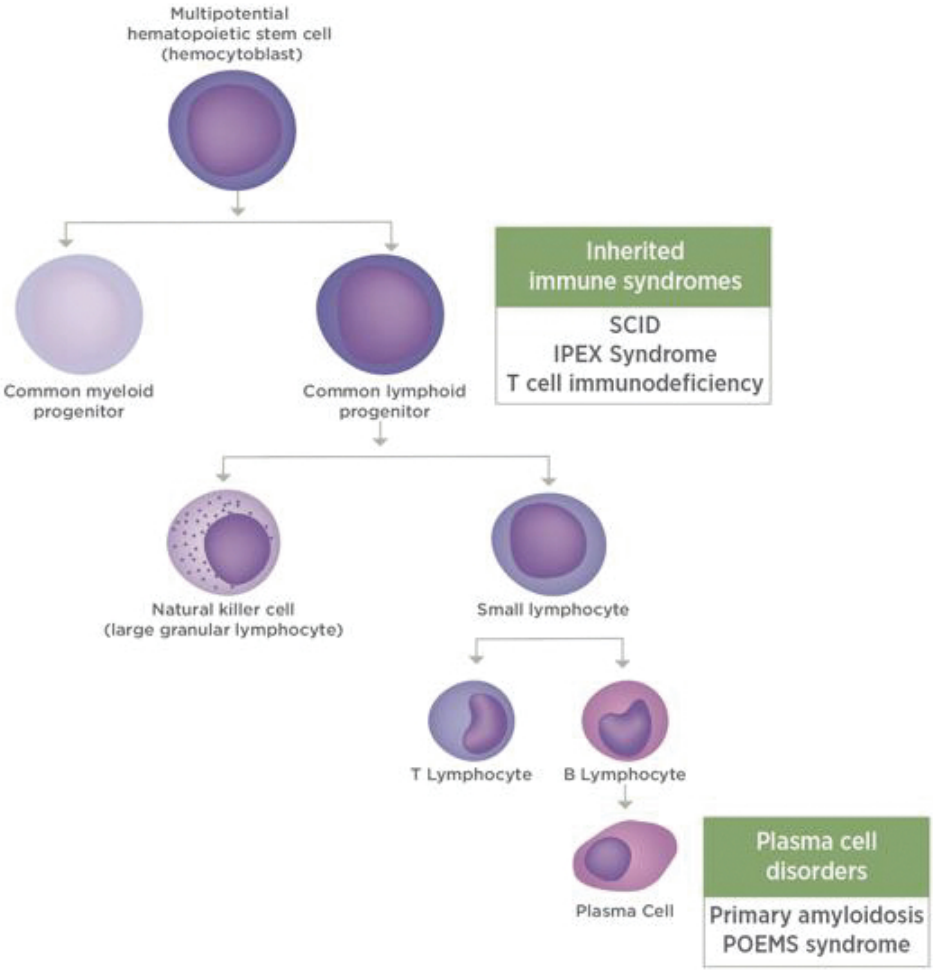
Use of Allo-HSCT to Treat Certain Severe Non-Malignant Blood, Immune and Metabolic Disorders

In 2017, more than 1,100 allo-HSCT procedures were performed to treat a wide range of severe non-malignant blood, immune and metabolic disorders, all of which involve functional defects or deficiencies of cells derived from HSCs that mature into our functioning blood and immune systems. Standard allo-HSCT entails transplanting HSCs collected from a healthy donor into these patients, to potentially cure the patient's defective cells by replacing them with healthy, donor-derived cells. As depicted in the figures below, HSCs differentiate broadly into common blood (myeloid) and immune (lymphoid) progenitor cells. These cells in turn further differentiate into cells that, if defective, can correspond to various categories of hematological or immune disorders.

Severe Non-malignant Blood Disorders for which Facilitated Allo-HSCT has Therapeutic Potential



Immune Indications for which Facilitated Allo-HSCT has Therapeutic Potential



The therapeutic principle of allo-HSCT for the range of severe non-malignant disorders noted above is to replace the defective or deficient HSCs in a patient's bone marrow with normal-functioning HSCs from a healthy donor. Thereafter, the donor HSCs would produce functional blood and immune cells that could potentially ameliorate or even functionally cure these disorders.

Many patients who might benefit from allo-HSCT do not receive it because they are unable to find a suitable HLA-matched donor. Approximately 30% of allo-HSCT candidates overall have suitable related donor matches. The risk of GvHD is positively correlated with the degree of HLA mismatch, and this risk is even greater if the donor is unrelated to the recipient. In 2017, less than half of allo-HSCTs for non-malignant indications were from HLA-matched sibling donors. According to the National Marrow Donor Program, which has over 25 million donors registered worldwide, there is a wide racial and ethnic disparity in the likelihood of finding a suitable match. As such, there is a significant unmet need for an approach to allo-HSCT that could enable better clinical outcomes regardless of the degree of HLA mismatch between donor and recipient, as mitigating the HLA-mismatch barrier could dramatically expand the pool of potential donors for allo-HSCT.

A second major limitation of allo-HSCT for non-malignant indications is that it usually entails fully myeloablative conditioning due to concerns that nonmyeloablative conditioning will not promote robust levels and durability of donor chimerism to effectively replace most of the defective HSCs in the recipient's bone marrow. The intensity and toxicity of myeloablative conditioning regimens is greater than for nonmyeloablative regimens and necessitates a long and costly hospitalization while the recipient's immune and blood systems reconstitute. According to the AHRQ HCUPNet, the average length of hospital stay for patients undergoing allo-HSCT in 2017 was 32 days, with an average charge per hospitalization of $572,945. Moreover, the risk of serious long-term sequelae, such as blood cancers, is significantly elevated by fully myeloablative conditioning. An analysis of more than 28,000 patients showed that one factor affecting the incidence of secondary cancers was the dose of TBI. Patients who received a single dose of greater than 1000 cGy (which is a dose consistent with fully myeloablative conditioning) were more likely to develop secondary cancers compared to those given a single dose of less than 1000 cGy, and this risk increased over time after transplant, reaching up to 7% at 15 years. Assuming a dose-response relationship, the risk of developing secondary cancers would be significantly reduced for patients that receive a significantly lower dose of TBI (e.g., 200 cGy), which is the dose that is currently used in our nonmyeloablative conditioning regimen.

Thus, we believe there is a significant unmet need for a nonmyeloablative approach to allo-HSCT for severe non-malignant blood, immune and metabolic disorders that could enable high levels of durable donor chimerism with less short- and long-term toxicity and correspondingly shorter hospital stays and lower costs.

FCR001 for Certain Severe Non-Malignant Disorders

We believe that FCR001, or our Facilitated Allo-HSCT Therapy more broadly, has the potential to address key limitations to current allo-HSCT, which has limited the use of allo-HSCT in severe non-malignant blood, immune and metabolic disorders despite its potentially curative impact on such disorders.

In our Phase 2 trial of LDKT recipients, FCR001 treatment induced, in a significant portion of our patients, high levels (>95%) of durable (median of six years, longest up to 11 years) donor whole blood chimerism and T-cell donor chimerism despite a nonmyeloablative conditioning regimen. As noted above in "Evidence of Immunocompetence in FCR-Treated Patients," we have observed evidence of reconstitution of immune and blood cell components (e.g. T-cells, B-cells, natural killer cells, monocytes, granulocytes, and red blood cells) in FCR001 recipients. We have also observed a low incidence of acute GvHD (grade II-IV of 5%; grade III-IV of 3%) and of chronic GvHD (3%) in our Phase 2 trial, despite the fact that many of our donor-recipient pairs were significantly HLA-mismatched and unrelated. By contrast, in a trial conducted by a third party at Johns Hopkins, HLA-related patients with hematologic malignancies who were transplanted with unmodified HSCs and with a nonmyeloablative conditioning regimen that was similar to ours, but somewhat more intensive, had a relatively high incidence of acute GvHD (grade II-IV of 34%; grade III-IV of 6%) and of chronic GvHD (25%). Patients on the Johns Hopkins protocol were treated with two post-transplant cyclophosphamide doses, while those treated in our Phase 2 trial with our nonmyeloablative regimen for FCR001 received only one post-transplant cyclophosphamide dose. These data are derived from two different clinical trials with differences in trial design and patient populations. No head-to-head clinical trials have been conducted.

We plan to prioritize FCR001 for one or more severe non-malignant blood, immune or metabolic disorders for advancement into IND-enabling studies by the end of 2021.

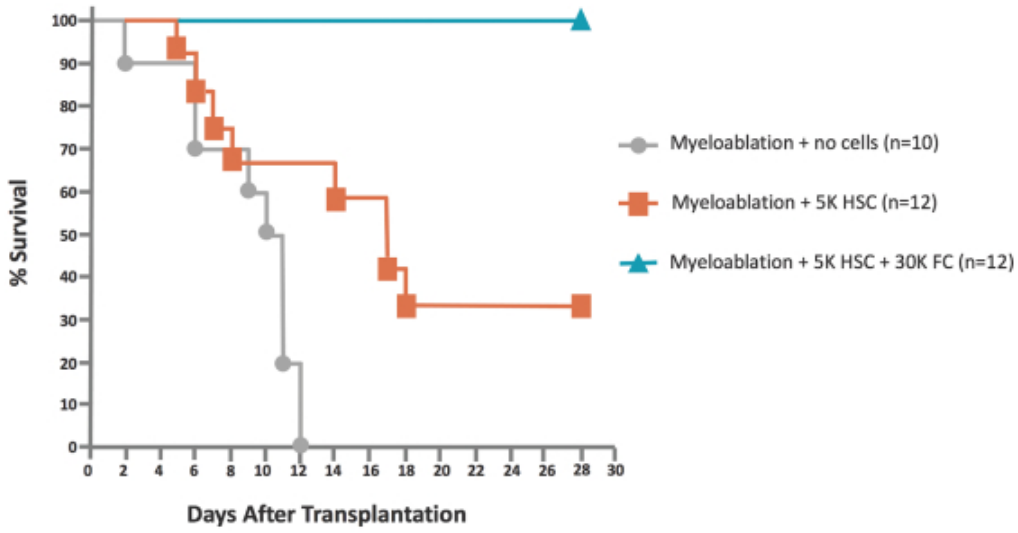
Preclinical Studies: Facilitating Cell Mechanism of Action

Preclinical research conducted by third parties has observed that high doses of purified HSCs can reconstitute lethally conditioned, allogeneic recipients, but that significantly lower numbers of HSCs are needed when whole marrow is transplanted. A university team led by our founder and Chief Scientific Officer, Dr. Suzanne T. Ildstad, originally discovered that FCs may serve to facilitate engraftment of HSCs in allogeneic settings. Subsequently, FCs have been observed by other investigators to be associated with enhanced allogeneic

HSC engraftments in both mouse and humanized mouse models. In addition, FCs have been observed to be associated with reduced rates of GvHD. Consistent with preclinical data generated in mouse models, enhanced engraftment of donor HSCs was observed in our Phase 2 trial of FCR001.

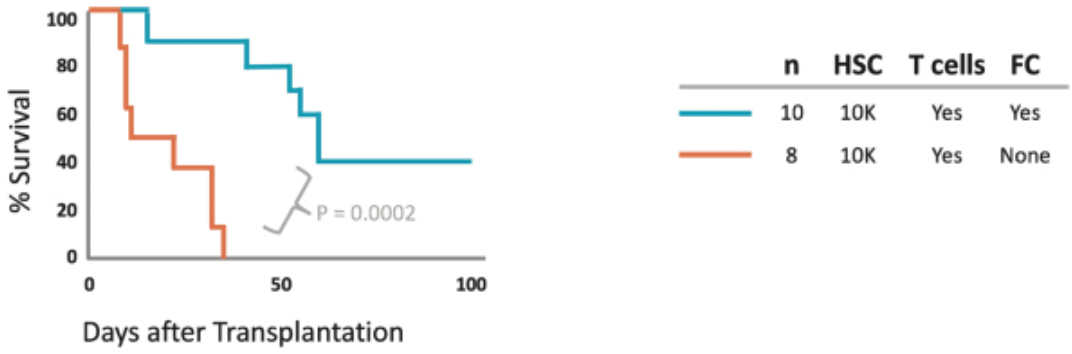
Our preclinical studies of FCR001 have observed the potential of FCs to augment engraftment of HSCs. Together with our former collaborator, Novartis, we evaluated the impact of FCs on HSC engraftment in lethally irradiated mice. We observed that, in lethally irradiated mice, transfer of 5,000 HSCs alone resulted in death due to engraftment failure; however, the transfer of 5,000 HSCs together with 30,000 FCs resulted in HSC engraftment and survival of all mice, as shown in the figure below. We believe that these data support the hypothesis that enriching the FC subpopulation in human HSC transplants may improve the outcome of allo-HSCT in the clinic.

Mouse FCs and Engraftment in allo-HSCT



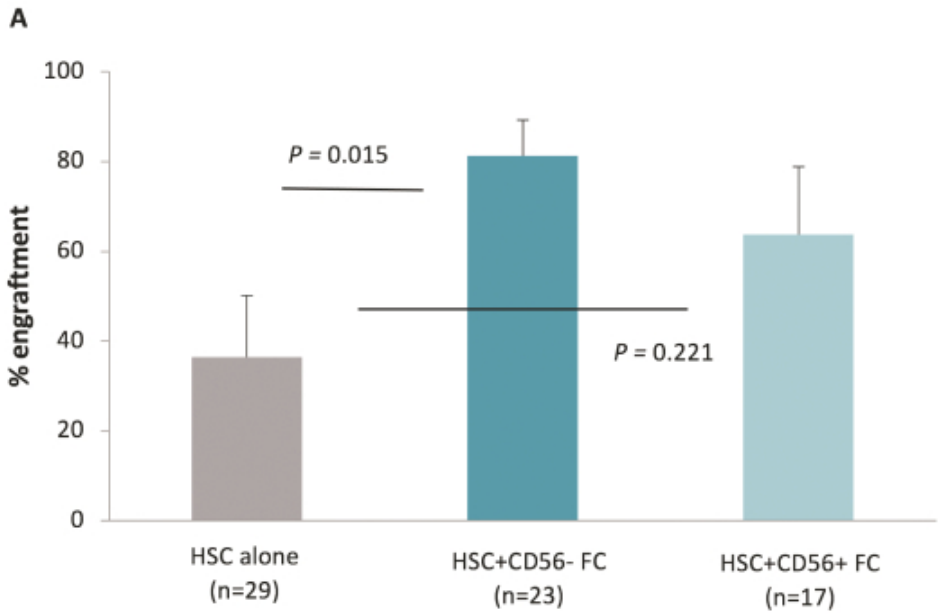
Although a limited number of donor T-cells are known to improve HSC engraftment, these same donor T-cells can also elicit GvHD. As shown in the figure below, we have observed that co-transfer of FCs with HSCs and T-cells in an *in vivo* allogeneic mouse model was associated with delays and reductions in the development of GvHD. Recipient mice were conditioned with lethal doses of TBI. Both experimental groups were transplanted with HSCs and T-cells, and one of the groups also received FCs. We observed that all mice in the group that only received HSCs and T-cells died due to GvHD within 42 days, as shown in the orange line of the graphic. When FCs were also transferred, we observed delayed development of GvHD and survival of 40% of these animals, as represented by the blue line of the graphic. We believe that these data support the hypothesis that FCs provide a protective effect against the development of allogeneic GvHD.

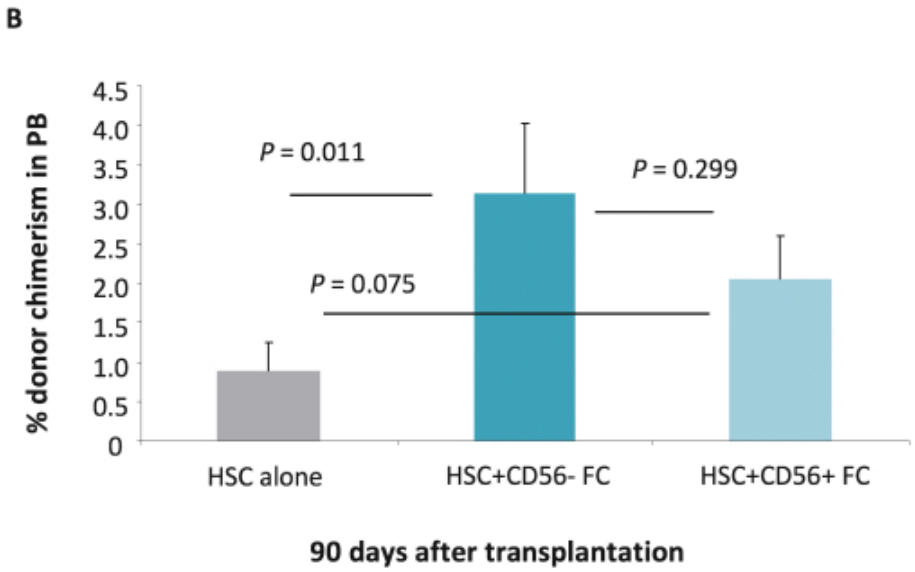
Evidence that Mouse FCs Protect Against Death from GvHD



We, together with Novartis and a university team, conducted a study in immunodeficient NSG mice to evaluate the role of human FC subpopulations in engraftment of HSCs and the establishment of chimerism *in vivo*. The human FC population makes up approximately 1.4% to 3.0% of the total mobilized peripheral blood progenitor cells which proliferate in the bone marrow and migrate into circulation. FCs are a heterogeneous population and comprise at least two distinct subsets distinguished by CD56 expression or lack thereof. HSCs and CD56- or CD56+ FCs were sorted from the same donor and transplanted into NSG mice given sublethal conditioning. The Figure A below shows the percentage of animals in which human HSCs engrafted, while Figure B shows the percentage of human HSCs cells in the peripheral blood (**PB**) of engrafted animals. As illustrated below, 90 days after transplantation, both FC subpopulations exhibited augmented engraftment of HSCs in this setting as compared to the HSC alone population.

Human FCs and Long-term HSC Engraftment in NSG Mice





Based on these preclinical studies, we believe that both subpopulations of CD56 FCs are relevant for facilitating engraftment of HSCs. Both subpopulations of CD56 FCs are components of FCR001.

Competition

The biotechnology and pharmaceutical industries are characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific capabilities, know-how and experience provide us with competitive advantages. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical, and existing or emerging biotechnology companies, academic research institutions and governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient enrollment in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

Living Donor Kidney Transplant (LDKT) and Solid Organ Transplant

There are currently no FDA- or EMA-approved cell therapies for inducing durable immune tolerance to a transplanted solid organ. Medeor Therapeutics, Inc. is conducting a Phase 3 clinical trial for MDR-101, an allogeneic cell therapy, to induce immune tolerance to a donated kidney only in 6 out of 6 HLA-matched LDKT donor-recipient pairs. In 2018, Medeor announced its intent to initiate additional clinical trials to explore tolerance induction in LDKT, for which enrollment has not yet commenced. ITB-MED AB is conducting an early-stage safety study of siplizumab, a humanized anti-CD2 monoclonal antibody in LDKT recipients. In addition, there are other T-cell-based approaches in early development stages that seek to induce immune tolerance in the transplantation of solid organs.

Furthermore, we also face competition more broadly across the solid organ transplantation market from cost-effective and reimbursable anti-rejection and immunosuppressive treatments. The most common medications used to prevent organ rejection are tacrolimus, mycophenolate mofetil and corticosteroids. In many cases, these drugs are administered in combination to enhance efficacy. FCR001 or other allo-HSCT candidates, if any are approved, may not be cost competitive with these existing drugs and other therapies. Some anti-rejection and immunosuppressive medicines are branded and subject to patent protection, while others are available on a generic basis. Insurers and other third-party payors may also encourage the use of generic products or specific branded anti-rejection and immunosuppressive products. As a result, obtaining market acceptance of, and gaining significant share of the market for, any of our therapies that we successfully introduce to the market may pose challenges. In addition, many companies, such as Novartis AG, are developing new therapeutics, and we cannot predict how the standard of care will evolve as our product candidates progress through clinical development.

Scleroderma and Severe Autoimmune Diseases

There are currently no FDA- or EMA-approved cell therapies for treating scleroderma. Current treatment options are focused on addressing organ or tissue-specific manifestations. Methotrexate is often prescribed for skin or musculoskeletal complications, proton pump inhibitors or H2 blockers for gastrointestinal reflux, and endothelin receptor antagonists, epoprostenol analogues or PDE-5 inhibitors for pulmonary artery hypertension. Boehringer Ingelheim's nindetanib and Roche's tocilizumab are the only FDA-approved therapies indicated for the treatment of SSc-associated interstitial lung disease. In addition, other companies, such as Acceleron Pharma, Inc., are exploring therapeutics for SSc, and others, such as Corbus Pharmaceuticals, Inc., Horizon Therapeutics, Plc., and Kadmon Holdings, Inc., are exploring therapeutics for dcSSc; however, these agents are not intended to be curative. Although not formally approved by FDA for this indication, autologous HSCT is occasionally used as a therapy for severe scleroderma and is reimbursed by some payors in the United States and Europe. In the future, we may pursue the development of FCR001 or another cell therapy as a treatment for other severe autoimmune diseases, and as a result, we may also face competition more broadly from other companies with approved products or product candidates in development.

License Agreement with University of Louisville Research Foundation, Inc.

In October 2018, we entered into an amended and restated exclusive license agreement (ULRF License Agreement) with University of Louisville Research Foundation, Inc. (ULRF) as an agent of the University of Louisville, relating to certain licensed patent rights and know-how related to human facilitating cells for our Facilitated Allo-HSCT Therapy. 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.

ULRF retained (i) the rights to publish the licensed technology, subject to our prior written approval and in accordance with the reciprocal nondisclosure agreement governing confidential information relating to the ULRF License Agreement, and (ii) the rights to practice the licensed patents and use the licensed technology, in each case solely for not-for-profit educational and non-commercial research purposes. The ULRF License Agreement is also subject to pre-existing rights of the U.S. government.

Pursuant to the terms of the ULRF License Agreement, we shall use commercially reasonable efforts to develop the products with the goal of achieving regulatory approval thereof and, following such approval, to commercialize such product in any country or countries for which such regulatory approval has been obtained.

As partial consideration for the license and rights, we have paid and will continue to pay ULRF a non-refundable, non-creditable annual license maintenance fee starting on the third anniversary date of the

agreement through the seventeenth anniversary date. In addition, we are obligated to pay ULRF non-refundable, non-creditable research and development, regulatory and sales milestone payments upon the occurrence of certain milestone events in an aggregate amount of approximately $1.625 million for development, regulatory and sales milestones. Each milestone is payable only once. One milestone has been achieved to date under the ULRF License Agreement. As of March 31, 2021, we have paid ULRF $125,000 in milestone payments and $100,000 in annual maintenance fees, for a total of $225,000.

As partial consideration for the license and rights, we also granted to ULRF 65,186 shares of contingent equity consideration. On or prior to an initial public offering or deemed liquidation event, we will either issue shares of common stock equal to such consideration or make an equivalent cash payment of such share amount multiplied by the price per share of common stock at the time of the initial public offering or deemed liquidation event, in full satisfaction of the contingent equity consideration owed to ULRF pursuant to the ULRF License Agreement. If we grant stock to ULRF pursuant to the ULRF License Agreement, then ULRF has agreed to enter into a lockup agreement for such duration and in the form requested by the underwriters of the initial public offering in the same manner as our directors, executive officers and certain stockholders. Dr. Ildstad is entitled to a portion of this compensation pursuant to investor rights under the University of Louisville's Intellectual Property Policy.

Furthermore, on a licensed product-by-licensed product, indication-by-indication and country-by-country basis, we are required to pay future tiered royalties ranging from 1.5% to 4% on annual aggregate net sales of all products during the term of the ULRF License Agreement, subject to certain reductions in connection with obtaining a license for any patents owned or controlled by a third party in order to commercialize the licensed product; provided, however, that the royalties due to ULRF shall not be reduced by more than fifty percent (50%). In the event that we sublicense the licensed patent rights, ULRF is also entitled to receive a tiered percentage of the non-royalty sublicensing revenue we receive. The Company's obligation to pay royalties continues until the expiration or abandonment of the last valid claim of any of the licensed patents under the ULRF License Agreement.

ULRF may terminate the ULRF License Agreement upon our material breach or bankruptcy. We may also terminate ULRF License Agreement upon prior written notice. Unless earlier terminated, the ULRF License Agreement will continue until the expiration or abandonment of the last valid claim of any of the licensed patents under the ULRF License Agreement.

Intellectual Property

The intellectual property that is available to us is critical to our business and we strive to protect it, including by obtaining, maintaining, defending, and enforcing patent protection in the United States and internationally for our proprietary technology, improvements, platforms, products and components thereof, novel biological discoveries, new therapeutic approaches and potential indications, and other inventions that are important to our business. For our product candidates, generally we initially pursue patent protection covering compositions of matter, methods of production, and methods of use. Throughout the development of our product, we will seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through methods of clinical production and quality control.

As of March 31, 2021, our patent portfolio includes four patent families, which are exclusively in-licensed from ULRF in our field. These families include issued patents and pending applications related generally to our facilitating cell product, methods of making our facilitating cell product, methods of using our facilitating cell product therapeutically, and methods of evaluating the viability or potency of our facilitating cell product. Specifically, we have exclusively in-licensed a patent portfolio that currently includes at least three issued U.S. patents, 31 issued patents issued in foreign jurisdictions, and 12 patent applications pending worldwide. The issued patents from three of the four families in our portfolio are expected to expire around 2029, and any patents that issue from the fourth family in our portfolio are expected to expire around 2038, absent any applicable patent term adjustments or extensions.

The first family includes issued patents in Australia, Canada, and Europe; there are no pending applications in this family. All of the issued claims in this family are directed to compositions that include at least 30% facilitating cells, methods of making such compositions, and/or methods of using such compositions. The European patent is validated in five European countries including France, Germany, Italy, Spain, and United Kingdom. This family of patents is in-licensed under an exclusive license agreement with ULRF, and is expected to expire in 2029, absent any applicable patent term adjustments or extensions.

The second family includes one issued U.S. patent, with claims directed to methods of increasing the number of facilitating cells by exposing them to the DOCK-2 protein. This patent is in-licensed under the same exclusive license agreement with ULRF, and is expected to expire in 2032, absent any applicable patent term adjustments or extensions.

The third family includes two issued U.S. patents and two pending U.S. applications, at least one issued patent in each of Australia, China, Europe, India, and Japan, and pending applications in both Canada and China. The claims in this family are directed to compositions that include at facilitating cells, methods of making such compositions, and/or methods of using such compositions absent a requirement for any particular amount of facilitating cells. The European patent is validated in 17 European countries, including Austria, Belgium, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Norway, Poland, Spain, Sweden, Switzerland, Turkey, and the United Kingdom, and also is validated in Hong Kong. This family of patents is in-licensed under the same exclusive license agreement with ULRF. The U.S. members of this family claim the benefit of priority to members of the first family (i.e., as a Continuation-in-Part), and are expected to expire in 2029, while the non-U.S. members of this family are expected to expire in 2031, absent any applicable patent term adjustments or extensions.

The fourth family includes pending applications in the U.S., Australia, Canada, China, Europe, India, Japan and Russia. These pending applications generally have claims directed to determining the potency of a composition that includes facilitating cells. This family of patents is co-owned by us and ULRF; this family of patents also falls within the same exclusive license agreement with ULRF. Patents that issue in this family are expected to expire in 2038, absent any applicable patent term adjustments or extensions.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the U.S., the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the U.S., the term of a patent may be lengthened by patent term adjustment (PTA), which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office (USPTO) in examining and granting a patent or the term of a patent may be shortened if a patent is terminally disclaimed over an earlier filed patent. The term of a patent that covers a drug or biological product may also be eligible for patent term extension (PTE) after FDA approval for a portion of the term effectively lost as a result of the FDA regulatory review period, subject to certain limitations and provided statutory and regulatory requirements are met. PTE can be for no more than five years, typically only one patent per approved product can be extended, the extension cannot extend the total patent term beyond 14 years from approval, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In addition, the length of the adjustment or extension granted could be less than that requested, and we may not receive the full PTA or PTE available if we fail to exercise due diligence during the testing phase or regulatory review process, fails to apply within applicable deadlines, fails to apply prior to expiration of relevant patents, or otherwise fails to satisfy applicable requirements.

As with many biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our products will depend on our success in obtaining effective patent claims and enforcing those patent claims. However, our owned and in-licensed pending patent applications, and any patent applications that may be filed in the future or licensed from third parties, may not result in issuance. The breadth of claims that may be allowed or enforced in our patents also cannot be predicted. Any of our issued patents or patents obtained in the future may be challenged, invalidated, infringed or

circumvented. In addition, because of the extensive time required for clinical development and regulatory review of a therapeutic product that may be developed, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting the protection such patent would afford the respective product and any competitive advantage such patent may provide. For more information, see the section entitled “Risk Factors—Risks Related to Intellectual Property.”

In addition to patents, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. However, trade secrets and know-how can be difficult to protect. We take measures to protect and maintain the confidentiality of proprietary information in order to protect aspects of the business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to require employees, consultants, outside scientific partners, sponsored researchers and other advisors (non-Talaris individuals) to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to non-Talaris individuals during the course of the relationship between us and non-Talaris individuals is to be kept confidential and not disclosed to third parties except in specific circumstances. The agreements we maintain with employees and consultants also provide that all inventions conceived by the employee or consultant in the course of employment or consulting relationships with us, or from the employee’s or consultant’s use of our confidential information, are our exclusive property and require such employees and consultants to assign their right, title and interest in such inventions to us. Although we take steps to protect our proprietary information and trade secrets, including through such contractual means with employees and consultants, we cannot guarantee that we have executed such agreements with all applicable counterparties, such agreements will not be breached, or that these agreements will afford us adequate protection of our intellectual property and proprietary rights. For more information, see the section entitled “Risk Factors—Risks Related to Intellectual Property.”

We have filed and obtained U.S. Registration No. 6180755 for the TALARIS THERAPEUTICS character mark for “biological preparations in the nature of allogeneic cell therapies for use in treating organ transplant patients” in International Class 5 and “providing laboratory services to hospitals and transplant centers involving manipulation of allogeneic cells used for cell therapy treatment of organ transplant patients” in International Class 42. We plan to register trademarks in connection with future products.

Commercialization

Subject to receiving marketing approvals, we expect to commence commercialization activities by building a focused sales and marketing organization in the United States to sell our products. Outside the United States, we expect to enter into distribution and other marketing arrangements with third parties for any of our product candidates that obtain marketing approval.

We also plan to build a marketing and sales management organization to create and implement marketing strategies for any products that we market through our own sales organization and to oversee and support our sales force. The responsibilities of the marketing organization would include developing educational initiatives with respect to approved products and establishing relationships with researchers and practitioners in relevant fields of medicine.

Manufacturing

Our manufacturing strategy is designed to meet the high quality and demand needs of clinical supply and commercial launch of any approved product, while also pursuing the goal of carefully managing our cost structure, maximizing optionality, and optimizing long-term cost of goods. Execution of our strategy includes the following three major features:

- **In-House Manufacturing Facility:** All finished product development and manufacturing is performed in-house in our GMP Cell Processing Facility, which we believe has sufficient capacity for all contemplated clinical trials.
- **Reliable Processing:** Our one-day manufacturing process is robust, reliable and has remained substantially unchanged from Phase 2 to Phase 3, and we believe it is sufficiently scalable to meet future commercial needs without substantial modification.
- **Robust Analytical Testing:** We have developed and qualified in-process assays to support our process, and potency assays required to for the timely release of our product.

Manufacturing Facility

We believe that operating our own manufacturing facility provides us with enhanced control of material supply and enables the more rapid implementation of process enhancements. We believe this approach positions us to support our multicenter clinical trials and potential future commercialization. Our GMP Cell Processing Facility is located in Louisville, Kentucky. The overall facility is approximately 20,000 square feet and includes two identical cleanroom GMP manufacturing suites, two identical quality control testing labs, gowning, changing and supply rooms, clean corridor, material warehouse, accessioning/ shipping rooms, freezer room and other support spaces.

Manufacturing Process and Analytical Testing

The manufacture of FCR001 involves complex processes, including detailed in-process analysis of cell types required for custom patient dosing, separation of the appropriate cells from the starting material with fast and efficient processing to maintain viability, and controlled cryopreservation designed to allow stable product storage until use. Our FCR001 process is substantially unchanged from Phase 2 to Phase 3, and we have manufactured and released multiple lots of clinical trial material for our Phase 2 and Phase 3 clinical trials.

The manufacturing process takes one day and does not require the costly and difficult cell expansion or genetic manipulation necessary for gene therapy and CAR-T manufacturing. The starting material, donated mobilized apheresed peripheral blood, is shipped to our GMP Cell Processing Facility and brought to the accessioning room, where it is inspected and received into the system, and then transported to one of the two dedicated manufacturing suites. Detailed analysis of the incoming apheresis product is performed during initial processing to precisely determine the HSC, FC, and aßTCR+ T-cell content, in order to set the requirements for downstream processing. The manufacturing process is carried out on semi-automated systems which use pre-sterilized, single-use, disposable kits. In order to meet the prescribed dose, our process removes a calculated amount of aßTCR+ T-cells and relatively enriches the product for HSCs and FCs. Samples of the product are then transported to the adjacent dedicated quality control lab for release testing. The final product is cryopreserved in a controlled rate freezer and stored in liquid nitrogen freezers. After testing for all finished product specifications and review of GMP requirements, the product is released by our in-house quality unit, and is later shipped in liquid nitrogen dry shippers to the transplant center, where it is stored until the transplant date.

Government Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, (FD&C Act), the Public Health Service Act (PHS Act) and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern,

among other things, the research, development, clinical trial, testing, manufacturing, quality control, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, marketing, promotion, advertising, post-approval monitoring, and post-approval reporting involving biological products. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals.

U.S. Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices (GLPs) and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an investigational new drug application (IND) which must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an independent institutional review board (IRB) or ethics committee at each clinical trial site before each study may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation of and submission to the FDA of a biologics license application (BLA) for marketing approval that includes sufficient evidence of establishing the safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies);
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current good manufacturing practices (cGMPs) to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (CGTPs) for human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA;
- review of the product candidate by an FDA advisory committee, where appropriate and if applicable; and
- FDA review and approval of the BLA, resulting in the licensure of the biological product for commercial marketing.

Before testing any biological product candidate, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product biological characteristics, chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

Prior to beginning the first clinical trial with a product candidate in the United States, an IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FD&C Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational

clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted to the FDA as part of an IND. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators which generally are physicians not employed by, or under, the control of the trial sponsor. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur.

An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee (DSMB). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study.

Certain information about certain clinical trials must also be submitted within specific timeframes to the NIH for public dissemination on its *clinicaltrials.gov* website.

Clinical trials typically are conducted in three sequential phases that may overlap or be combined:

- *Phase 1*. The investigational product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2*. The investigational product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3*. The investigational product is administered to an expanded patient population to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for approval and product labeling.

In some cases, FDA may require, or firms may voluntary pursue, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory agencies require extensive

monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor, acting on its own or based on a recommendation from the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and also must develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP and as applicable CGTP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Processes

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review to determine if it is substantially complete before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act (PDUFA) for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the

application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Where applicable, the FDA also will not approve the product if the manufacturer is not in compliance with the CGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human patient. The primary intent of the CGTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through appropriate screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure cGMP, CGTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

Under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings precautions or interactions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase IV post-market studies and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan drug designation 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 full 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 drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug many not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Orphan drug designation may also entitle a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions. To be eligible for fast track designation, new drugs and biological product candidates must be intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. One benefit of fast track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.

Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

A product candidate is eligible for priority review if it treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, a product candidate may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

RMAT Designation

As part of the 21st Century Cures Act, enacted in December 2016, Congress created the Regenerative Medicine Advanced Therapy (RMAT) designation to facilitate an efficient development program for, and expedite review of, a product candidate that meets the following criteria: (1) it qualifies as a RMAT, which is defined as 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. A sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may, as appropriate, fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like some of FDA's other expedited development programs, RMAT designation does not change the standards for approval but may help expedite the development or approval process.

Post-Approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. We currently rely, and may continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Manufacturers also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detentions or refusal to permit the import or export of the product, restrictions on the marketing or manufacturing of the product, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the Affordable Care Act), signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

In addition to exclusivity under the BPCIA, a biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Additional Regulation

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and

disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

U.S. Foreign Corrupt Practices Act, U.K. Bribery Act and Other Laws

The U.S. Foreign Corrupt Practices Act of 1977 (FCPA) prohibits companies and their employees, agents, and intermediaries from engaging in certain activities to obtain or retain business or secure any improper advantage, or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize, directly or indirectly, the payment of anything of value to any employee or official of a foreign government or public international organization, or political party, political party official, or political candidate in an attempt to obtain or retain business or to otherwise influence the recipient working in an official capacity. The scope of the FCPA also includes employees and officials of state- owned or controlled enterprises, which may include healthcare professionals in many countries.

Equivalent laws have been adopted in other non-U.S. countries that impose similar obligations, including the U.K. Bribery Act 2010 (Bribery Act). As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. The Bribery Act also imposes liability for failing to prevent a person associated with us from committing a bribery offense.

There also are other laws and regulations governing international operations, including regulations administered by the governments of the United Kingdom and the United States and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws.

Failure to comply with the Bribery Act, the FCPA and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, where applicable.

Other Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS) (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice (DOJ), and individual U.S. attorney offices within the DOJ, and state and local governments. For example, our clinical research, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), and similar state laws, each as amended, as applicable:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, 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. 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 money penalties statute;

- the federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, 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 an obligation to pay or transmit money 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. 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 anti-inducement law, which prohibits, among other things, the offering or giving of remuneration, which 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;
- HIPAA, which created new federal criminal statutes that prohibit, among other things, 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 by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations 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, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the 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;
- the federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers, including physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

In addition to the above, on November 20, 2020, the Office of Inspector General (OIG) finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. The effective date of the new safe harbors has been delayed by the Biden administration until January 1, 2023. We continue to evaluate what effect, if any, these rules will have on our business.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute and False Claims Act, and may apply to our business practices, including, but not limited to, research, distribution, sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers. 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. Several states also impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties. Finally, there are state and foreign laws governing the privacy and security of health information (e.g., the California Consumer Privacy Act), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines, imprisonment and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the federal False Claims Act as well as under the false claims laws of several states.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs (such as Medicare and Medicaid), and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. The approval and commercialization of any of our other cell therapies outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, which may also adversely affect our business.

The risk of our being found in violation of these laws is increased by the fact that many of these laws have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial cost.

Healthcare Reform

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the Affordable Care Act was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual, nondeductible fees based on pharmaceutical companies' share of sales to federal healthcare programs; imposed a new federal excise tax on the sale of certain medical devices; expanded healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance; expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; expanded the entities eligible for discounts under the PHS Act's pharmaceutical pricing program, also known as the 340B Drug Pricing Program; created new requirements to report financial arrangements with physicians and teaching hospitals, commonly referred to as the Physician Payments Sunshine Act; created a new requirement to annually report the identity and quantity of drug samples that manufacturers and authorized distributors of record provide to physicians; created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established the Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There have been executive, legal and political challenges to certain aspects of the Affordable Care Act. During his presidency, former President Trump signed several executive orders and numerous other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act.

Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. For example, on January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices;

however, 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. Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Bipartisan Budget Act of 2018 (BBA), among other things, amends the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, the Tax Cuts and Jobs Act of 2017 (Tax Act), included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full Affordable Care Act. The United States Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet ruled on the constitutionality of the Affordable Care Act, on February 10, 2021, the Biden administration withdrew the federal government's support for overturning the Affordable Care Act. Further, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs 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 Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to legislation amendments to the statute, including the BBA, will stay in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent 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, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the former Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives.

For example, on July 24, 2020 and September 13, 2020, former President Trump signed several Executive Orders aimed at lowering drug pricing that seek to implement several of the administration's proposals. In response, the FDA released a final rule 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. Further, on November 20 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation (MFN) Model

under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period and was scheduled to begin on January 1, 2021 and end on December 31, 2027. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. Additionally, on November 20, 2020, HHS finalized 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 the implementation of which have also been delayed until January 1, 2023. However, it is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any cell therapies for which we obtain regulatory approval. In the United States and markets in other countries, sales of any cell therapies for which we receive regulatory approval for commercial sale will depend, in part, on the availability of coverage and reimbursement from payors. Payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers generally rely on these third-party payors to reimburse all or part of the associated healthcare. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a payor not to cover our cell therapies could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development and manufacturing costs. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

In addition, coverage and reimbursement for products can differ significantly from payor to payor. One payor’s decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS. 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.

Additionally, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process. Payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and

reimbursement for any product, we may need to conduct expensive evidence generation studies in order to demonstrate the medical necessity and cost-effectiveness of such a product, in addition to the costs required to obtain regulatory approvals. If payors do not consider a product to be cost-effective compared to current standards of care, they may not cover the product as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to cover its costs or make a profit.

Employees and Human Capital Resources

As of March 31, 2021, we had 82 full-time employees and 24 consultants. Eleven of our employees have MD or PhD degrees. Within our workforce, 65 employees are engaged in research and development and 17 are engaged in business development, finance, legal, and general management and administration. Our human capital resources objectives include identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Facilities

Our corporate headquarters is located in Louisville, Kentucky, where we lease and occupy 19,585 square feet of office and laboratory space. The current term of our Louisville lease expires November 1, 2023 with an option to extend the term by successive one-year renewal periods in each case upon six months' prior written notice. We also lease office space in Wellesley, Massachusetts, where we lease and occupy 1,040 square feet under a month-to-month lease. We believe our existing facilities in Louisville and Wellesley are sufficient for our needs for the foreseeable future. To meet the future needs of our business, we may lease additional or alternate space, and we believe suitable additional or alternative space will be available in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. 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.

MANAGEMENT

Executive Officers and Directors

The following table sets forth the name, age and position of each of our executive officers and directors as of March 31, 2021.

Name	Age	Position
Executive Officers:		
Scott Requadt	53	President, Chief Executive Officer and Director
Mary Kay Fenton	57	Chief Financial Officer
Suzanne T. Ildstad, MD	68	Chief Scientific Officer and Director
Nancy Krieger, MD	54	Chief Medical Officer
Michael Zdanowski	54	Chief Technology Officer
Non-Employee Directors:		
Francois Nader, MD (2), (3)	64	Chairman of the Board
Sandip Agarwala (1)	41	Director
Nicholas G. Galakatos, PhD (2)	63	Director
Geoff MacKay (2) (3)	54	Director
Mark D. McDade (1)	65	Director
Gaurav D. Shah, MD (3)	46	Director
Sapna Srivastava, PhD (1)	50	Director

(1) Member of the Audit Committee
(2) Member of the Compensation Committee
(3) Member of the Nominating and Corporate Governance Committee

Executive Officers

Scott Requadt has served as our President and Chief Executive Officer and as a member of our board of directors since November 2018. Mr. Requadt has over 19 years of operating and investment experience in the biopharmaceutical industry. Mr. Requadt was most recently a Managing Director of Clarus Ventures, LLC (Clarus) (acquired by The Blackstone Group Inc. (Blackstone) in 2018), where he was an investment professional from September 2005 to October 2018, and a venture partner of Blackstone from November 2018 to December 2020, where he sourced, led and managed multiple investments for Clarus spanning therapeutics, medtech and diagnostics. He currently serves on the board of directors of ESSA Pharmaceuticals, Inc. (Nasdaq: EPIX) and has previously served on the board of directors of Avrobio, Inc. (Nasdaq: AVRO), VBI Vaccines, Inc. (Nasdaq: VBIV) and TyRx, Inc. Prior to joining Clarus in September 2005, Mr. Requadt was Director, Business Development of TransForm Pharmaceuticals, Inc. (Transform) from 2001 until it was acquired by Johnson & Johnson (NYSE: JNJ) in 2005. Prior to TransForm, Mr. Requadt was an M&A attorney at the New York-based law firm of Davis Polk & Wardwell LLP from 1995 to 1999, where he represented numerous private equity, pharmaceutical and technology clients. Mr. Requadt holds a B.Com (Joint Honors in Economics & Finance) from McGill University, an LLB (JD) from University of Toronto and an MBA from Harvard Business School, where he was a Baker Scholar. We believe that Mr. Requadt is qualified to serve as a member of our board of directors due to his substantial investing and operating experience in the biopharmaceutical industry.

Mary Kay Fenton has served as our Chief Financial Officer since March 2021. Ms. Fenton previously served as the Vice President of Strategic Operations, Vertex Cell & Genetic Therapies of Vertex Pharmaceuticals, Inc. (Nasdaq: VRTX) from October 2019 through February 2021. Ms. Fenton joined Vertex

upon completion of the acquisition of Semma Therapeutics, Inc. (Semma) by Vertex in October 2019. From May 2019 until October 2019, Ms. Fenton served as the Chief Financial Officer and Chief Operating Officer of Semma. From January 2006 until December 2018, Ms. Fenton served as Chief Financial Officer of Achillion Pharmaceuticals, Inc. (Achillion) (acquired by Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN)), and from October 2000 until January 2006, Ms. Fenton held various financial positions of increasing responsibility at Achillion. Prior to joining Achillion, Ms. Fenton held various positions within the Technology Industry Group at PricewaterhouseCoopers LLP from August 1991 until October 2000, including as Senior Manager responsible for the life sciences practice in Connecticut. Ms. Fenton also serves on the board of directors of Oncorus, Inc. (Nasdaq: ONCR). Ms. Fenton holds an MBA in finance from the Graduate School of Business at the University of Connecticut and an AB in economics from the College of the Holy Cross.

Suzanne T. Ildstad, MD, is our founder and has served us in various roles since our inception, including as Chief Scientific Officer since November 2018 and a member of our board of directors since February 2002. Her seminal discovery of facilitating cells led to our founding in 2002 and Dr. Ildstad served as our founding Chief Executive Officer from 2002 until November 2018. Dr. Ildstad has spent her career developing allogeneic cellular therapies for transplantation immunology and transitioning novel discoveries from the bench to the clinic. Dr. Ildstad is also the founding director of the Institute for Cellular Therapeutics of the University of Louisville and is a Professor (with Tenure), Department of Surgery, a Distinguished University Scholar and Jewish Hospital Distinguished Professor of Transplantation. She has received numerous awards and honors, including election to the National Academy of Medicine and National Academy of Inventors as well as the Mayo Clinic Distinguished Alumnus Award. She has authored over 230 manuscripts and is a named inventor or co-inventor on over 35 patents. Dr. Ildstad holds a BSc from University of Minnesota and an MD from Mayo Clinic Medical School. Dr. Ildstad also completed her surgery residency at Massachusetts General Hospital, an immunology fellowship at National Institutes of Health, and a pediatric surgery/transplant fellowship at Cincinnati Children’s Hospital.

Nancy Krieger, MD, has served as our Chief Medical Officer since November 2018. Dr. Krieger has over 15 years of diverse global experience in the pharmaceutical industry, in cellular therapy, solid organ and stem cell transplantation, immunology/inflammation, bone metabolism, rare diseases, as well as liver and chronic kidney disease. Prior to joining Talaris, she advanced through roles of increasing responsibility at Novartis AG (NYSE: NVS) from February 2007 to November 2018, most recently as a senior global program clinical head in immunology and dermatology from July 2017 to November 2018 and previously as executive director, global program medical director, immunology and dermatology from October 2009 to July 2017. Dr. Krieger also served as a medical director at Bristol-Myers Squibb Company (NYSE: BMY) from June 2004 to February 2007, playing a significant role in the clinical development of the Belatacept Transplant Program. Dr. Krieger completed her transplant fellowship at the University of Wisconsin, and general surgical residency at Stanford University, including a 3-year postdoctoral fellowship in Stanford’s immunology department. Dr. Krieger holds an AB in Biology from Occidental College and an MD from Columbia University College of Physicians and Surgeons.

Michael Zdanowski has served as our Chief Technology Officer since October 2020. Mr. Zdanowski is an accomplished leader in cell therapy technical operations with over 25 years of relevant experience. He has led manufacturing, logistics, QA/QC and process and analytical development groups for stem cell organizations, and led design, construction and/or validation of equipment and facilities for commercial manufacturing for such firms as Pfizer Inc. (NYSE: PFE), Bayer AG (OTC: BAYZF) and Regeneron Pharmaceuticals Inc. (Nasdaq: REGN). He was most recently Senior Vice President of BioPharmaceutical Operations for Medeor Therapeutics from March 2018 to April 2020. Previously, Mr. Zdanowski was Vice President of GMP Operations for the New York Stem Cell Foundation from September 2016 to March 2018 and Vice President of Manufacturing for Mesoblast Limited (Nasdaq: MESO) from April 2013 to August 2016. Mr. Zdanowski has prepared FDA & EU CMC submissions for several late-stage stem cell products, including the BLA supporting the first FDA approval for an allogeneic stem cell therapy product HemaCord. He received his MBA from Columbia University and degrees in Mechanical Engineering and Philosophy from the University of Pennsylvania.

Non-Employee Directors

Francois Nader, MD, has served as Chairman of our board of directors since November 2018. Dr. Nader also currently serves as chairman of Acceleron Pharma, Inc. (Nasdaq: XLRN), and as independent director of Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) and Moderna, Inc (Nasdaq: MRNA). Dr. Nader is a leading value builder in the biopharma industry. Dr. Nader was President, Chief Executive Officer and Executive Director of NPS Pharmaceuticals, Inc. from March 2008 to February 2015, when the company was sold to Shire plc (Nasdaq: SHPG). Dr. Nader was recognized as the EY National Life Science Entrepreneur of the Year® in 2013 and was awarded the Ellis Island Medal of Honor in 2017. Dr. Nader is the past chairman of BioNJ and Prevail Therapeutics Inc. (acquired by Eli Lilly and Company (NYSE: LLY)) and has served on the board of Biotechnology Innovation Organization (BIO), NPS Pharmaceuticals, Inc., Baxalta, Inc. (acquired by Shire plc (Nasdaq: SHPG)), Clementia Pharmaceuticals, Inc. (acquired by Ipsen SA (OTC: IPSEY)), Advanced Accelerator Applications SA (acquired by Novartis AG (NYSE: NVS)), Trevena, Inc. (TRVN) and Noven, Inc. (acquired by Hisamitsu Pharmaceutical Co., Inc). Dr. Nader earned his French Doctorate in Medicine from St. Joseph University in Lebanon and his Physician Executive MBA from the University of Tennessee. We believe Dr. Nader is qualified to serve on our board of directors because of his experience as public company CEO, integrated healthcare markets and medical and regulatory affairs and his extensive experience as a director of numerous public and private biopharmaceutical companies.

Sandip Agarwala has served as a member of our board of directors since November 2018. Mr. Agarwala has been a Managing Director of Longitude Capital Management, a healthcare venture capital firm that invests in transformative healthcare companies, since January 2014. Mr. Agarwala currently serves on the board of directors of Cydan Development Inc., Endeavor Biomedicines Inc., LEXEO Therapeutics Inc., Opna Immuno-Oncology SA, and has been a board observer of Inozyme Pharma Inc (Nasdaq: INZY) and Aptinyx, Inc. (Nasdaq: APTX). He has also led Longitude Capital's royalty and structured investment strategy since April 2013. Mr. Agarwala holds an MBA in Finance and Health Care Management from the Wharton School of the University of Pennsylvania and a BSE in Systems Engineering from the University of Pennsylvania. We believe Mr. Agarwala is qualified to serve on our board of directors because of his experience and leadership both in the healthcare and venture capital fields.

Nicholas G. Galakatos, PhD, has served as a member of our board of directors since November 2018. Dr. Galakatos is the Global Head of Life Sciences of Blackstone. Prior to joining Blackstone, Dr. Galakatos was a co-Founder and Managing Director of Clarus, since the firm's inception in 2005. Dr. Galakatos is currently the chairman of the board of directors of Anthos Therapeutics, Inc. (Anthos), a private, clinical-stage cardiovascular biotechnology company founded in 2019, and a member of the board of directors of Praxis Precision Medicines, Inc. (Nasdaq: PRAX). Previously, Dr. Galakatos also served on the board of directors of publicly traded public companies Entasis Therapeutics Holdings Inc. (Nasdaq: ETTX), NanoString Technologies, Inc. (Nasdaq: NSTG) and Catabasis Pharmaceuticals, Inc. (Nasdaq: CATB). Dr. Galakatos is a member of the Director's Council of the Koch Institute at the Massachusetts Institute of Technology (MIT), and a member of the Board of Trustees at Reed College. Dr. Galakatos received a B.A. in chemistry from Reed College and a PhD in organic chemistry from MIT. We believe Dr. Galakatos is qualified to serve on our board of directors because of his business, investing and leadership experience in the life sciences industry and his scientific background.

Geoff MacKay has served as a member of our board of directors since November 2018. Mr. MacKay has also served as the president and chief executive officer of AvroBio, Inc. since November 2015. From April 2015 to June 2017, Mr. MacKay served as interim chief executive officer of eGenesis, Inc., a biotechnology company, and from December 2003 to December 2014, he served as chief executive officer of Organogenesis Inc. (Nasdaq: ORGO). Prior to that, from February 1993 to December 2003, Mr. MacKay served in various senior leadership positions within the global transplantation & immunology franchise at Novartis Canada, Global (Basel), USA (NYSE: NVS). Mr. MacKay previously served on the board of RepliCel Life Sciences Inc. (OTC: REPCF), Gemstone Biotherapeutics LLC and Centre for Commercialization of Regenerative Medicine, as chairperson of the board of MassBio, chairperson of the board of the Alliance of Regenerative Medicine, and on the advisory

council to the Health Policy Commission for Massachusetts. Mr. MacKay holds a B.A. in psychology and a graduate certificate in marketing management from McGill University. We believe Mr. MacKay is qualified to serve on our board of directors because of his extensive executive experience in the life sciences industry.

Mark D. McDade has served as a member of our board of directors since November 2018. Since January 2017, Mr. McDade has been Managing Partner of the Qiming US Healthcare Fund, a venture capital firm based in Seattle and formed in January 2017. Prior to Qiming, from April 2008, Mr. McDade was Executive Vice President, Corporate Development, and from January 2009, EVP and Chief Operating Officer, at UCB S.A. (OTC: UCBJF), a Belgian biopharmaceutical company, until his retirement from UCB in October 2016. From November 2002 to September 2007, Mr. McDade served as Chief Executive Officer and a member of the board of directors of PDL BioPharma, Inc. (Nasdaq: PDLI), a biotechnology company. From 2000 to 2002, Mr. McDade was Chief Executive Officer of Signature BioScience, Inc., a drug discovery company. Mr. McDade currently serves on the board of directors of Lupin Limited, a global biopharmaceutical company based in Mumbai, India. Previously, Mr. McDade also served on the board of directors of Dermira, Inc. (Nasdaq: DERM), and as chairman of the board of Aimmune Therapeutics, Inc. (Nasdaq: AIMT), until both companies were acquired by Eli Lilly and Company (NYSE: LLY) and Nestle SA (OTC: NSRGY), respectively, in March and October 2020. Previously, Mr. McDade also served on the board of directors of publicly traded companies Phillips Edison Grocery Center REIT II, Inc. and Five Prime Therapeutics, Inc. (Nasdaq: FPRX). Mr. McDade received a BA in History from Dartmouth College and an MBA from the Harvard Business School. We believe that Mr. McDade is qualified to serve on our board of directors due to his executive management, leadership and investing experience in the life sciences industry, as well as his extensive experience as a director of public biopharmaceutical companies.

Gaurav D. Shah, MD, has served as a member of our board of directors since December 2020. Dr. Shah has served as the co-founder, President, and Chief Executive Officer since October 2015, and a member of the board of directors since June 2020, of Rocket Pharmaceuticals (Nasdaq: RCKT). Prior to this role, from January 2011 to September 2015, Dr. Shah held various leadership positions at Novartis AG (NYSE: NVS), including Global Program Head for CAR-T-19, Global Clinical Program Head for CTL-019 and Biosimilars, and Global Clinical Leader for Afinitor. Prior to Novartis, Dr. Shah was a Medical Director at Eli Lilly and Company (NYSE: LLY) from July 2008 to December 2010, where he oversaw clinical development of numerous programs, including olaratumab. During his industry tenure, he has participated in several drug development programs resulting in successful regulatory approvals, such as CTL-019 in pediatric ALL, the first cell and gene therapy approved in the U.S., as well as various successful commercial launches. Prior to that, Dr. Shah was an Assistant Professor of Medicine/Oncology at Columbia University. Dr. Shah holds his BSc in behavioral neuroscience from Harvard College (summa cum laude, Phi Beta Kappa) and a MD from Columbia University. Dr. Shah also completed his internal medicine residency at Brigham and Women’s Hospital, and hematology/oncology fellowship training at Memorial-Sloan Kettering. We believe Dr. Shah is qualified to serve on our board of directors due to his extensive experience in the biopharmaceutical industry, including his current role as chief executive officer and in other management positions.

Sapna Srivastava, PhD, has served as a member of our board of directors since January 2021. Dr. Srivastava has over 20 years of experience as a senior executive in the biopharmaceutical industry. From September 2017 to January 2019, Dr. Srivastava served as the Chief Financial and Strategy Officer at Abide Therapeutics, Inc., a biopharmaceutical company that was acquired by H. Lundbeck A/S in 2019. From April 2015 to December 2016, Dr. Srivastava served as the Chief Financial and Strategy Officer at Intellia Therapeutics, Inc. (Nasdaq: NTLA), a genome editing company. Previously, for nearly 15 years Dr. Srivastava was a senior biotechnology analyst at Goldman Sachs, Morgan Stanley, and ThinkEquity Partners, LLC. She began her career as a research associate at JP Morgan. Dr. Srivastava currently serves on the board of directors of SQZ Biotechnologies Company (Nasdaq: SQZ) and Asclepix Therapeutics, Inc. Dr. Srivastava holds a PhD from NYU University School of Medicine and a BS from St. Xavier’s College, University of Bombay. We believe Dr. Srivastava is qualified to serve as a member of our board of director due to her extensive experience in the biopharmaceutical industry, including her prior experience as a chief financial officer and in other management positions.

Composition of Our Board of Directors

Our board consists of nine members, each of whom are members pursuant to the board composition provisions of our certificate of incorporation and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, professional and personal experiences, and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation that will become effective in connection with the closing of this offering and amended and restated bylaws that became effective upon the effectiveness of the registration statement of which this prospectus is a part, also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director Independence

Our board of directors has determined that all members of the board of directors, except Suzanne T. Ildstad, Scott Requadt and Geoff MacKay, are independent directors, including for purposes of the rules of the Nasdaq Global Market and the SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of the Nasdaq Global Market and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers. Dr. Ildstad is not an independent director under these rules because she is the Chief Scientific Officer of the Company. Similarly, Mr. Requadt is not an independent director under these rules because he is the President and Chief Executive Officer of the Company. Under the Nasdaq Global Market rules, Mr. MacKay is not an independent director until at least January 2022 because he currently serves as an executive officer of AvroBio, Inc., of which Mr. Requadt served as a member of the compensation committee until his resignation in January 2019.

Staggered Board

In accordance with the terms of our amended and restated certificate of incorporation that will become effective in connection with the closing of this offering and our amended and restated bylaws that became effective upon the effectiveness of the registration statement of which this prospectus is a part, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2022 for Class I directors, 2023 for Class II directors and 2024 for Class III directors.

- Our Class I directors are Francois Nader, MD, Scott Requadt, and Mark D. McDade;

- Our Class II directors are Nicholas G. Galakatos, PhD, Suzanne T. Ildstad, MD, and Sandip Agarwala; and
- Our Class III directors are Sapna Srivastava, PhD, Gaurav D. Shah, MD, and Geoff MacKay.

Our amended and restated certificate of incorporation that will become effective in connection with the closing of this offering and amended and restated bylaws that became effective upon the effectiveness of the registration statement of which this prospectus is a part provide that the number of our directors shall be fixed from time to time by a resolution of the majority of our board of directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Leadership Structure

Currently, the role of chairman of the board of directors is separated from the role of Chief Executive Officer. Our Chief Executive Officer is responsible for recommending strategic decisions and capital allocation to the board of directors and to ensure the execution of the recommended plans. The chairman of the board of directors is responsible for leading the board of directors in its fundamental role of providing advice to and independent oversight of management. Our board of directors recognizes the time, effort and energy that the Chief Executive Officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the board of directors' oversight responsibilities continue to grow. While our amended and restated bylaws and corporate governance guidelines will not require that our chairman and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Role of the Board in Risk Oversight

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including the four risks more fully discussed in the section entitled "Business" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which will operate pursuant to a charter to be adopted by our board of directors that became effective upon the effectiveness of the registration statement of which this prospectus is a part. The board of directors may also establish other committees from time to time to assist the Company and the

board of directors. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees complied with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations, if applicable. Upon our listing on Nasdaq, each committee's charter will be available on our website at www.talaristx.com. The reference to our website address does not constitute incorporation by reference of the information contained at or available through our website, and you should not consider it to be part of this prospectus.

Audit Committee

Sandip Agarwala, Mark D. McDade, and Sapna Srivastava, PhD serve on the audit committee, which is chaired by Dr. Srivastava. Our board of directors has determined that each are "independent" for audit committee purposes as that term is defined by the rules of the SEC and Nasdaq, and that each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Dr. Srivastava as the "audit committee financial expert," as defined under the applicable rules of the SEC. The audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee's review and discussions with management and our independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our financial statements and our compliance with legal and regulatory requirements as they relate to our financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;
- reviewing all related person transactions for potential conflict of interest situations and approving all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

Nicholas Galakatos, PhD, Francois Nader, MD, and Geoff MacKay serve on the compensation committee, which is chaired by Dr. Galakatos. Our board of directors has determined that Dr. Galakatos and Dr. Nader are "independent" as defined in the applicable Nasdaq rules and that each of Dr. Galakatos, Dr. Nader, and Mr. Mackay is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, and an outside director, as defined pursuant to Section 162(m) of the Internal Revenue Code of 1986, as amended. We are permitted to phase in our compliance with the independent compensation committee requirements set forth by Nasdaq listing standards as follows: (1) one independent member at the time of listing, (2) a majority of

independent members within 90 days of listing and (3) all independent members within one year of listing. Our board of directors intends to cause our compensation committee to comply with the transition rules within the applicable time periods. The compensation committee's responsibilities include:

- reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer;
- evaluating the performance of our Chief Executive Officer in light of such corporate goals and objectives and based on such evaluation, recommending to the board of directors the cash compensation of our Chief Executive Officer, and grants and awards to our Chief Executive Officer under equity-based plans;
- reviewing and approving the cash compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- reviewing and approving the retention or termination of any consulting firm or outside advisor to assist in the evaluation of compensation matters and evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- retaining and approving the compensation of any compensation advisors;
- reviewing and recommending to the board of directors our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors; and
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement.

Nominating and Corporate Governance Committee

Geoff MacKay, Francois Nader, MD, and Gaurav Shah, MD serve on the nominating and corporate governance committee, which is chaired by Dr. Nader. We are permitted to phase in our compliance with the independent compensation committee requirements set forth by Nasdaq listing standards as follows: (1) one independent member at the time of listing, (2) a majority of independent members within 90 days of listing and (3) all independent members within one year of listing. Our board of directors intends to cause our nominating and corporate governance committee to comply with the transition rules within the applicable time periods. The nominating and corporate governance committee's responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- reviewing and recommending to the board of directors appropriate corporate governance guidelines; and
- overseeing the evaluation of our board of directors.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance

Our board of directors has adopted a written code of business conduct and ethics that applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions. A current copy of this code is posted on the Corporate Governance section of our website, which is located at www.talaristx.com. The information on our website is deemed not to be incorporated in this prospectus or to be a part of this prospectus. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

Limitations on Liability and Indemnification Maters

As permitted by Delaware law, provisions in our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering, and amended and restated bylaws, which became effective upon the effectiveness of this registration statement, limit or eliminate the personal liability of directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, a director exercise an informed business judgment based on all material information reasonably available to him or her. Consequently, a director will not be personally liable to us or our stockholders for monetary damages or breach of fiduciary duty as a director, except for liability for:

- any breach of the director’s duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- any act related to unlawful stock repurchases, redemptions or other distributions or payments of dividends; or
- any transaction from which the director derived an improper personal benefit.

These limitations of liability do not limit or eliminate our rights or any stockholder’s rights to seek non-monetary relief, such as injunctive relief or rescission. These provisions will not alter a director’s liability under other laws, such as the federal securities laws or other state or federal laws. Our amended and restated certificate of incorporation, which will become effective immediately prior to the closing of this offering also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Delaware law, our amended and restated bylaws, which became effective upon the effectiveness of this registration statement, provide that:

- we will indemnify our directors, officers, employees and other agents to the fullest extent permitted by law;
- we must advance expenses to our directors and officers, and may advance expenses to our employees and other agents, in connection with a legal proceeding to the fullest extent permitted by law; and
- the rights provided in our amended and restated bylaws are not exclusive.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director or officer, then the liability of our directors or officers will be so eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in connection with their services to us, regardless of whether our bylaws permit such indemnification. We have obtained such insurance.

In addition to the indemnification that is provided for in our amended and restated certificate of incorporation and amended and restated bylaws, we plan to enter into separate indemnification agreements with each of our directors and executive officers, which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements may require us, among other things, to indemnify our directors and executive officers for some expenses, including attorneys' fees, expenses, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of his service as one of our directors or executive officers or any other company or enterprise to which the person provides services at our request. We believe that these provisions and agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

This description of the indemnification provisions of our amended and restated certificate of incorporation, our amended and restated bylaws and our indemnification agreements is qualified in its entirety by reference to these documents, each of which is filed as an exhibit to the registration statement of which this prospectus forms a part.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

There is no pending litigation or proceeding naming any of our directors or officers as to which indemnification is being sought, nor are we aware of any pending or threatened litigation that may result in claims for indemnification by any director or officer.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plans would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

EXECUTIVE COMPENSATION

Overview

The following discussion contains forward-looking statements that are based on our current plans and expectations regarding our future compensation programs. The actual amount and form of compensation that we pay and the compensation policies and practices that we adopt in the future may differ materially from the currently-planned programs that are summarized in this discussion.

The compensation provided to our named executive officers for the fiscal year ended December 31, 2020 is detailed in the 2020 Summary Compensation Table and accompanying footnotes and narrative that follow.

Our named executive officers for the fiscal year ended December 31, 2020, which consisted of our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, were:

- Scott Requadt, our President, Chief Executive Officer and Director
- Dr. Suzanne T. Ildstad, our Chief Scientific Officer
- Dr. Nancy Krieger, our Chief Medical Officer

2020 Summary Compensation Table

The following table provides information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the fiscal year ended December 31, 2020.

Name and Principal Position	Year	Salary ($)	Option Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)(2)	All Other Compensation ($)(3)	Total($)
Scott Requadt(4)						
President, Chief Executive Officer and Director	2020	400,000	2,934,475	128,000	16,763	3,479,238
Dr. Suzanne T. Ildstad						
Chief Scientific Officer and Director(4)	2020	376,000	—	95,880	14,195	486,075
Nancy Krieger						
Chief Medical Officer	2020	375,000	614,210	92,813	14,951	1,096,974

(1) The amounts reported represent the aggregate grant date fair value of the stock options awarded to the named executive officers during fiscal year 2020, calculated in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and does not correspond to the actual economic value that may be received upon exercise of the stock option or any sale of any of the underlying shares of common stock.

(2) The amounts represent actual bonuses earned as of December 31, 2020, upon the attainment of one or more pre-established company and individual performance goals established by our board of directors on an annual basis by Mr. Requadt, Dr. Ildstad, and Dr. Krieger. The amounts were paid in 2021.

(3) The amounts represent an annual matching contribution under our 401(k) Plan.

(4) Mr. Requadt and Dr. Ildstad are also members of our board of directors but did not receive any additional compensation in their capacity as a director.

Narrative to Summary Compensation Table

Base Salaries

Each named executive officer's base salary is a fixed component of annual compensation for performing specific duties and functions, and has been established by our board of directors taking into account each individual's role, responsibilities, skills and expertise. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. For fiscal year 2020, the annual base salary for (i) Mr. Requadt was $400,000, (ii) Dr. Ildstad was $376,000 and (iii) Dr. Krieger was $375,000.

Annual Bonuses

For the fiscal year ended December 31, 2020, each named executive officer was eligible to earn an annual cash bonus based on the achievement of corporate performance metrics, in the case of Mr. Requadt, and corporate and individual performance metrics, in the case of Drs. Ildstad and Krieger. The target annual bonus for Mr. Requadt, Dr. Ildstad, and Dr. Krieger for 2020 was 40%, 30% and 30% of their respective annual base salary.

Equity Compensation

Although we do not yet have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants promote executive retention because they incentivize our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our named executive officers and may grant equity incentive awards to them from time to time.

In February 2020, our board of directors approved equity awards to our employees, including the named executive officers. Mr. Requadt and Dr. Krieger were granted 331,775 stock options and 92,523 stock options, respectively, as described in more detail in the "Outstanding equity awards at fiscal 2020 year-end" table.

In August 2020, Mr. Requadt and Dr. Krieger were granted 118,782 stock options and 33,043 stock options, respectively, as described in more detail in the "Outstanding equity awards at fiscal 2020 year-end" table.

In October 2020, Mr. Requadt and Dr. Krieger were granted 577,736 stock options and 109,485 stock options, respectively, as described in more detail in the "Outstanding equity awards at fiscal 2020 year-end" table.

Employment Arrangements with our Named Executive Officers

We have entered into an offer letter with each of the named executive officers in connection with their employment with us, which set forth the terms and conditions of their respective employment.

Scott Requadt

On November 1, 2018, we entered into an Offer Letter with Scott Requadt (Requadt Offer Letter), who currently serves as our Chief Executive Officer (CEO). The Requadt Offer Letter provides that Mr. Requadt will

also serve as a member of our board of directors for so long as he serves as the CEO of the Company, or until his earlier resignation or removal. The Requadt Offer Letter explicitly provides that Mr. Requadt will be deemed to have voluntarily resigned from our board of directors, effective immediately, upon his cessation of service as the CEO.

The Requadt Offer Letter sets forth his initial annual base salary of $375,000, his initial target annual bonus opportunity of 40% of his then-current base salary, his initial equity grant, and his eligibility to participate in our employee benefit plan generally. Mr. Requadt's current base salary is $450,000. The receipt of an annual bonus is based upon the attainment of performance goals established by the Board and is contingent upon Mr. Requadt's continued employment on the date the bonus is paid.

The Requadt Offer Letter provides that Mr. Requadt's employment is at-will and may be terminated at any time for any reason; provided, that in the event that Mr. Requadt terminates his employment for "Good Reason," as defined in the Requadt Offer Letter, he must provide at least 60 days' advance written notice.

In the event that Mr. Requadt's employment is terminated by us without "Cause" as defined in the Requadt Offer Letter, or by him for Good Reason, Mr. Requadt will be entitled to continued payment of his base salary for a period equal to nine months, paid ratably in accordance with the Company's regular payroll cycle and payment or reimbursement for up to 12 months of health benefit continuation under COBRA (the Severance Benefits). Mr. Requadt must remain available to provide consulting services as reasonably requested by the Company to be eligible to receive the Severance Benefits.

In addition, in the event that Mr. Requadt's employment is terminated by us without Cause, or by him with Good Reason, in each case, within three months prior to or 12 months following a "Change in Control" as defined in the 2018 Plan, Mr. Requadt will be entitled to a lump sum payment equal to his annual bonus target for the year of termination and the unvested portion of all Company equity awards then held by him will immediately vest and become exercisable (such accelerated vesting of equity is included in the term "Severance Benefits"). Mr. Requadt's entitlement to the Severance Benefits is subject to the execution of an effective release of claims in favor of us (a Release).

Additionally, in the event Mr. Requadt's employment is terminated without Cause and he agrees to be bound by, and complies with, a non-competition provision contained in the Release, in addition to the Severance Benefits, he will receive a lump sum payment equal to three months' of base salary. Mr. Requadt is not obligated to agree to this non-competition provision to otherwise receive the Severance Benefits.

Separately, Mr. Requadt is subject to a Confidential Information, Inventions Assignment, and Restrictive Covenant Agreement (the NDA), which he entered into at the commencement of employment with the Company. The NDA includes non-competition and non-solicitation protections covering the one-year period following Mr. Requadt's termination of employment, as well as non-disclosure, intellectual property assignment and non-disparagement obligations. In consideration of Mr. Requadt's agreement to be bound by, and compliance with, the terms, conditions, and restrictions set forth in the NDA, if Mr. Requadt is terminated for Cause, or if he resigns with or without Good Reason, he will be entitled to a lump sum payment in the amount equal to three months of base salary. This lump sum payment is not conditioned upon his execution of a Release.

Suzanne T. Ildstad, MD

On November 1, 2018, we entered into an Offer Letter with Suzanne T. Ildstad (Ildstad Offer Letter), who currently serves as our Chief Scientific Officer. The Ildstad Offer Letter sets forth her initial annual base salary of $365,000, her initial target annual bonus opportunity of 30% of her then-current base salary, and her eligibility to participate in our employee benefit plan generally. Dr. Ildstad's current base salary is $390,000. The receipt of an annual bonus is based upon the attainment of performance goals established by our board of directors or CEO and is contingent upon continued employment on the date the bonus is paid.

The Ildstad Offer Letter recognizes that Dr. Ildstad is employed by the University of Louisville and is currently on "entrepreneurial leave." The Ildstad Offer Letter includes a carveout in her NDA for her work with the University of Louisville and permits her to spend up to 5% of her working time fulfilling her responsibilities to the University of Louisville. Dr. Ildstad must notify us in the event she receives compensation from the University of Louisville that exceeds 10% of her base salary from us.

The Ildstad Offer Letter provides that Dr. Ildstad's employment is at-will and may be terminated at any time for any reason; provided, that in the event that Dr. Ildstad terminates her employment for "Good Reason" as defined in the Ildstad Offer Letter, she must provide at least 30 days' advance written notice.

In the event that Dr. Ildstad's employment is terminated by us without "Cause" as defined in the Ildstad Offer Letter, or by her for Good Reason, Dr. Ildstad will be entitled to the Severance Benefits. Dr. Ildstad must remain available to provide consulting services as reasonably requested by the Company to be eligible to receive the Severance Benefits.

In addition, in the event that Dr. Ildstad's employment is terminated by us without Cause, or by her with Good Reason, in each case, within three months prior to or 12 months following a "Change in Control" as defined in the 2018 Plan, Dr. Ildstad will be entitled to a lump sum payment equal to her annual bonus target for the year of termination and the unvested portion of all Company equity awards then held by her will immediately vest and become exercisable (such accelerated vesting of equity is included in the term "Severance Benefits"). Dr. Ildstad's entitlement to the Severance Benefits is subject to the execution of a Release.

Dr. Ildstad is subject to an NDA, which she entered into at the commencement of her employment with the Company. The NDA includes non-competition and non-solicitation protections covering the one-year period following Dr. Ildstad's termination of employment, as well as non-disclosure, intellectual property assignment and non-disparagement obligations. The NDA's intellectual property assignment provision contains a carveout for inventions developed in connection with Dr. Ildstad's work for the University of Louisville.

Nancy Krieger, MD

On November 1, 2018, we entered into an Offer Letter with Nancy Krieger (Krieger Offer Letter), who currently serves as our Chief Medical Officer. The Krieger Offer Letter sets forth her initial annual base salary of $350,000, her initial target annual bonus opportunity of 30% of her then-current base salary, her initial equity grant and her eligibility to participate in our employee benefit plan generally. Dr. Krieger's current base salary is $415,000. The receipt of an annual bonus is based upon the attainment of performance goals established by our board of directors or CEO and is contingent upon continued employment on the date the bonus is paid.

The Krieger Offer Letter provides that Dr. Krieger's employment is at-will, and may be terminated at any time for any reason; provided, that in the event that Dr. Krieger terminates her employment for "Good Reason" as defined in the Krieger Offer Letter, she must provide at least 30 days' advance written notice.

In the event that Dr. Krieger's employment is terminated by us without "Cause" as defined in the Krieger Offer Letter, or by her for Good Reason, Dr. Krieger will be entitled to the Severance Benefits. Dr. Krieger must remain available to provide consulting services as reasonably requested by the Company to be eligible to receive the Severance Benefits.

In addition, in the event that Dr. Krieger's employment is terminated by us without Cause, or by her with Good Reason, in each case, within three months prior to or 12 months following a "Change in Control" as defined in our Equity Incentive Plan, Dr. Krieger will be entitled to a lump sum payment equal to her annual bonus target for the year of termination and the unvested portion of all Company equity awards then held by her will immediately vest and become exercisable (such accelerated vesting of equity is included in the term "Severance Benefits"). Dr. Krieger's entitlement to the Severance Benefits is subject to the execution of a Release.

Dr. Krieger is subject to an NDA. The NDA includes non-competition and non-solicitation protections covering the one-year period following Dr. Krieger's termination of employment, as well as non-disclosure, intellectual property assignment and non-disparagement obligations.

Executive Severance and Change of Control Plan

Our board of directors adopted the Executive Severance and Change of Control Plan (the "Severance Plan"), which became effective on April 15, 2021, and in which our named executive officers participate. If an eligible executive is party to an employment or letter agreement with us that contains a more favorable definition of a defined term in the Severance Plan or provides for more favorable terms or provisions than provided under the Severance Plan, then the more favorable definition, term or provision, or relevant combination thereof, shall be applicable for the benefit of such eligible executive; provided, however, that in no event shall there be duplication of payments or benefits.

The Severance Plan provides that upon a (A) termination of an eligible executive by us for any reason other than for "cause," (as defined in the Severance Plan), death or "disability," (as defined in the Severance Plan), or (B) resignation by an eligible executive for "good reason" (as defined in the Severance Plan), outside of the "change of control period" (as defined in the Severance Plan), the eligible executive will be entitled to receive, subject to the execution and delivery of an effective release of claims in favor of the Company and continued compliance with all applicable restrictive covenants, (i) continuation of the eligible executive's base salary for 15 months (in the case of our Chief Executive Officer), or nine months (in the case of our other named executives officers) and (ii) continuation of group health benefits, with the cost of the regular premium for such benefits shared in the same relative proportion by us and the eligible executive as in effect until the earlier of (x) 12 months following the "date of termination" (as defined in the Severance Plan) and (y) the date the eligible executive becomes eligible for health benefits through another employer. The payments under (i) will be paid in substantially equal installments in accordance with our payroll practices for our named executive officers.

The Severance Plan also provides that upon a (A) termination of an eligible executive by us other than for cause, death or disability or (B) resignation by an eligible executive for good reason in each case within the change of control period, the eligible executive will be entitled to receive, in lieu of the payments and benefits described above and subject to the execution and delivery of an effective release of claims in favor of the Company and continued compliance with all applicable restrictive covenants, (i) a lump sum amount equal to 1.5 times (in the case of our Chief Executive Officer) or 1.0 times (in the case of our other named executive officers) the sum of such eligible executive's base salary and target annual bonus in effect immediately prior to the date of termination (or immediately prior to the change of control, if higher), (ii) a lump sum in cash equal to a pro rata portion of the eligible executive's target bonus for the year in which the termination occurs, (iii) continuation of group health benefits, with the cost of the regular premium for such benefits shared in the same relative proportion by us and the eligible executive as in effect until the earlier of (x) 18 months (in the case of our Chief Executive Officer) or 12 months (in the case of our other named executive officers) following the date of termination and (y) the date the eligible executive becomes eligible for health benefits through another employer, and (iv) for all outstanding and unvested equity awards of the Company, full accelerated vesting of such awards.

The payments and benefits provided under the Severance Plan in connection with a change in control may not be eligible for a federal income tax deduction by us pursuant to Section 280G of the Internal Revenue Code of 1986, as amended (the "Code"). These payments and benefits may also subject an eligible executive to an excise tax under Section 4999 of the Code. If the payments or benefits payable in connection with a change in control would be subject to the excise tax imposed under Section 4999 of the Code, then those payments or benefits will be reduced if such reduction would result in a higher net after-tax benefit to the eligible executive.

Outstanding Equity Awards at Fiscal 2020 Year-End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2020:

		Option Awards(1)					Stock Awards(1)(2)	
Name	Grant Date	Vesting Commencement Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($)(2)
Scott Requadt	12/20/2018	12/20/2018	—	—			272,051(3)	1,556,132
President, Chief Executive Officer and Director	02/07/2020	02/07/2020	—	—			248,832(4)	1,423,319
	08/20/2020	08/20/2020	118,782(6)	—	3.90	08/20/2030		
	10/02/2020	10/02/2020	577,736(7)	—	5.72	10/02/2030		
Dr. Suzanne T. Ildstad	—	—	—	—	—	—	—	—
Chief Scientific Officer and Director								
Dr. Nancy Krieger	12/20/2018	—	—	—			75,570(5)	432,260
Chief Medical Officer	02/07/2020	02/07/2020	—	—			69,393(4)	396,928
	08/20/2020	08/20/2020	33,043(8)	—	3.90	08/20/2030		—
	10/02/2020	10/02/2020	109,485(9)	—	5.72	10/02/2030		

(1) All stock options and stock awards have been granted pursuant to the terms of our 2018 Equity Incentive Plan, as amended. Except as otherwise may be noted below, all stock options to our named executive officers have been granted with an early exercise feature. In the event of an early exercise, all options exercised that are still subject to vesting conditions are treated as restricted stock until those vesting conditions are met. In the event of a termination of the holder's employment prior to meeting the vesting conditions, we have the right to repurchase any unvested shares at the original purchase price. Upon certain terminations of employment in connection with a change in control, vesting of unvested options and stock awards is fully accelerated, as described above under "—Employment Agreements with our Named Executive Officers".

(2) There was no public market for our common stock as of December 31, 2020. The fair market value of our common stock as of December 31, 2020 used in these calculations was determined by our board in reliance on an independent valuation.

(3) Represents shares acquired upon the exercise of a stock option with an early exercise feature. These shares vest in equal monthly installments until November 1, 2022.

(4) Represents shares acquired upon the exercise of a stock option with an early exercise feature. These shares vest in equal monthly installments until December 5, 2023.

(5) Represents shares acquired upon the exercise of a stock option with an early exercise feature. These shares vest in equal monthly installments until November 16, 2022.

(6) This stock option vests in 48 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service, and is subject to an early exercise feature. Of the shares subject to this option, 9,898 shares were vested as of December 31, 2020.

(7) This stock option vests in 48 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service, and is subject to an early exercise feature. Of the shares subject to this option, 24,072 shares were vested as of December 31, 2020.

(8) This stock option vests in 48 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service, and is subject to an early exercise feature. Of the shares subject to this option, 2,753 shares were vested as of December 31, 2020.

(9) This stock option vests in 48 equal monthly installments following the vesting commencement date, subject to the named executive officer's continuous service, and is subject to an early exercise feature. Of the shares subject to this option, 4,561 shares were vested as of December 31, 2020.

Employee Benefits and Equity Compensation Plans

Second Amended and Restated 2018 Equity Incentive Plan

Our board of directors adopted, and our stockholders approved our 2018 Plan in November 2018. Our 2018 Plan was most recently amended in February 2020. Our 2018 Plan allows for the grant of incentive stock options to our employees, and grants of non-qualified stock options, restricted stock awards to the officers, employees, directors, and consultants of the company and our subsidiary corporations, and other stock-based awards to the officers, employees, directors, and consultants of the company and our subsidiary corporations.

Authorized Shares. No shares will be available for future issuance under the 2018 Plan following the effectiveness of the registration statement of which this prospectus forms a part. However, our 2018 Plan will continue to govern outstanding awards granted thereunder. As of March 31, 2021, we reserved an aggregate of 5,454,915 shares of our common stock for the issuance of options and other equity awards under the 2018 Plan. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of March 31, 2021, stock options to purchase 3,381,382 shares of our common stock at a weighted average exercise price of $4.74 per share, and 839,536 shares of restricted stock were outstanding under the 2018 Plan and 408,415 shares remained available for future issuance under the 2018 Plan. Our board of directors has determined not to make additional awards under the 2018 Plan following the closing of this offering.

Only shares of common stock that have actually been issued under the 2018 Plan in connection with an award shall be counted against the maximum aggregate number of shares of common stock available under the 2018 Plan. Any shares of common stock that are forfeited or canceled, expire, are surrendered or otherwise become unexercisable before the shares of common stock have been issued under the 2018 Plan shall be deemed not to have been issued for purposes of determining the maximum aggregate number of shares of common stock that may be issued under the 2018 Plan, and such unissued shares of common stock shall become available for future grant under the 2021 Stock Plan. If any award granted under the 2018 Plan expires, terminates, is canceled or is forfeited for any reason (in the case of any stock option, without having been exercised in full), or is settled in cash, the number of shares of common stock underlying such award (in the case of any stock option, to the extent unexercised) shall again be available for issuance under the 2018 Plan.

Administration. Our board of directors or a committee or subcommittee designated by our board of directors administers our 2018 Plan. Subject to the provisions of our 2018 Plan, the committee has full authority and discretion to take any actions it deems necessary or advisable for the administration our 2018 Plan, including the recipients, the number of shares or the amount of other consideration subject to each award, to approve forms of award agreements for use under the 2018 Plan, the exercise price, if any, the vesting schedule applicable to the awards for use under our 2018 Plan, to determine whether, to what extent and under what circumstances to provide loans to participants in order to exercise awards or to purchase or pay for shares of common stock issuable pursuant to awards under the plan, and establish additional terms, conditions, rules or procedures to accommodate the terms of any corporate transaction, award exchange program, award deferral program, or other such program, provided, however, that no award shall be subject to any such additional terms, conditions, rules, or procedures that are inconsistent with the provisions of the 2018 Plan.

Options. Stock options may be granted under our 2018 Plan. The 2018 Plan permits the granting of (i) stock options to purchase shares of common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code and (ii) stock options that do not so qualify. The stock option exercise price per share of our common stock underlying each stock option was determined by our board or directors or a committee appointed by the board of directors, and must have been at least equal to 100% of the fair market value of a share of our common stock on the date of grant. The term of each stock option may not have exceeded 10 years from

the date of grant. In the case of an incentive stock option granted to a grantee who, at the time of grant of such stock option, owned stock representing more than 10% of the combined voting power of all classes of stock of the Company, its subsidiaries or its parent or a 10% owner, the exercise price per share of our common stock underlying each such stock option must have been at least equal to 110% of the fair market value of a share of our common stock on the date of grant. the term of each stock option may not have exceeded five years from the date of grant. Stock options shall be exercisable at such time or times and subject to such terms and conditions as shall be determined by the committee at the time of grant. In the event that a written employment agreement between the Company and a participant provides for a vesting schedule that is more favorable than the vesting schedule provided in the form of award agreement, the vesting schedule in such employment agreement shall govern, provided that such agreement is in effect on the date of grant and applicable to the specific stock option. Any unvested shares of common stock received in accordance with an early exercise shall be subject to a repurchase right in favor of the Company. The administrator will determine the methods of payment of the exercise price of a stock option as specified in the applicable award agreement or later authorized by the administrator under the terms of the 2018 Plan.

Restricted Stock. The 2018 Plan allows for the grant of shares of restricted stock. Restricted stock awards are grants of shares of our common stock that are subject to various restrictions, including restrictions on transferability and forfeitures provisions. Shares of restricted stock will vest, and the restrictions on such shares will lapse, in accordance with terms and conditions established by the committee.

Other Stock-Based Awards. The 2018 Plan allows for the grant of other stock-based awards. The committee is authorized to grant other stock-based awards that are payable in, valued in whole or in part by reference to, or otherwise based on shares of common stock, including, shares of common stock awarded purely as a bonus and not subject to any restrictions or conditions, shares of common stock in payment of amounts due under an incentive or performance plan sponsored or maintained by the Company, stock appreciation rights, stock equivalent units, restricted stock units, deferred stock units, phantom stock, phantom stock units, cash awards, and awards valued by reference to book value of shares of common stock. The committee may condition the grant or vesting of other stock-based awards upon the attainment of performance goals or such other factors as the committee may determine. Other stock-based awards and any underlying common stock shall vest or be forfeited to the extend set forth in the award agreement or as otherwise determined by the committee.

Termination. After a participant's termination of employment, consultancy or directorship (other than a termination for cause), and not in the event of a participant's change of status from employee, director or consultant to any other status, if the participant is involuntarily terminated without cause, all his or her stock options that are vested and exercisable may be exercised within a period of 90 days following such termination. If the participant's termination is voluntary, the participant generally may exercise his or her stock options, to the extent vested as of such date of termination, for 30 days following such termination; provided, that if the termination is due to death or disability, the stock option generally will remain exercisable, to the extent vested as of such date of termination, until the one-year anniversary of such termination. In the event the participant engages in "detrimental activity" (as defined in the 2018 Plan) prior to any exercise of his or her stock options, all stock options (whether vested or unvested) shall terminate and expire (and in the case of restricted stock and other stock-based awards, all unvested restricted stock and other stock-based awards shall be immediately forfeited). In the event of a termination for cause or the discovery that the participant engaged in "detrimental activity" (as defined in the 2018 Plan), the Company shall have the right for a period of 90 days from the anniversary thereof, to repurchase any shares of common stock previously acquired by the participant under the 2018 Plan.

Transferability or Assignability of Awards. Our awards are subject to transfer restrictions as the committee may determine. The 2018 Plan generally does not allow for the transfer or assignment of awards, other than, at the discretion of the plan administrator, by will or the laws of descent and distribution, by gift to an immediate family member, or by instrument to an inter vivos or testamentary trust in which the award is passed to beneficiaries upon the death of the participant. Prior to any proposed transfer of shares of common stock, the

participant must provide a written transfer notice to the Company fully describing the proposed transfer. If the Company determines that the transfer notice is insufficient, the Company has the right to repurchase all or any part of the shares of common stock by delivering to the participant (or his or her estate or legal representative) written notice of such exercise within 20 days after the date the Company has determined the proposed transfer to be insufficient.

Change in Control. The 2018 Plan provides that upon the occurrence of a "change in control" (as defined in the 2018 Plan), the administrator may (a) accelerate the vesting of the award, (b) in the case of stock options, accelerate the expiration of the term of the stock option to the date of the change in control, (c) cancel unvested awards for no consideration, and cancel vested awards for fair value, and (d) provide for the issuance of substitute award that will substantially preserve the otherwise applicable terms of any affected award previously granted. For purposes of the 2018 Plan, the completion of this initial public officer by itself, is not considered a change in control.

Certain Adjustments. In the event of certain changes in our capitalization, the number of shares available for future grants, the number of shares covered by each outstanding equity grant and the exercise price under each outstanding option will be proportionately adjusted.

Our board of directors may amend, suspend, or terminate the 2018 Plan at any time, subject to stockholder approval where such approval is required by applicable law. The board of directors may also amend, modify, or terminate any outstanding award, including the exercise price of such award, provided that no amendment to an award may adversely affect any of the rights of a participant under any awards previously granted without his or her consent.

2021 Stock Option and Incentive Plan

In connection with this offering, in April 2021, our board of directors, upon the recommendation of the compensation committee adopted the 2021 Stock Plan, which was subsequently approved by our stockholders. The 2021 Stock Plan became effective on the date immediately prior to the date on which the registration statement of which this prospectus is a part was declared effective by the SEC. The 2021 Stock Plan is expected to replace our 2018 Plan, as our board of directors has determined not to make additional awards under the 2018 Plan following the closing of this offering. The 2021 Stock Plan will provide flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce.

We will initially reserve 3,015,907 shares of our common stock (Initial Limit) for the issuance of awards under the 2021 Stock Plan. The 2021 Stock Plan will provide that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2022, by 5% of the outstanding number of shares of our common stock on the immediately preceding December 31, or such lesser number of shares as determined by our compensation committee (the Annual Increase). This number will be subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2021 Stock Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2021 Stock Plan will be added back to the shares of common stock available for issuance under the 2021 Stock Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options may not exceed the Initial Limit cumulatively increased on January 1, 2022, and on each January 1 thereafter by the lesser of the Annual Increase for such year or 3,015,907 shares of common stock.

The grant date fair value of all awards made under our 2021 Stock Plan and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed $800,000; provided, however, that such amount shall be $1,200,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

The 2021 Stock Plan will be administered by our compensation committee. Our compensation committee will have full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2021 Stock Plan. Persons eligible to participate in the 2021 Stock Plan will be those full or part-time employees, non-employee directors and consultants of the Company and its affiliates, as selected from time to time by our compensation committee in its discretion.

The 2021 Stock Plan will permit the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Internal Revenue Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant. The term of each stock appreciation right will be fixed by our compensation committee and may not exceed ten years from the date of grant. Our compensation committee will determine at what time or times each stock appreciation right may be exercised.

Our compensation committee will be permitted to award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment or service relationship with us through a specified vesting period. Our compensation committee will also be permitted to grant shares of common stock that are free from any restrictions under the 2021 Stock Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee will be permitted to grant cash bonuses under the 2021 Stock Plan to participants, subject to the achievement of certain performance goals.

The 2021 Stock Plan will provide that upon the effectiveness of a “sale event,” as defined in the 2021 Stock Plan, an acquirer or successor entity may assume, continue or substitute outstanding awards under the 2021 Stock Plan. To the extent that awards granted under our 2021 Stock Plan are not assumed or continued or substituted by the successor entity, except as may be otherwise provided in the relevant award certificate, all awards with time-based vesting, conditions or restrictions will become fully vested and nonforfeitable as of the effective time of the sale event, and all awards with conditions and restrictions relating to the attainment of performance goals may become vested and nonforfeitable in connection with a sale event in the compensation committee’s discretion or to the extent specified in the relevant award certificate. Upon the effective time of the sale event, all outstanding awards granted under the 2021 Stock Plan will terminate to the extent not assumed, continued or substituted. In the event of such termination, individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) within a specified period of time prior to the sale event. In addition, in connection with the termination of the 2021 Stock Plan upon a sale event, we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options and stock appreciation rights equal to the difference between the per share cash consideration

payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights and we may make or provide for a payment, in cash or in kind, to participants holding other vested awards.

Our board of directors will be permitted to amend or discontinue the 2021 Stock Plan and our compensation committee will be permitted to amend the exercise price of options and amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to the 2021 Stock Plan will require the approval of our stockholders. Except in the case of adjustments for recapitalizations or other similar corporate transactions, in no event may the compensation committee exercise its discretion to reduce the exercise price of outstanding stock options and stock appreciation rights or effect the repricing of such awards through cancellation and re-grants without stockholder consent.

No awards will be granted under the 2021 Stock Plan after the date that is 10 years from the date of stockholder approval. No awards under the 2021 Stock Plan have been made prior to the date of this prospectus.

2021 Employee Stock Purchase Plan

In connection with this offering, in April 2021, our board of directors, upon the recommendation of the compensation committee, adopted the 2021 Employee Stock Purchase Plan (2021 ESPP), which was subsequently approved by our stockholders. The 2021 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code. The 2021 ESPP initially reserves and authorizes the issuance of up to a total of 852,971 shares of common stock to participating employees. The 2021 ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2022 and each January 1 thereafter through January 1, 2031, by the least of (i) one (1%) of the outstanding number of shares of our common stock on the immediately preceding December 31, (ii) 3,000,000 shares or (iii) such lesser number of shares of common stock as determined by the 2021 ESPP administrator. The number of shares reserved under the 2021 ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

All individuals classified as employees on the payroll records of the Company and each designated subsidiary whose customary employment is for more than 20 hours per week are eligible to participate in the 2021 ESPP, except as determined by the compensation committee in advance of the offering. However, any participating employee who would own 5% or more of the total combined voting power or value of all classes of stock after an option were granted under the 2021 ESPP would not be eligible to purchase shares under the 2021 ESPP.

We may make one or more offerings each year to our employees to purchase shares under the 2021 ESPP. The first offering will begin on the effective date of the registration statement of which this prospectus is part and will end on the following December 31. Each eligible employee as of the effective date of the registration statement for the offering will be deemed to be a participant in the ESPP at that time and must authorize payroll deductions or other contributions by submitting an enrollment form by the deadline. Unless otherwise determined by the compensation committee, subsequent offerings will usually begin each January 1 and July 1 thereafter and will continue for six-month periods (provided that no offering shall last longer than 27 months). Each eligible employee may elect to participate in any subsequent offering by submitting an enrollment form at least 15 days before the relevant offering date. Each eligible employee may elect to participate in any subsequent offering by submitting an enrollment form at least 15 business days before the relevant offering date (or by such other deadline determined by the compensation committee).

Each employee who is a participant in the 2021 ESPP may purchase shares of our common stock by authorizing payroll deductions of up to fifteen (15%) of his or her base compensation during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares of our common stock on the last business day of the purchase period at a price equal to 85% of the fair market value of the shares of our common stock on the first business day or the last business day of the purchase period, whichever is lower. Under applicable tax rules, an employee may

purchase no more than $25,000 worth of shares of common stock, valued at the start of the offering period, under the 2021 ESPP in any calendar year.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the 2021 ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

Senior Executive Cash Incentive Bonus Plan

In April 2021, our board of directors adopted the Senior Executive Cash Incentive Bonus Plan (Bonus Plan). The Bonus Plan provides for cash bonus payments based upon the attainment of performance targets established by our compensation committee. The payment targets will be related to financial and operational measures or objectives with respect to our company, or corporate performance goals, as well as individual performance objectives.

Our compensation committee may select corporate performance goals from among the following: developmental, publication, clinical or regulatory milestones; cash flow (including, but not limited to, operating cash flow and free cash flow); revenue; corporate revenue; earnings before interest, taxes, depreciation and amortization; net income (loss) (either before or after interest, taxes, depreciation and/or amortization); changes in the market price of our common stock; economic value-added; acquisitions, licenses or strategic transactions; financing or other capital raising transactions; operating income (loss); return on capital, assets, equity or investment; stockholder returns; return on sales; total shareholder return; gross or net profit levels; productivity; expense efficiency; margins; operating efficiency; customer satisfaction; working capital; earnings (loss) per share of our common stock; bookings, new bookings or renewals; sales or market shares; number of prescriptions or prescribing physicians; coverage decisions; leadership development, employee retention, and recruiting and other human resources matters; operating income and/or net annual recurring revenue, any of which may be measured in absolute terms, as compared to any incremental increase, in terms of growth, or as compared to results of a peer group.

Each executive officer who is selected to participate in the Bonus Plan will have a target bonus opportunity set for each performance period. The bonus formulas will be adopted in each performance period by the compensation committee and communicated to each executive. The corporate performance goals will be measured at the end of each performance period after our financial reports have been published or such other appropriate time as the compensation committee determines. If the corporate performance goals and individual performance objectives are met, payments will be made as soon as practicable following the end of each performance period, but not later than 74 days after the end of the fiscal year in which such performance period ends. Subject to the rights contained in any agreement between the executive officer and us, an executive officer must be employed by us on the bonus payment date to be eligible to receive a bonus payment. The Bonus Plan also permits the compensation committee to approve additional bonuses to executive officers in its sole discretion.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax-advantaged basis. Plan participants are able to defer eligible compensation subject to applicable annual Internal Revenue Code limits. We provide a discretionary matching contribution of up to 3% of employer contributions to employees who satisfy the minimum service requirements. The 401(k) plan is intended to be qualified under Section 401(a) of the Internal Revenue Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Internal Revenue Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a nonqualified deferred compensation plan sponsored by us during the fiscal year ended December 31, 2020.

Other Benefits

Our named executive officers are eligible to participate in our employee benefit plans on the same basis as our other employees, including our health and welfare plans.

DIRECTOR COMPENSATION

Non-Employee Director Compensation Table

The following table presents the total compensation for each person who served as a non-employee member of our board of directors during the fiscal year ended December 31, 2020. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2020 for their services as members of the board of directors. Scott Requadt, our Chief Executive Officer, and Suzanne T. Ildstad, our Chief Scientific Officer, received no additional compensation for their service as directors. See "Executive Compensation" for more information on the compensation paid to or earned by Mr. Requadt and Dr. Ildstad as employees for year ended December 31, 2020.

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)(3)	Total($)
Sandip Agarwala	—	—	—
Nicholas G. Galakatos	—	—	—
Geoff MacKay	35,000	115,303	150,303
Mark D. McDade	—	—	—
Francois Nader	75,000(4)	541,006	616,606
Gaurav Shah	2,536	303,482	306,018

(1) Amounts represent annual cash retainers payable to each of Mr. MacKay and Dr. Shah. Dr. Shah became a member of our board of directors in December 2020 and the amount reported represents his pro-rated earnings for the fourth quarter of 2020.

(2) The amounts reported represent the aggregate grant date fair value of the stock options awarded to the non-employee directors during fiscal year 2020, calculated in accordance with ASC Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the awards reported in this column are set forth in the notes to our financial statements included elsewhere in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and does not correspond to the actual economic value that may be received upon exercise of the stock option or any sale of any of the underlying shares of common stock.

(3) As of December 31, 2020, each of our non-employee members of our board of directors who held such position held the following aggregate number of unexercised options as of such date:

Name	Number of Securities Underlying Unexercised Options
Geoff MacKay	76,788
Francois Nader	81,373
Gaurav Shah	76,635

(4) This amount reflects the annual retainer payable to Dr. Nader, which he has deferred pursuant to the Company's Deferred Compensation Plan.

Director Letter Agreements

In connection with their service to the board of directors, we entered into letter agreements with each of Dr. Nader, Mr. MacKay, Dr. Shah and Dr. Sapna Srivastava, pursuant to which each is eligible to receive a $35,000 annual cash compensation retainer ($75,000, in the case of Dr. Nader) paid in arrears in equal quarterly installments. These letter agreements will terminate upon the closing of this offering.

Deferred Compensation Plan

On December 21, 2018, our board of directors adopted the Company's Deferred Compensation Plan (the DCP), for the purpose of providing a deferred compensation arrangement to any independent members of our board of directors in consideration of services rendered to us as an inducement for their continued services in the future.

Our board of directors (excluding any participants) administers our DCP. Subject to the provisions of our DCP, our board of directors has full authority and discretion to take any actions it deems necessary or advisable for the administration our DCP, including, to determine who is eligible to participate in the DCP, to determine the eligible for and the amount of benefits payable under the DCP, to establish rules for determining when and how elections can be made, to adopt any rules relating to administering the DCP and to take any other action it deems appropriate to administer the DCP.

Our board of directors may permit a participant to defer "eligible cash compensation" (as defined in the DCP) payable in cash by the Company for any calendar year or other specified period. An election to defer eligible cash compensation must be made before the year in which it is earned. However, the board of directors may permit a participant, in the first year of eligibility for the DCP, to make a deferral election within 30 days of first becoming eligible, provided that the deferral election may relate only to eligible cash compensation attributable to the period following the deferral election. Except as otherwise determine by the board of directors, participants are always 100% vested in their contributions to the DCP.

Non-Employee Director Compensation Policy

In connection with this offering, our board of directors adopted a non-employee director compensation policy that became effective upon the date immediately preceding the date on which the registration statement of which this prospectus is a part was declared effective. The policy is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering as set forth below:

Position	Annual Retainer
Board of Directors:	
Members (other than chair)	$ 35,000
Retainer for chair	$ 40,000
Audit Committee:	
Members (other than chair)	$ 7,500
Retainer for chair	$ 15,000
Compensation Committee:	
Members (other than chair)	$ 5,000
Retainer for chair	$ 10,000
Nominating and Corporate Governance Committee:	
Members (other than chair)	$ 4,000
Retainer for chair	$ 8,000

In addition, the non-employee director compensation policy provides that, upon initial election to our board of directors, each non-employee director will be granted an option to purchase 29,002 shares of our common stock (the Initial Grant). The Initial Grant will vest in equal annual installments over three (3) years, subject to continued service through the applicable vesting date. Furthermore, on the date of each of our annual meetings of stockholders after the completion of this offering, each non-employee director who continues as a non-employee director following such meeting will be granted an option to purchase 14,501 shares of our common stock (the Annual Grant). The Annual Grant will vest in full on the earlier of (i) the first anniversary of the grant date or (ii) our next annual meeting of stockholders, subject to continued service through the applicable vesting date.

Such awards are subject to full accelerated vesting upon the sale of the company and upon the death or disability of the non-employee director.

The grant date fair value of all equity awards and all other cash compensation paid by us to any non-employee director in any calendar year for services as a non-employee director shall not exceed $800,000; provided, however, that such amount shall be $1,200,000 for the calendar year in which the applicable non-employee director is initially elected or appointed to the board of directors.

We will reimburse all reasonable out-of-pocket expenses incurred by non-employee directors for their attendance at meetings of our board of directors or any committee thereof.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions or series of transactions since January 1, 2018, to which we were or will be a party, in which:

- the amount involved in the transaction exceeds, or will exceed, the lesser of $120,000 or one percent of the average of the Company's total assets for the last two completed fiscal years; and
- in which any of our executive officers, directors or holder of five percent or more of any class of our voting capital stock, including their immediate family members or affiliated entities, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and our directors are described elsewhere in this prospectus under "Executive Compensation" and "Management—Director Compensation."

Private Placement of Securities

Common Stock

We were initially organized as a Delaware limited liability company on February 15, 2002, under the name Regenerex LLC, controlled by Suzanne T. Ildstad, our founder and Chief Scientific Officer. On October 30, 2018, we converted to a Delaware corporation under the name of "Regenerex, Inc." and on March 6, 2019, we changed our name to "Talaris Therapeutics, Inc." Upon such conversion, all of our outstanding membership interests were exchanged on a proportional basis for shares of common stock.

Series A Preferred Stock Financings

First Closing

In November 2018, in connection with the initial closing of our Series A preferred stock financing, we sold an aggregate of 22,500,000 shares of our Series A preferred stock at a purchase price of $1.00 per share for an aggregate purchase price of $22,500,000. Each share of our Series A preferred stock will automatically convert into approximately 0.187 shares of our common stock (or approximately 0.187 shares of non-voting common stock upon the election of the holder thereof) immediately prior to the completion of this offering. The following table summarizes purchases of our Series A preferred stock by related persons:

Participant	Affiliated Director(s) or Officer(s)	Shares of Series A Preferred Stock	Total Purchase Price
Clarus Lifesciences III, L.P.(1)	Nicholas G. Galakatos	14,625,000	$ 14,625,000
Longitude Venture Partners III, L.P.(2)	Sandip Agarwala	3,937,500	$ 3,937,500
Qiming U.S. Healthcare Fund, L.P.(3)	Mark D. McDade	3,937,500	$ 3,937,500

(1) Such entity is affiliated with Blackstone, which holds five percent or more of our capital stock. Nicholas G. Galakatos is a senior managing director of Blackstone and a member of our board of directors.
(2) Longitude Venture Partners III, L.P. beneficially holds more than five percent of our capital stock. Mr. Agarwala, a member of our board of directors, is a Managing Director of Longitude Capital Management, which is an affiliate of Longitude Venture Partners III, L.P.
(3) Such entity is an affiliate of Qiming Venture Partners, which holds five percent or more of our capital stock. Mark D. McDade is a managing partner of Qiming U.S. Healthcare Fund and a member of our board of directors.

Second Closing

In December 2019, in connection with the second closing of our Series A preferred stock financing, we sold an aggregate of 17,500,000 shares of Series A preferred stock at a purchase price of $1.00 per share and

16,000,000 Units at a purchase price of $1.25 per Unit for an aggregate purchase price of $37,500,000. Each Unit is comprised of one share of Series A-1 preferred stock and one Product Interest Right. See "Agreements with our Stockholders—Product Interest Rights Agreement." The following table summarizes purchases of our Series A preferred stock and Units by related persons:

Participant	Affiliated Director(s) or Officer(s)	Shares of Series A Preferred Stock	Units	Total Purchase Price
Entities affiliated with Blackstone(1)	Nicholas G. Galakatos	11,375,000	10,400,000	$ 24,375,000
Longitude Venture Partners III, L.P.(2)	Sandip Agarwala	3,062,500	2,800,000	$ 6,562,500
Qiming U.S. Healthcare Fund, L.P.(3)	Mark D. McDade	3,062,500	2,800,000	$ 6,562,500

(1) Consists of (i) 11,375,000 shares of Series A preferred stock held by Clarus Lifesciences, III, L.P., (ii) 2,666,666 Units held by Clarus Defined Exit I, L.P., (iii) 1,066,667 Units held by Clarus DE II, L.P., (iv) 2,154,298 Units held by Clarus IV-A, L.P., (v) 1,404,268 Units held by Clarus IV-B, L.P., (vi) 2,590,152 Units held by Clarus IV-C, L.P. and (vii) 517,949 Units held by Clarus IV-D, L.P. Such entities are affiliated with Blackstone, which holds five percent or more of our capital stock. Nicholas G. Galakatos is a senior managing director of Blackstone and a member of our board of directors.

(2) Longitude Venture Partners III, L.P. beneficially holds more than five percent of our capital stock. Mr. Agarwala, a member of our board of directors, is a Managing Director of Longitude Capital Management, which is an affiliate of Longitude Venture Partners III, L.P.

(3) Such entity is an affiliate of Qiming Venture Partners, which holds five percent or more of our capital stock. Mark D. McDade is a managing partner of Qiming U.S. Healthcare Fund and a member of our board of directors.

Third Closing

In August 2020, in connection with the third closing of our Series A preferred stock financing, we sold an aggregate of 12,000,000 of our Units at a purchase price of $1.25 per Unit for an aggregate purchase price of $15,000,000. The following table summarizes purchases of our Units by related persons:

Participant	Affiliated Director(s) or Officer(s)	Units	Total Purchase Price
Entities affiliated with Blackstone(1)	Nicholas G. Galakatos	4,000,000	$ 5,000,000
Longitude Venture Partners III, L.P.(2)	Sandip Agarwala	4,000,000	$ 5,000,000
Qiming U.S. Healthcare Fund, L.P.(3)	Mark D. McDade	4,000,000	$ 5,000,000

(1) Consists of (i) 1,025,641 Units held by Clarus Defined Exit I, L.P., (ii) 410,257 Units held by Clarus DE II L.P., (iii) 828,576 Units held by Clarus IV-A, L.P., (iv) 540,103 Units held by Clarus IV-B, L.P., (v) 996,212 Units held by Clarus IV-C, L.P. and (vi) 199,211 Units held by Clarus IV-D, L.P. Such entities are affiliated with Blackstone, which holds five percent or more of our capital stock. Nicholas G. Galakatos is a senior managing director of Blackstone and a member of our board of directors.

(2) Longitude Venture Partners III, L.P. beneficially holds more than five percent of our capital stock. Mr. Agarwala, a member of our board of directors, is a Managing Director of Longitude Capital Management, which is an affiliate of Longitude Venture Partners III, L.P.

(3) Such entity is an affiliate of Qiming Venture Partners, which holds five percent or more of our capital stock. Mark D. McDade is a managing partner of Qiming U.S. Healthcare Fund and a member of our board of directors.

Series B Preferred Stock Financing

In two closings held on September 2020, we sold an aggregate of 62,499,993 shares of our Series B preferred stock at a purchase price of $1.84 per share for an aggregate purchase price of approximately

$115,000,000. Each share of our Series B preferred stock will automatically convert into approximately 0.187 shares of our common stock (or approximately 0.187 shares of non-voting common stock upon the election of the holder thereof) immediately prior to the completion of this offering. The following table summarizes purchases of our Series B preferred stock by related persons:

Participant	Affiliated Director(s) or Officer(s)	Shares of Series B Preferred Stock	Total Purchase Price
Entities affiliated with Blackstone(1)	Nicholas G. Galakatos	2,717,391	$ 5,000,000
Longitude Venture Partners III, L.P.(2)	Sandip Agarwala	2,173,913	$ 4,000,000
Entities affiliated with Qiming(3)	Mark D. McDade	1,358,695	$ 2,499,999
Citadel Multi-Strategy Equities Master Fund Ltd.(4)	—	13,586,956	$ 24,999,999
Viking Global Opportunities Illiquid Investments Sub-Master LP(5)	—	13,586,956	$ 24,999,999

(1) Consists of (i) 696,767 shares of Series B preferred stock held by Clarus Defined Exit I, L.P., (ii) 278,707 shares of Series B preferred stock held by Clarus DE II, L.P., (iii) 562,891 shares of Series B preferred stock held by Clarus IV-A, L.P., (iv) 366,918 shares of Series B preferred stock held by Clarus IV-B, L.P., (v) 676,774 shares of Series B preferred stock held by Clarus IV-C, L.P. and (vi) 135,334 shares of Series B preferred stock held by Clarus IV-D, L.P. Such entities are affiliated with Blackstone, which holds five percent or more of our capital stock. Nicholas G. Galakatos is a senior managing director of Blackstone and a member of our board of directors.

(2) Longitude Venture Partners III, L.P. beneficially holds more than five percent of our capital stock. Mr. Agarwala, a member of our board of directors, is a Managing Director of Longitude Capital Management, which is an affiliate of Longitude Venture Partners III, L.P.

(3) Consists of (i) 1,086,956 shares of Series B preferred stock held by Qiming U.S. Healthcare Fund II, L.P. and (ii) 271,739 shares of Series B preferred stock held by Gary Rieschel. Such entity and individual are affiliates of Qiming Venture Partners, which holds five percent or more of our capital stock. Mark D. McDade is a managing partner of Qiming U.S. Healthcare Fund and a member of our board of directors.

(4) Such entity holds five percent or more of our capital stock.

(5) Such entity holds five percent or more of our capital stock.

Agreements with Our Stockholders

In connection with our preferred stock financings, we entered into an investors' rights agreement, voting agreement and right of first refusal agreement, in each case, with the purchasers of our preferred stock and certain holders of our common stock.

Our amended and restated investors' rights agreement (Investor Rights Agreement), provides certain holders of our preferred stock with a participation right to purchase their pro rata share of new securities that we may propose to sell and issue, subject to certain exceptions. Such participation right will terminate upon the closing of this offering. The Investor Rights Agreement further provides certain holders of our capital stock with the right to demand that we file a registration statement, subject to certain limitations, and to request that their shares be covered by a registration statement that we are otherwise filing. See "Description of Capital Stock—Registration rights" appearing elsewhere in this prospectus, for additional information regarding such registration rights.

Our voting agreement (Voting Agreement) provides for drag-along rights in respect of sales by certain holders of our capital stock. The Voting Agreement also contains provisions with respect to the elections of our board of directors and its composition. The rights under the Voting Agreement will terminate upon the closing of this offering.

Our right of first refusal and co-sale agreement (Right of First Refusal and Co-Sale Agreement) provides for rights of first refusal and co-sale rights in respect of sales by certain holders of our capital stock. The rights under the Right of First Refusal and Co-Sale Agreement will terminate upon the closing of this offering.

Product Interest Rights Agreement

In connection with our Series A and Series A-1 preferred stock financing, in November 2018, we entered into a Product Interest Rights Agreement (Product Interest Agreement) with the purchasers of our Series A-1 preferred stock. Pursuant to the Product Interest Agreement, we issued 28,000,000 Units, each comprised of one share of Series A-1 preferred stock and one product interest right, for cash consideration of $35,000,000. Each product interest right entitles the holder thereof, upon its election, to receive specified payments in connection with the commercial sale of FCR001. After the first commercial sale of product, the product interest right entitles the holders to a product interest payment for each product interest right held equal to 1/48,000,000 multiplied by 9% of net product sales on a territory-by-territory basis. If we enter into a license of rights to develop and/or commercialize a product, the holder is entitled to a product interest payment for each product interest right equal to 1/48,000,000 multiplied by 30% of licensing income. The product interest right payment term shall commence upon the first commercial sale of product, on a territory-by-territory basis, and continue until the fifteenth anniversary thereafter, or any earlier date that there are no remaining product interest rights outstanding. Because we have not made any commercial sales of FCR001, we have not made any payments with respect to the product interest rights.

Holders of Units may either transfer the shares of Series A-1 preferred stock (or the shares of common stock issued upon the conversion thereof) or the product interest right underlying the unit, but not both. Upon transfer, the component of the Unit, including the shares of common stock issued upon the conversion of the shares Series A-1 preferred stock upon the consummation of this offering, that is not transferred shall be automatically canceled, forfeited, and extinguished for no consideration. On March 12, 2021, we entered into a Termination Agreement with the purchasers of our Series A-1 preferred stock, terminating the Product Interest Rights Agreement and the rights and obligations thereunder subject to the consummation of this offering.

Related Party Transactions

David Tollerud, MD, Dr. Ildstad's spouse, joined us as Chief Operating Officer in 2016 and in 2018 was appointed as our Vice President, Scientific Affairs. During the years ended December 31, 2018, 2019 and 2020, Dr. Tollerud received total cash compensation, including base salary, bonus and other compensation, of $77,250, $218,875, and $256,599, respectively. Such appointment was ratified by our board of directors in November 2018, and such compensation was approved by our board of directors.

Suzanne Tollerud, Dr. Ildstad's daughter, joined us as Director of Business Operations in 2014 and in 2018 was appointed as our Vice President, Business Operations. In 2019, she was promoted to our Vice President, Operations. During the years ended December 31, 2018, 2019 and 2020, Ms. Tollerud received total cash compensation, including base salary, bonus and other compensation, of $174,992, $206,000, and $282,767, respectively.

In connection with the commencement of her employment, Ms. Tollerud was granted an option to purchase 63,084 shares of common stock, one-fourth of which vested on the first anniversary of the grant date and the remaining three-fourths of which will vest in equal monthly installments over three years, subject to continued service through the applicable vesting date. Ms. Tollerud was awarded three additional grants of options to purchase common stock in 2020, all of which vest in 48 equal monthly installments from the vesting commencement date. She received an award for 36,822 options on February 7, 2020, an award for 13,192 options on August 20, 2020 and an award for 23,258 options on October 2, 2020. Such appointment and compensation, including option awards, were approved by our board of directors.

Indemnification Agreements

In connection with this offering, we intend to enter into new agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for

certain expenses (including attorneys' fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person's status as a member of our board of directors to the maximum extent allowed under Delaware law.

Policies for Approval of Related Party Transactions

Our board of directors reviews and approves transactions with directors, officers and holders of 5% or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party's relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party's relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

In connection with this offering, we have adopted a written related party transactions policy that such transactions must be approved by our audit committee. This policy was effective on the date on which the registration statement of which this prospectus is a part was declared effective by the SEC.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of March 31, 2021, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than 5% of our common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The percentage of beneficial ownership prior to this offering in the table below is based on 32,436,352 shares of common stock and no non-voting common stock deemed to be outstanding as of March 31, 2021, assuming the conversion of all outstanding shares of our preferred stock immediately prior to the closing of this offering, and the initial public offering price of $17.00 per share. The percentage of beneficial ownership after this offering in the table below is based on 40,111,352 shares of common stock assumed to be outstanding after the closing of the offering, assuming the conversion of all outstanding shares of our preferred stock into 23,242,498 shares of our common stock and 1,150,000 shares of our non-voting common stock. The information in the table below assumes no exercise of the underwriters' option to purchase additional shares.

Unless otherwise noted below, the address for each beneficial owner listed in the table below is c/o Talaris Therapeutics, Inc., 570 S. Preston St, Louisville, KY 40202.

	Prior to Offering			After Offering		
Name of Beneficial Owner	**Number of Common Stock Beneficially Owned**	**Number of Non-Voting Common Stock Beneficially Owned**	**Percentage of Common Stock Beneficially Owned**	**Number of Common Stock Beneficially Owned**	**Number of Non-Voting Common Stock Beneficially Owned**	**Percentage of Common Stock Beneficially Owned**
Entities affiliated with Blackstone(1)	8,059,315	—	24.85%	8,059,315	—	20.09%
Longitude Venture Partners III, L.P.(2)	2,985,775	—	9.21%	2,985,775	—	7.44%
Entities affiliated with Qiming(3)	2,833,398	—	8.74%	2,833,398	—	7.06%
Citadel Multi-Strategy Equities Master Fund Ltd.(4)	2,539,617	—	7.83%	1,389,617	1,150,000	6.15%
Viking Global Opportunities Illiquid Investments Sub-Master LP(5)	2,539,617	—	7.83%	2,539,617	—	6.33%
Named Executive Officers and Directors:						
Scott Requadt, *President, Chief Executive Officer and Director*(6)	1,596,050	—	4.82%	1,596,050	—	3.91%
Suzanne T. Ildstad, MD, *Chief Scientific Officer and Director*(7)	4,806,446	—	14.82%	4,806,446	—	11.98%
Nancy Krieger, MD, *Chief Medical Officer*(8)	392,761	—	1.21%	392,761	—	*
Francois Nader, MD, *Chairman*(9)	477,060	—	1.47%	477,060	—	*
Sandip Agarwala, *Director*	—	—	—	—	—	—

	Prior to Offering			After Offering		
	Number of Common Stock Beneficially Owned	Number of Non-Voting Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned	Number of Common Stock Beneficially Owned	Number of Non-Voting Common Stock Beneficially Owned	Percentage of Common Stock Beneficially Owned
Nicholas G. Galakatos, PhD, *Director*	—	—	—	—	—	—
Geoff MacKay, *Director*(10)	76,788	—	*	76,788	—	*
Mark D. McDade, *Director*	—	—	—	—	—	—
Gaurav D. Shah, MD, *Director*(11)	76,635	—	*	76,635	—	*
Sapna Srivastava, PhD, *Director*(12)	76,635	—	*	76,635	—	*
All executive officers and directors as a group (12 persons)(13)	8,091,158	—	23.68%	8,091,158	—	19.33%

* Less than one percent.

(1) Consists of (i) 4,859,812 shares of common stock issuable upon conversion of convertible Series A preferred stock held by Clarus Lifesciences III, L.P., (ii) 690,150 shares of common stock issuable upon conversion of Series A-1 preferred stock and 130,236 shares of common stock issuable upon conversion of Series B preferred stock held by Clarus Defined Exit I, L.P., (iii) 276,060 shares of common stock issuable upon conversion of Series A-1 preferred stock and 52,094 shares of common stock issuable upon conversion of Series B preferred stock held by Clarus DE II, L.P., (iv) 557,546 shares of common stock issuable upon conversion of Series A-1 preferred stock and 105,213 shares of common stock issuable upon conversion of Series B preferred stock held by Clarus IV-A, L.P., (v) 363,433 shares of common stock issuable upon conversion of Series A-1 preferred stock held and 68,582 shares of common stock issuable upon conversion of Series B preferred stock by Clarus IV-B, L.P., (vi) 670,347 shares of common stock issuable upon conversion of Series A-1 preferred stock and 126,499 shares of common stock issuable upon conversion of Series B convertible preferred stock held by Clarus IV-C, L.P. and (vii) 134,047 shares of common stock issuable upon conversion of Series A-1 preferred stock and 25,296 shares of common stock issuable upon conversion of Series B preferred stock held by Clarus IV-D, L.P. Clarus Lifesciences III, L.P., Clarus Defined Exit I, L.P., Clarus DE II, L.P., Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P. are collectively referred to as the “Clarus Funds.” Clarus Ventures III GP, L.P. is the general partner of Clarus Lifesciences III, L.P. Blackstone Clarus III L.L.C. is the general partner of Clarus Ventures III GP, L.P. Clarus Ventures DE GP, L.P. is the general partner of each of Clarus Defined Exit I, L.P. and Clarus DE II, L.P. Blackstone Clarus DE L.L.C. is the general partner of Clarus Ventures DE GP, L.P. Clarus IV GP, L.P. is the general partner of each of Clarus IV-A, L.P., Clarus IV-B, L.P., Clarus IV-C, L.P. and Clarus IV-D, L.P. Blackstone Clarus GP L.P. is the general partner of Clarus IV GP, L.P. Blackstone Clarus GP L.L.C. is the general partner of Blackstone Clarus GP L.P. The sole member of Blackstone Clarus GP L.L.C. is Blackstone Holdings I L.P. The sole member of each of Blackstone Clarus III L.L.C. and Blackstone Clarus DE L.L.C. is Blackstone Holdings II L.P. The general partner of each of Blackstone Holdings I L.P. and Blackstone Holdings II L.P. is Blackstone Holdings I/II GP L.L.C. The sole member of Blackstone Holdings I/II GP L.L.C. is The Blackstone Group Inc. The sole holder of the Series II preferred stock of The Blackstone Group Inc. is Blackstone Group Management L.L.C. Blackstone Group Management L.L.C. is wholly-owned by Blackstone’s senior managing directors and controlled by its founder, Stephen A. Schwarzman. Each of such entities and Mr. Schwarzman may be deemed to beneficially own the shares beneficially owned by the Clarus Funds directly or indirectly controlled by it or him, but each (other than the Clarus Funds to the extent of their direct holdings) disclaims beneficial ownership of such shares. The address for each of the Clarus Funds, Clarus Ventures III GP, L.P., Clarus Ventures DE GP, L.P. and Clarus IV GP, L.P. is c/o Clarus Ventures LLC, 101 Main Street, Suite 1210, Cambridge, MA 02142. The address for each of the other Blackstone entities and Mr. Schwarzman is c/o The Blackstone Group Inc., 345 Park Avenue, New York, NY 10154.

(2) Consists of (i) 1,308,410 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 1,271,027 shares of common stock issuable upon conversion of Series A-1 preferred stock, and (iii) 406,338 shares of common stock issuable upon conversion of Series B preferred stock held by Longitude Venture Partners III, L.P. (LVP III). Longitude Capital Partners III, LLC (LCP III) is the general partner of LVP III and may be deemed to have voting and investment power over the shares of the Company

held by LVP III. Patrick G. Enright and Juliet Tammenoms Bakker are managing members of LCP III and may be deemed to share voting and investment power over the shares held by LVP III. Sandip Agarwala is a member of LCP III and may be deemed to share voting and investment power over the shares of the Company held by LVP III. Each of these individuals disclaims beneficial ownership of such shares except to the extent of his or her pecuniary interest therein. The address for each of these entities and individuals is 2740 Sand Hill Rd., 2nd Floor, Menlo Park, CA 94025.

(3) Consists of (i) 1,308,410 shares of common stock issuable upon conversion of Series A preferred stock held by Qiming U.S. Healthcare Fund, L.P., (ii) 523,364 shares of common stock issuable upon conversion of Series A-1 preferred stock held by Qiming U.S. Healthcare Fund, L.P., (iii) 747,663 shares of common stock issuable upon conversion of Series A-1 preferred stock held by Qiming U.S. Healthcare Fund II, L.P., (iv) 203,169 shares of common stock issuable upon conversion of Series B preferred stock held by Qiming U.S. Healthcare Fund II, L.P. and (v) 50,792 shares of common stock issuable upon conversion of Series B preferred stock held by Gary Rieschel. The general partner of Qiming U.S. Healthcare Fund, L.P. is Qiming U.S. Healthcare GP, LLC. The general partner of Qiming U.S. Healthcare Fund II, L.P. is Qiming U.S. Healthcare GP II, LLC. Gary Rieschel is the managing member of Qiming U.S. Healthcare GP, LLC. Gary Rieschel and Mark D. McDade are the managing members of Qiming U.S. Healthcare GP II, LLC. Each of Qiming U.S. Healthcare GP II, LLC, Mr. Rieschel and Mr. McDade may be deemed to beneficially own the shares beneficially owned by Qiming U.S. Healthcare Fund II, L.P., but each disclaims beneficial ownership of such shares. The address for each of these entities and individuals is 11100 NE 8th St., Suite 200, Bellevue, WA 98004.

(4) Consists of (i) 1,389,617 shares of common stock and (ii) 1,150,000 shares of non-voting common stock issuable upon conversion of Series B preferred stock held directly by Citadel Multi-Strategy Equities Master Fund Ltd. (Citadel). The non-voting common stock is convertible into voting common stock on a one-for-one basis subject to a blocker provision in the Company's third amended and restated certificate of incorporation that precludes such conversion to the extent that, following conversion, Citadel and its affiliates would beneficially own more than 9.9% of the total voting common stock outstanding. See the limitations described below under "Description of Capital Stock." Citadel Advisors LLC (Citadel Advisors) acts as the portfolio manager of Citadel. Citadel Advisors Holdings LP (CAH) is the sole member of Citadel Advisors, and Citadel GP LLC (CGP) is the general partner of CAH. Kenneth Griffin owns a controlling interest in CGP and may be deemed to share voting and dispositive power over shares held by Citadel. The foregoing should not be construed as an admission that Mr. Griffin or any of the Citadel related entities listed above is the beneficial owner of any securities of the Company other than the securities actually owned by such person (if any). The address for this entity is c/o Citadel Advisors, 601 Lexington Avenue, New York, NY 10022.

(5) Consists of 2,539,617 shares of common stock issuable upon conversion of Series B preferred stock held by Viking Global Opportunities Illiquid Investments Sub-Master LP (Opportunities Fund). The Opportunities Fund has the authority to dispose of and vote the shares directly owned by it, which power may be exercised by its general partner, Viking Global Opportunities Portfolio GP LLC (Opportunities GP), and by Viking Global Investors LP (VGI), which provides managerial services to Opportunities Fund. O. Andreas Halvorsen, David C. Ott and Rose Shabet, as Executive Committee members of Viking Global Partners LLC (the general partner of VGI) and Opportunities GP, have shared authority to direct the voting and disposition of investments beneficially owned by VGI and Opportunities GP. The business address of the Opportunities Fund is c/o Viking Global Investors LP, 55 Railroad Avenue, Greenwich, CT 06830.

(6) Consists of (i) 146,481 shares of common stock, (ii) 303,285 shares of restricted common stock issued upon early exercise of stock options, (iii) 288,389 shares of common stock held by Requadt Family Limited Partnership, (iv) 161,377 shares of restricted common stock issued upon early exercise of stock options, held by Requadt Family Limited Partnership, and (v) 696,518 shares of common stock subject to options with an early exercise feature. Scott Requadt exercises voting and dispositive power over the shares beneficially owned by Requadt Family Limited Partnership.

(7) Consists of 4,806,446 shares of common stock.

(8) Consists of (i) 120,911 shares of common stock, (ii) 129,322 shares of restricted common stock issued upon early exercise of stock options, and (iii) 142,528 shares of common stock subject to options with an early exercise feature.

(9) Consists of (i) 184,301 shares of common stock, (ii) 211,386 shares of restricted common stock issued upon early exercise of stock options, and (iii) 81,373 shares of common stock subject to options with an early exercise feature.
(10) Consists of 76,788 shares of common stock subject to options with an early exercise feature.
(11) Consists of 76,635 shares of common stock subject to options with an early exercise feature.
(12) Consists of 76,635 shares of common stock subject to options with an early exercise feature.
(13) Includes options to purchase 1,739,260 shares of common stock with an early exercise feature held by executive officers and directors, as described in notes 6 through 12 above.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation, which will be effective in connection with the closing of this offering and amended and restated bylaws, which became effective upon the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock, non-voting common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Upon completion of this offering, our authorized capital stock will consist of 140,000,000 shares of common stock, par value $0.0001 per share, 10,000,000 shares of non-voting common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share, all of which shares of preferred stock will be undesignated.

As of March 31, 2021, 32,436,352 shares of our common stock and non-voting common stock were outstanding, including 839,536 shares of non-vested restricted common stock, and held by 51 stockholders of record. This amount assumes the conversion of all outstanding shares of our preferred stock into 23,242,498 shares of voting common stock and 1,150,000 shares of non-voting common stock, which will occur immediately prior to the closing of this offering.

Common Stock and Non-Voting Common Stock

The holders of our common stock and non-voting common stock have identical rights subject to two exceptions. First, except as otherwise expressly provided in our certificate of incorporation or as required by applicable law, on any matter that is submitted to a vote by our stockholders, holders of our common stock are entitled to one vote per share of common stock, and holders of our non-voting common stock are not entitled to any votes per share of non-voting common stock, including for the election of directors. Second, holders of our common stock have no conversion rights, while holders of our non-voting common stock shall have the right to convert each share of our non-voting common stock held into one share of common stock at such holder's election, provided that as a result of such conversion, such holder, together with its affiliates and any members of a Schedule 13(d) group with such holder, would not beneficially own in excess of 9.9% of our common stock following such conversion, unless otherwise expressly provided for in our certificate of incorporation. However, this ownership limitation may be increased to any other percentage designated by such holder of non-voting common stock upon 61 days' notice to us or decreased at any time. Holders of our non-voting common stock are also permitted to make certain transfers to non-affiliates upon which, such transferred shares would immediately convert to shares of our common stock.

Holders of our common stock and non-voting common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock and non-voting common stock have no preemptive rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock and non-voting common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Immediately prior to the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock

in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our Company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Options

As of March 31, 2021, we had outstanding options under our 2018 Plan to purchase an aggregate of 3,381,382 shares of our common stock, with a weighted-average exercise price of $4.74 per share.

Registration Rights

Upon the completion of this offering, certain holders of our voting common stock and non-voting common stock, including those issuable upon the conversion of non-voting common stock and preferred stock, will be entitled to rights with respect to the registration of these securities under the Securities Act. These rights are provided under the terms of an investors' rights agreement between us and the holders of our preferred stock. The investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning six months after the completion of this offering, certain holders of our voting common stock and non-voting common stock, including those issuable upon the conversion of shares of our non-voting common stock and preferred stock upon closing of this offering, will be entitled to demand registration rights. Under the terms of the investors' rights agreement, we will be required, upon the written request of a majority of holders of the registerable securities then outstanding that would result in an aggregate offering price of at least $10 million, to file a registration statement on Form S-1 with respect to at least 30% of the registrable securities then outstanding and to use commercially reasonable efforts to effect the registration of all or a portion of these shares for public resale.

Short-form Registration Rights

Upon the completion of this offering, certain holders of our voting common stock and non-voting common stock, including those issuable upon the conversion of shares of our non-voting common stock and preferred stock upon closing of this offering, are also entitled to short-form registration rights. Pursuant to the investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of at least 20% in interest of these holders to sell registrable securities at an aggregate price of at least $5 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only two registrations in any twelve month period pursuant to this provision of the investor rights agreement.

Piggyback Registration Rights

Upon the completion of this offering, certain holders of our voting common stock and non-voting common stock, including those issuable upon the conversion of shares of our non-voting common stock and preferred stock upon closing of this offering, are entitled to piggyback registration rights. If we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the investors' rights

agreement, we and the underwriters may limit the number of shares included in the underwritten offering to the number of shares which we and the underwriters determine in our sole discretion will not jeopardize the success of the offering.

Indemnification

Our investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The demand registration rights and short-form registration rights granted under the investor rights agreement will terminate on the third anniversary of the completion of this offering.

Anti-takeover Effects of Our Certificate of Incorporation and Bylaws and Delaware Law

Our certificate of incorporation and bylaws include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions include the items described below.

Board Composition and Filling Vacancies

Our certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our certificate of incorporation also will provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our certificate of incorporation provides that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our certificate of incorporation and bylaws provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our bylaws limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to

our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our bylaws specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Certificate of Incorporation and Bylaws

Any amendment of our certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, and limitation of liability must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment, voting together as a single class, except that the amendment of the provisions relating to notice of stockholder business and nominations and special meetings must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class, or, if our board of directors recommends that the stockholders approve the amendment, by the affirmative vote of the majority of the outstanding shares entitled to vote on the amendment, in each case voting together as a single class.

Undesignated Preferred Stock

Our certificate of incorporation provides for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock and non-voting common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for any state law claims for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (3) any action asserting a claim arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws, (4) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws, or (5) any action asserting a claim that is governed by the internal affairs doctrine; provided, however, that the this provision shall not apply to any causes of action arising under the Securities Act or Exchange Act. In addition, our bylaws 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, including all causes of action asserted

against any defendants to such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. Any person or entity purchasing or otherwise acquiring any interest in our securities shall be deemed to have notice of and consented to these forum provisions. These forum provisions may impose additional costs on stockholders, may limit our stockholders' ability to bring a claim in a forum they find favorable, and the designated courts may reach different judgments or results than other courts. Please also see "Risk Factors—Our bylaws that became effective upon the effectiveness of the registration statement of which this prospectus is a part 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."

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges, or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Nasdaq Global Market Listing

Our common stock has been approved for listing on the Nasdaq Global Market under the trading symbol “TALS.” The non-voting common stock is not listed for trading on any securities exchange and we do not plan to list the non-voting common stock on any securities exchange.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock and non-voting common stock will be Computershare Trust Company, N.A. The transfer agent and registrar’s address is 250 Royall Street, Canton, Massachusetts 02021, and its telephone number is (800) 962-4284.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of December 31, 2020, upon the completion of this offering, 40,086,910 shares of our common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares and no exercise of outstanding options. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below.

Rule 144

In general, a person who has beneficially owned restricted securities for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted securities for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of common stock then outstanding, which will equal 400,869 shares immediately after this offering assuming no exercise of the underwriters' option to purchase additional shares, based on the number of shares of common stock outstanding as of December 31, 2020; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under "Underwriting" included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Lock-Up Agreements

We, all of our directors and executive officers, and the holders of substantially all of our capital stock and securities convertible into or exchangeable for our capital stock have entered into lock-up agreements with the underwriters and/or are subject to market standoff agreements or other agreements with us, which prevents them

from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock, including non-voting common stock, for a period of not less than 180 days from the date of this prospectus without the prior written consent of the representatives, subject to certain exceptions. Morgan Stanley & Co. LLC, SVB Leerink LLC and Evercore Group, L.L.C., may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. See “Underwriting” appearing elsewhere in this prospectus for more information.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See “Description of Capital Stock—Registration rights” appearing elsewhere in this prospectus for more information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a corporation or other organization taxable as a corporation for U.S. federal income tax purposes that is created or organized in or under laws other than the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is not subject to U.S. federal income tax on a net income basis; or
- a trust the income of which is not subject to U.S. federal income tax on a net income basis and that (1) is not subject to the primary supervision of a court within the United States or over which no U.S. persons have authority to control all substantial decisions and (2) has not made an election to be treated as a U.S. person.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset, generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any aspects of U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code or any U.S. federal tax other than the income tax (including, for example, the estate tax). This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;

- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and partners and investors therein);
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- investors in pass-through entities (or entities that are treated as disregarded entities for U.S. federal income tax purposes); and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "Gain on sale or other taxable disposition of our common stock." Any such distributions will also be subject to the discussions below under the sections entitled "Backup withholding and information reporting" and "Withholding and information reporting requirements—FATCA."

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussions below under "Backup withholding and information reporting" and "Withholding and information reporting requirements—FATCA," a non-U.S. holder generally will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on our common stock" also may apply;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale of other taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market, within the meaning of the applicable Treasury Regulations, and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the U.S. federal income tax rates applicable to United States persons (as defined in the Code), except that the branch profits tax generally will not apply. If we are a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, a non-U.S. holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to distributions on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in "Distributions on our common stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless

the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

The Foreign Account Tax Compliance Act (FATCA), generally imposes a U.S. federal withholding tax at a rate of 30% on certain types of payments made to a foreign entity unless (i) if the foreign entity is a "foreign financial institution," such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a "foreign financial institution," such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Under applicable U.S. Treasury regulations, withholding under FATCA currently applies to payments of dividends on our common stock. Such withholding may also apply to gross proceeds from the sale or disposition of our common stock, although under proposed U.S. Treasury Regulations, no withholding would apply to such gross proceeds. The preamble to the proposed regulations specifies that taxpayers (including withholding agents) are permitted to rely on the proposed regulations pending finalization. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

The preceding discussion of U.S. federal income tax considerations is for general information only. It is not tax advice. Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state and local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, SVB Leerink LLC, Evercore Group L.L.C. and Guggenheim Securities, LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

Name	Number of Shares
Morgan Stanley & Co. LLC	3,530,000
SVB Leerink LLC	2,382,750
Evercore Group L.L.C.	2,029,750
Guggenheim Securities, LLC	882,500
Total:	8,825,000

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of $0.714 per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 1,323,750 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional 1,323,750 shares of common stock.

	Per Share	Total	
		No Exercise	Full Exercise
Public offering price	$ 17.00	$ 150,025,000.00	$ 172,528,750.00
Underwriting discounts and commissions to be paid by us:	$ 1.19	$ 10,501,750.00	$ 12,077,012.50
Proceeds, before expenses, to us	$ 15.81	$ 139,523,250.00	$ 160,451,737.50

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately $2,825,000. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority of up to $30,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock has been approved for listing on The Nasdaq Global Market under the trading symbol “TALS.”

We and all directors and officers and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC, SVB Leerink LLC and Evercore Group L.L.C. on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the restricted period), subject to certain exceptions:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock, including non-voting common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock or non-voting common stock.

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of Morgan Stanley & Co. LLC, SVB Leerink LLC and Evercore Group L.L.C. on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph to do not apply in certain circumstances, including:

- transactions relating to shares of common stock or other securities acquired (i) from the underwriters in the offering (other than issuer-directed shares of common stock purchased in the offering by our officers or directors) or (ii) in open market transactions after the completion of the offering, provided that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in the offering or such open market transactions, or
- transfers of shares of common stock or any security convertible into common stock as a bona fide gift or to a charitable organization or educational institution in a transfer not involving a disposition for value; or
- transfers or dispositions of common stock or any security convertible into common stock to any immediate family member of the holder or any trust for the direct or indirect benefit of the holder or an immediate family member of the holder, or if the holder is a trust, to a grantor, trustee or beneficiary of the trust (including such beneficiary’s estate) of the holder;
- transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock (i) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the undersigned upon the death of the undersigned or (ii) by operation of law pursuant to orders of a court or regulatory agency, in connection with a negotiated divorce settlement or pursuant to a qualified domestic relations order;

- if the holder is an entity, transfers, dispositions or distributions of shares of common stock or any security convertible into common stock (i) to another corporation, partnership, limited liability company, trust or other business entity that is an affiliate (within the meaning set forth in Rule 405 under the Securities Act of 1933, as amended, and including the subsidiaries of the holder) of the holder, (ii) to any investment fund or other entity controlling, controlled by, managing or managed by or under common control with the holder or affiliates of the holder (including, for the avoidance of doubt, where the holder is a partnership, to its general partner or a successor partnership or fund, or any other funds managed by such partnership) or (iii) to its stockholders, limited partners, general partners, limited liability company members or other equityholders or to the estate of any such stockholders, limited partners, general partners, limited liability company members or equityholders;
- transfers or dispositions of common stock or any security convertible into or exercisable or exchangeable for common stock to the company (i) pursuant to any contractual arrangement in effect on the date of this agreement and described in this preliminary prospectus contained in the registration statement relating to this offering at the time the registration statement became effective as well as in the final prospectus relating to this offering that provides for the repurchase of the holder's common stock or other securities by the company or (ii) in connection with the termination of the holder's employment with or service to the company; provided that any filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common stock shall indicate by footnote disclosure or otherwise the nature of the transfer or disposition;
- transfers or dispositions of common stock or other securities to us in connection with the conversion of any convertible security into, or the exercise of any option or warrant for, common stock (including by way of "net" or "cashless" exercise solely to cover withholding tax obligations in connection with such exercise and any transfer to us for the payment of taxes as a result of such exercise) in each case pursuant to any equity incentive plan described in this preliminary prospectus contained in the registration statement relating to this offering at the time the registration statement became effective as well as in the final prospectus relating to this offering, to the extent permitted by the instruments representing such options outstanding as of the date of this prospectus; provided that (i) any such common stock received is subject to the terms of the lock-up agreement and (ii) no filing under Section 16 of the Exchange Act, reporting a reduction in beneficial ownership of common stock, or other public announcement is required or voluntarily made during the restricted period (other than a filing that relates to the applicable circumstances described in this clause);
- (i) transfers of common stock (or any securities convertible into or exercisable or exchangeable for common stock) pursuant to a bona fide third-party tender offer for shares of our capital stock made to all holders of our securities, merger, consolidation or other similar transaction approved by our board of directors the result of which is that any person (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than us, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of the total voting power of our voting stock and (ii) entry into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of common stock or such other securities in connection with a transaction described in (i) above; provided that in the event that such change of control transaction is not completed, the common stock (or any security convertible into or exercisable or exchangeable for common stock) owned by the holder shall remain subject to the restrictions contained in the lock-up agreement;
- facilitating the establishment of a trading plan on behalf of a shareholder, officer or director pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period.

Morgan Stanley & Co. LLC, SVB Leerink LLC and Evercore Group L.L.C., in their joint discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time. In certain circumstances, the release of shares of common stock from the lock-up restrictions described above will trigger a pro rata release of shares of common stock held by certain other holders.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters (the selling group members), if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our

sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (Corporations Act) and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (Exempt Investors), who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

European Economic Area

In relation to each Member State of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or

(c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

Hong Kong

Shares of our common stock may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to shares of our common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

Israel

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728—1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728—1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the Addressed Investors); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728—1968, subject to certain conditions (the Qualified Investors). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728—1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728—1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728—1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728—1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728—1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728—1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor's name, address and passport number or Israeli identification number.

Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended, the FIEL) has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors (QII)

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "QII only private placement" or a "QII only secondary distribution" (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a "small number private placement" or a "small number private secondary distribution" (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

People's Republic of China

This prospectus will not be circulated or distributed in the People's Republic of China (the PRC), and the securities will not be offered or sold, and will not be offered or sold to any person for re-offering or resale directly or indirectly to any residents of the PRC except pursuant to any applicable laws and regulations of the PRC. Neither this prospectus nor any advertisement or other offering material may be distributed or published in the PRC, except under circumstances that will result in compliance with applicable laws and regulations.

Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the SFA), (ii) to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where shares of our common stock are subscribed or purchased under Section 275 by a relevant person which is: (i) a corporation (which is not an accredited investor) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (ii) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary is an accredited investor, shares, debentures and units of shares and debentures of that corporation or the beneficiaries' rights and interest in that trust shall not be transferable for 6 months after that corporation or that trust has acquired shares of our common stock under Section 275 except: (a) to an institutional investor under Section 274 of the SFA or to a relevant person, or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275 of the SFA; (b) where no consideration is given for the transfer; or (c) by operation of law.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document does not constitute a prospectus within the meaning of, and has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company, the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this

document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA (FINMA), and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

United Arab Emirates

The securities have not been, and are not being, publicly offered, sold, promoted or advertised in the United Arab Emirates (including the Dubai International Financial Centre) other than in compliance with the laws of the United Arab Emirates (and the Dubai International Financial Centre) governing the issue, offering and sale of securities. Further, this prospectus does not constitute a public offer of securities in the United Arab Emirates (including the Dubai International Financial Centre) and is not intended to be a public offer. This prospectus has not been approved by or filed with the Central Bank of the United Arab Emirates, the Securities and Commodities Authority or the Dubai Financial Services Authority.

United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

(a) to any legal entity which is a qualified investor as defined under Article 2 of the U.K. Prospectus Regulation;

(b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the U.K. Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or

(c) in any other circumstances falling within Section 86 of the FSMA.

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the U.K. Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares and the expression “U.K. Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters related to this offering will be passed upon for the underwriters by Cooley LLP, Boston, Massachusetts.

EXPERTS

The financial statements included in this Prospectus, have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 (File Number 333-255316) under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at www.talaristx.com. Upon completion of the offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendment to those reported filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

TALARIS THERAPEUTICS, INC.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Talaris Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Talaris Therapeutics, Inc. (the "Company") as of December 31, 2020 and 2019, the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' deficit, and cash flows, for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

February 26, 2021 (May 3, 2021, as to the effects of the subsequent events described in Note 16)

We have served as the Company's auditor since 2019.

TALARIS THERAPEUTICS, INC.

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

	As of December 31,		
	2020	2019	Pro forma 2020 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 17,589	$ 38,978	$ 17,589
Marketable securities	131,899	—	131,899
Prepaid and other current assets	1,263	1,816	1,263
Total current assets	150,751	40,794	150,751
Property and equipment, net	2,013	1,127	2,013
Other assets	14	20	14
Total assets	$152,778	$ 41,942	$ 152,778
Liabilities and Stockholders' Equity (Deficit)			
Current liabilities:			
Accounts payable	$ 767	$ 667	$ 767
Accrued expenses	2,637	1,623	2,637
Total current liabilities	3,404	2,291	3,404
Share repurchase liability	996	—	996
Contingent stock liability	373	63	373
Total liabilities	4,774	2,354	4,774
Commitments and contingencies (Note 8)			
Convertible preferred stock			
Series A convertible preferred stock, $0.0001 par value, 40,000,000 shares authorized, issued and outstanding (liquidation preference of $40,000) as of December 31, 2020 and 2019; no shares authorized, issued or outstanding pro forma as of December 31, 2020	37,383	37,383	—
Series A-1 convertible preferred stock, $0.0001 par value, 28,000,000 shares authorized, issued and outstanding (liquidation preference of $35,000) as of December 31, 2020 and 48,000,000 shares authorized and 16,000,000 issued and outstanding (liquidation preference of $20,000) as of December 31, 2019; no shares authorized, issued or outstanding pro forma as of December 31, 2020	34,272	19,307	—
Series B convertible preferred stock, $0.0001 par value, 62,499,993 shares authorized, issued and outstanding (liquidation preference of $114,994) as of December 31, 2020 and no shares authorized, issued and outstanding as of December 31, 2019; no shares authorized, issued and outstanding pro forma as of December 31, 2020	114,496	—	—
Total convertible preferred stock	186,151	56,690	—
Stockholders' equity (deficit)			
Common stock, $0.0001 par value, 36,366,101 shares authorized and 7,087,130 issued and outstanding as of December 31, 2020 and 28,037,383 shares authorized and 6,390,137 issued and outstanding as of December 31, 2019; 36,366,101 shares authorized and 31,479,628 issued and outstanding pro forma as of December 31, 2020	1	1	3
Additional paid-in-capital	4,879	3,204	191,029
Accumulated deficit	(43,014)	(20,307)	(43,014)
Accumulated other comprehensive loss	(13)	—	(13)
Total stockholders' equity (deficit)	(38,147)	(17,102)	148,005
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$152,778	$ 41,942	$ 152,778

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)

	Years Ended December 31,	
	2020	2019
Operating expenses		
Research and development	$ 15,278	$ 13,369
General and administrative	7,406	5,009
Total operating expenses	22,684	18,378
Loss from operations	(22,684)	(18,378)
Interest and other income (expense), net	(23)	223
Net loss	$ (22,707)	$ (18,155)
Unrealized loss on marketable securities	(13)	—
Total other comprehensive loss	(13)	—
Total comprehensive loss	$ (22,720)	$ (18,155)
Net loss attributable to common stockholders	$ (22,707)	$ (18,155)
Net loss per common share, basic and diluted	$ (3.40)	$ (2.84)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	6,685,066	6,383,261
Pro forma net loss per common share, basic and diluted	$ (1.07)	
Pro forma weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	21,192,565	

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

TALARIS THERAPEUTICS, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(in thousands, except share amounts)

	Series A Convertible Preferred Stock		Series A-1 Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Additional		Accumulated Other	Total
	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Outstanding Shares	Amount	Paid-in Capital	Accumulated Deficit	Comprehensive Income (Loss)	Stockholders' Deficit
Balance at January 1, 2019	22,500,000	$20,490	—	$ —	—	$ —	6,378,736	$ 1	$ 2,964	$ (2,151)	$ —	$ 814
Issuance of Series A convertible preferred stock, net of issuance costs	17,500,000	16,893	—	—	—	—	—	—	—	—	—	—
Issuance of Series A-1 convertible preferred stock, net of issuance costs	—	—	16,000,000	19,307	—	—	—	—	—	—	—	—
Issuance of common stock	—	—	—	—	—	—	7,476	0	7	—	—	7
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	3,925	0	4	—	—	4
Stock-based compensation expense	—	—	—	—	—	—	—	—	229	—	—	229
Net loss	—	—	—	—	—	—	—	—	—	(18,155)	—	(18,155)
Balance at December 31, 2019	40,000,000	$37,383	16,000,000	$19,307	—	$ —	6,390,137	$ 1	$ 3,204	$ (20,307)	$ —	$ (17,102)
Issuance of Series A-1 convertible preferred stock, net of issuance costs	—	—	12,000,000	14,966	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs	—	—	—	—	62,499,993	114,496	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	696,993	0	653	—	—	653
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,022	—	—	1,022
Net loss	—	—	—	—	—	—	—	—	—	(22,707)	—	(22,707)
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	(13)	(13)
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)

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

TALARIS THERAPEUTICS, INC.

STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31, 2020	2019
Cash flows from operating activities:		
Net loss	$ (22,707)	$(18,155)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	447	379
Accretion and amortization of marketable securities, net	95	—
Stock-based compensation expense	1,022	229
Fair value adjustment of contingent stock liability	310	3
Gain on disposal of property and equipment	—	(38)
Other	7	7
Changes in operating assets and liabilities:		
Prepaid and other current assets	553	(1,461)
Other assets	6	(20)
Accounts payable	100	321
Accrued expenses	955	1,075
Net cash used in operating activities	(19,212)	(17,660)
Cash flows from investing activities:		
Purchases of property and equipment	(1,286)	(562)
Purchases of marketable securities	(158,237)	—
Maturities of marketable securities	26,224	—
Net cash used in investing activities	(133,300)	(562)
Cash flows from financing activities:		
Proceeds from issuances of Series A convertible preferred stock	—	17,500
Proceeds from issuances of Series A-1 convertible preferred stock	15,000	20,000
Proceeds from issuances of Series B convertible preferred stock	115,000	—
Preferred stock issuance costs	(526)	(1,300)
Proceeds from exercise of stock options	1,649	4
Net cash provided by financing activities	131,123	36,204
Net increase (decrease) in cash and cash equivalents	(21,389)	17,982
Cash and cash equivalents at beginning of period	38,978	20,997
Cash and cash equivalents at end of period	$ 17,589	$ 38,978
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment additions included in accounts payable and accrued expenses	$ 86	$ 38
Preferred stock issuance costs included in accounts payable and accrued expenses	$ 11	$ —

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

TALARIS THERAPEUTICS, INC

NOTES TO FINANCIAL STATEMENTS

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 non-malignant blood, immune and metabolic disorders. The Company believes that these indications, individually and collectively, represent a significant unmet need and commercial opportunity. The Company is located and headquartered in Louisville, Kentucky and Wellesley, Massachusetts.

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 years ended December 31, 2020 and December 31, 2019, the Company incurred a net loss of $22.7 million and $18.2 million, respectively, and used $19.2 million and $17.7 million in cash for operations, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of $43.0 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 on hand of $17.6 million and marketable securities of $131.9 million as of December 31, 2020, 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.

The Company is seeking to complete an initial public offering ("IPO") of its common stock. Upon the completion of a qualified public offering on specified terms, the Company's outstanding convertible preferred stock will automatically convert into shares of common stock (see note 9).

Additional funding will be needed to finance future clinical, pre-clinical, manufacturing and commercial activities. To date, the Company has principally financed its operations through private placements of convertible preferred stock (see Note 9), together with payments under a former research collaboration with Novartis, Inc. and research grants. In the event the Company does not complete an IPO, the Company will seek additional funding through private equity and debt financings and other arrangements. 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 (US GAAP).

Use of Estimates

The preparation of financial statements in conformity with US 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 fair value of the Company's common stock, determination of the fair value of stock option grants and estimates related to the amount of accrued research and development expenses as of the balance sheet date. Management evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors, including the current economic environment, and makes adjustments when the facts and circumstances dictate. These estimates are based on information available as of the date of the financial statements; therefore, actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. As of December 31, 2020 and 2019, cash consists primarily of checking and savings deposits and money market fund holdings.

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 December 31, 2020 and 2019.

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 our 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 December 31, 2020 and 2019 (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 is a private company 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.

In determining the exercise prices for options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been 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.

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 December 31, 2020 and December 31, 2019.

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 are participating securities. These participating securities do 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' deficit. The Company's comprehensive loss included unrealized losses related to marketable securities for the year ended December 31, 2020. Comprehensive loss was equal to net loss for the year ended December 31, 2019.

Recently Issued Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments—Credit Losses*, ("ASC 326"), which introduces a new model for recognizing credit losses on financial instruments based on an estimate of current expected credit losses. The new model will apply to (1) loans, accounts receivable, trade receivables, and other financial assets measured at amortized cost; (2) loan commitments and certain other off-balance-sheet credit exposures; (3) debt securities and other financial assets measured at fair value through other comprehensive income; and (4) beneficial interests in securitized financial assets. The Company adopted ASC 326 in January 2021, and does not expect the standard to have a material impact on the 2021 financial statements.

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. ASC 842 will be effective for the Company on January 1, 2022, with early adoption permitted. The Company is in the process of evaluating its lease contracts under the new standard and the adoption of ASC 842 is expected to result in the recognition of additional lease liability and right-to-use assets on the balance sheet.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (ASC 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. ASU No. 2018-13 removes certain disclosures, modifies certain disclosures, and adds additional disclosures. ASU No. 2018-13 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2019. The adoption of ASU 2018-13 in January 2020 had no material impact on the financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. Prior to the adoption of ASU 2018-07, the measurement date for non-employee awards was generally the date the services are completed, resulting in financial reporting period adjustments to equity-based compensation during the vesting terms for changes in the fair value of the awards. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. The Company adopted ASU 2018-07 in January 2019. The impact of adoption was immaterial to the Company's financial statements.

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)*:

	December 31, 2020			
	Total	Level 1	Level 2	Level 3
Financial assets:				
Money market funds (cash equivalents)	$ 13,943	$13,943	$ —	$ —
Marketable securities	131,899	11,169	120,730	—
Total financial assets measured at fair value	$145,842	$25,112	$120,730	$ —
Financial liabilities:				
Contingent stock liability	$ 373	$ —	$ —	$ 373
Total financial liabilities measured at fair value	$ 373	$ —	$ —	$ 373

	December 31, 2019			
	Total	Level 1	Level 2	Level 3
Financial liabilities:				
Contingent stock liability	$ 63	$ —	$ —	$ 63
Total financial liabilities measured at fair value	$ 63	$ —	$ —	$ 63

The contingent stock liability in the table above represents 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 (see Note 8). A rollforward of the contingent common stock liability, which is measured at fair value for the years ended December 31, 2020 and 2019, is represented as follows *(in thousands)*:

Fair value as of January 1, 2019	$ 60
Change in fair value	3
Fair value as of December 31, 2019	63
Change in fair value	310
Fair value as of December 31, 2020	$373

Valuation techniques used to measure fair value maximize the use of relevant observable inputs and minimize the use of unobservable inputs. The Company's contingent stock liability is 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 has been no public market for the Company's common stock to date, the estimated fair value has been 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 the most recent valuation. Historically, these third-party valuations of the Company's common stock were performed contemporaneously when events have occurred which management believes would have an impact on the valuation of the Company. The Company's common stock valuation was prepared using the option-pricing method, or OPM, which uses a market approach to estimate enterprise value. Changes in the fair value of the contingent stock liability are recognized within interest and other income, net in the statement of operations. The fair values of the Company's common stock used to value the contingent stock liability as of December 31, 2020 and December 31, 2019 were $1.07 and $0.18, respectively.

4. Marketable Securities

The fair value of the Company's marketable securities as of December 31, 2020 is based on level 1 and level 2 inputs. The Company had no marketable securities as of December 31, 2019. 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 year ended December 31, 2020. 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 December 31, 2020, none of the Company's investments were determined to be other than temporarily impaired.

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

	December 31, 2020			
	Amortized Cost	Unrealized Gain	Unrealized (Loss)	Estimated Fair Value
Commercial paper	$ 73,331	$ 3	$ (10)	$ 73,324
Corporate debt securities	33,319	1	(11)	33,309
Government and agency securities	25,262	4	—	25,266
Total	$131,912	$ 8	$ (21)	$131,899

5. Prepaid and Other Current Assets

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

	December 31,	
	2020	2019
Contract research organization prepaid	$ 558	$1,538
Interest receivable	374	—
Prepaid insurance	97	115
Prepaid service and maintenance contracts	88	91
Prepaid subscriptions	70	33
Other	76	39
Total prepaid expenses	$1,263	$1,816

6. Property and Equipment, Net

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

	December 31,	
	2020	2019
Equipment	$ 2,666	$ 2,521
Leasehold improvements	580	287
Computer equipment	264	47
Furniture and fixtures	255	—
Construction in progress	491	68
Total property and equipment	4,256	2,923
Less accumulated depreciation	(2,243)	(1,796)
Property and equipment, net	$ 2,013	$ 1,127

Depreciation expense was $0.4 million for the years ended December 31, 2020 and 2019.

7. Accrued Expenses

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

	December 31,	
	2020	2019
Accrued bonus	$1,159	$1,025
Contract research organization accruals	521	91
Professional services/consulting accruals	314	134
Franchise taxes payable	156	32
Paid time off accrual	139	90
Other	348	251
Total accrued expenses	$2,637	$1,623

8. Commitments and Contingencies

Leases

The Company currently has three active lease agreements for office and laboratory space and related equipment. The primary 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. The Company maintains a lease for office space in Wellesley, Massachusetts, with a termination date in March 2021 with an option to extend. The Company maintains a third lease for ancillary office space also in Louisville, Kentucky. This lease has a termination date in December 2021.

The future minimum rent payments relating to all three of the Company’s facility operating leases under the terms and conditions existing as of December 31, 2020, are summarized as follows *(in thousands)*:

Years Ending December 31,	
2021	$ 515
2022	$ 496
2023	$ 414
2024	$ —
Total	$1,425

The Company incurred rent expense of $0.6 million and $0.3 million for the years ended December 31, 2020 and 2019, respectively.

License Agreement

In October 2018, the Company entered an amended and restated exclusive license agreement with the 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. On or prior to the Company's first underwritten public offering or any transaction that is treated as a deemed liquidation event, the Company may 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. At December 31, 2020 and December 31, 2019, the Company measured the fair value of the contingent equity consideration and recorded a contingent stock liability of $0.4 million and $0.1 million, respectively, in other liabilities (see Note 3).

The Company incurred a $0.1 million milestone payment to ULRF in June 2020 which was recorded as research and development expense. The Company also incurred $0.1 million in expense in February 2020 related to an annual maintenance fee pursuant to the license agreement for the year ended December 31, 2020. The Company did not incur any expense related to the annual license maintenance fee or milestone payments during the year ended December 31, 2019.

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

Issuances of Convertible Preferred Stock

In November 2018, the Company issued 22,500,000 shares of Series A Convertible Preferred Stock at $1.00 per share for gross cash proceeds of $22.5 million. The Company incurred issuance costs of $2.0 million, which have been recorded as a reduction to the value of Series A Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets. In connection with the initial issuance of the Series A Convertible Preferred Stock, the purchasers received the right to purchase, and the Company had the obligation to sell, additional shares of Series A Convertible Preferred Stock at $1.00 per share and a unit, comprised of one share of Series A-1 Convertible Preferred Stock and one product interest right (each a "Unit"), at $1.25 per Unit (together, the "Tranche Rights") upon achieving certain milestones related to the Company's research and clinical developments in a series of tranches (the "Tranche 2," "Tranche 3," and "Tranche 4") milestones.

In December 2019, the Tranche 2 milestone was met and the Company issued an additional 17,500,000 shares of Series A Convertible Preferred Stock at $1.00 per share for gross cash proceeds of $17,500,000 and 16,000,000 Units (consisting of 16,000,000 shares of Series A-1 Convertible Preferred Stock and 16,000,000 shares of product interest rights) at $1.25 per Unit for gross cash proceeds of $20.0 million. The Company incurred issuance costs of $1.3 million in relation to Tranche 2, which have been recorded as a reduction to the value of Series A-1 Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets.

In August 2020, the holders of Series A-1 Convertible Preferred Stock voted to amend the Preferred Stock and Unit Purchase Agreement (“SPA”) and waive the requirements of the Tranche 3 milestone. The Company issued an additional 12,000,000 Units (consisting of 12,000,000 shares of Series A-1 Convertible Preferred stock and 12,000,000 shares of product interest rights) at $1.25 per Unit for gross cash proceeds of $15.0 million.

In September 2020, the Company issued 62,499,993 shares of Series B Convertible Preferred Stock at $1.84 per share for gross cash proceeds of $115.0 million. The Company incurred issuance costs of $0.5 million in relation to the issuance of Series B Convertible Preferred Stock, which have been recorded as a reduction to the value of Series B Convertible Preferred Stock in mezzanine equity in the accompanying balance sheets.

In conjunction with the Series B Convertible Preferred Stock financing in September 2020, all holders of the Company’s preferred stock entered into an amendment to the SPA to terminate all rights, liabilities and obligations in respect to the Tranche 4 milestone.

Tranche Rights

The Company determined that the Tranche Rights did not meet the definition of a freestanding financial instrument because the Tranche Rights are not legally detachable from the initial Series A Convertible Preferred Stock issued. The Company made this determination due to the express prohibition of the transfer of the Tranche Rights. Further, the Company determined that the Tranche Rights do not meet the definition of an embedded derivative that would require bifurcation from the initial Series A Preferred Stock issued. Therefore, at the initial issuance of the Series A Convertible Preferred Stock in November 2018, there was no separate recognition of the Tranche Rights.

Product Interest Rights

After the first commercial sale of product, the product interest right entitles the holders to a product interest payment for each product interest right held equal to 1/48,000,000 multiplied by 9% of net product sales on a territory-by-territory basis. If the Company enters into a license of rights to develop and/or commercialize a product, the holder is entitled to a product interest payment for each product interest right equal to 1/48,000,000 multiplied by 30% of licensing income. If the holder does not participate or events occur in which the holder transfers its ownership, it must determine to transfer either its shares or the unit purchase right. If the holder elects to receive a product interest payment, then a corresponding total number of Series A-1 Convertible Preferred Stock initially underlying a Unit (the “Unit Share”), will be canceled and forfeited. The total number of Unit Shares canceled and forfeited will be determined by dividing the product interest payment received by the fair value of the Unit Share at such time. The product interest right payment term shall commence upon the first commercial sale of product, on a territory-by-territory basis, and continue until the fifteenth anniversary thereafter, or any earlier date that there are no remaining product interest rights outstanding.

If at any time, the Unit is transferred, the holder must elect to transfer either (i) the Unit share underlying the Unit or (ii) the product interest right underlying the Unit. If the holder elects to transfer the Unit Share, the corresponding product interest right underlying the Unit shall be automatically canceled, forfeited, and extinguished for no consideration. If the holder elects to transfer the product interest right, the corresponding Unit Share unit shall be automatically canceled and forfeited for no consideration.

The Company determined the product interest rights did not meet the definition of a freestanding financial instrument because the product interest rights are not legally detachable or separately exercisable from the Unit Shares. Further, the Company determined that the product interest rights do not meet the definition of an embedded derivative that would require bifurcation from the Unit Share. Therefore, upon issuance of Units in December 2019, there was no separate recognition of the product interest rights.

Rights and Privileges of Convertible Preferred Stock

The rights and privileges of the Series A, Series A-1 and Series B Convertible Preferred Stock (together, "Convertible Preferred Stock") are as follows:

Voting Rights—The holders of each series of Convertible Preferred Stock are entitled to vote on all matters and shall have the number of votes equal to the number of shares of common stock into which the preferred stock is convertible.

Dividends—The Company shall not declare, pay, or set aside any dividends on shares of any other class or series of capital stock (other than dividends on shares of common stock payable in shares of common stock), unless the holders of the Convertible Preferred Stock receive a dividend on each outstanding share of Convertible Preferred Stock in an amount at least equal to (i) in the case of a dividend on common stock or any class or series that is convertible into common stock, that dividend per share of Convertible Preferred Stock as would equal the product of (A) the dividend payable on each share of such class or series determined, if applicable, as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of a share of the applicable series of Convertible Preferred Stock or (ii) in the case of a dividend on any class or series that is not convertible into common stock, at a rate per share of the applicable series of Convertible Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of capital stock by the original issuance price of such class or series of capital stock and (B) multiplying such fraction by an amount equal to the original issue price of the applicable series of Convertible Preferred Stock. No dividends were declared or paid during the years ended December 31, 2020 and December 31, 2019.

Liquidation Preference—In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the Company, the holders of shares of Convertible Preferred Stock will receive, in preference to any distribution to the holders of common stock an amount per share equal to the greater of (i) the applicable original issue price of such series of Convertible Preferred Stock, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Convertible Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding-up, or deemed liquidation event. If upon any such liquidation, dissolution, or winding-up of the Company or deemed liquidation event, the assets available for distribution to the Company's stockholders are not sufficient to pay the holders of Convertible Preferred Stock the full amount to which they shall be entitled, the holders of Convertible Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts, which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

In the event of a deemed liquidation event, if the Company does not effect a dissolution within 90 days after such deemed liquidation event, each holder of Convertible Preferred Stock has the right to require the redemption of such shares, and if voting together as a majority, has the right to require redemption of all outstanding Convertible Preferred Stock in accordance with the liquidation preferences afforded to holders of the Convertible Preferred Stock. Any shares of Convertible Preferred Stock that are redeemed or otherwise acquired by the Company or any of its subsidiaries be automatically and immediately canceled and retired and shall not be reissued, sold, or transferred. Neither the Company nor any of its subsidiaries may exercise any voting or other rights granted to the holders of Convertible Preferred Stock following redemption. A Deemed Liquidation Event shall include a merger or consolidation (other than one in which the capital stock of the Company outstanding

immediately prior to such merger or consolidation continue to represent a majority by voting power of the capital stock of the surviving corporation) or a sale, lease, transfer, exclusive license, or other disposition of all or substantially all of the assets of the Company.

Conversion

Conversion Ratio—Each share of Convertible Preferred Stock shall be convertible, at the option of the holder thereof, at any time into such number of fully paid and nonassessable shares of common stock as is determined by dividing the applicable original issue price by the applicable conversion price (Series A original issue price is $1.00 per share and applicable conversion price is $5.35 per share; Series A-1 original issue price is $1.25 and applicable conversion price is $6.69 per share; Series B original issue price is $1.84 per share and applicable conversion price is $9.84 per share), subject to adjustment in the case of termination or fractional shares.

Mandatory Conversion—All outstanding shares of Convertible Preferred Stock are automatically convertible based upon either (a) the closing of a firm-commitment underwritten public offering in which the aggregate gross proceeds to the Company of at least $60,000,000 of gross proceeds to the Company and have an offering price to the public of at least $9.84 per share or (b) the vote or written consent of holders of at least a majority of the Convertible Preferred Stock outstanding at that time with respect to the conversion of the Convertible Preferred Stock then all outstanding shares of Convertible Preferred Stock shall automatically be converted into shares of common stock at the then effective conversion rate and such shares may not be reissued.

10. Common Stock

Common Stock Reserved

The number of shares of common stock that have been reserved for the potential conversion of Preferred Stock, and outstanding stock options granted and stock options available for grant under the Company's 2018 Equity Incentive Plan (the "2018 Plan") are as follows:

	December 31,	
	2020	2019
Conversion of Series A Preferred Stock	7,476,632	7,476,632
Conversion of Series A-1 Preferred Stock	5,233,637	2,990,651
Conversion of Series B Preferred Stock	11,682,229	—
Restricted stock related to early exercise of common stock options	932,279	—
Outstanding common stock options	2,745,185	1,536,428
Common stock options available for grant	1,143,820	1,524,461
Contingent stock	65,186	65,186
Total	29,278,968	13,593,358

11. Stock-Based Compensation

2018 Equity Incentive Plan

The Company's 2018 Plan, as amended, 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 2018 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.

The total number of shares of common stock that may be authorized under the 2018 Plan is 5,454,915 shares, of which 1,143,820 remained available for future grant as of December 31, 2020. 3,072,290 shares were authorized under the 2018 Plan as of December 31, 2019, of which 1,524,461 remained available for future grant as of December 31, 2019. As the 2018 Plan is designed to maintain the fully diluted percentage of total authorized shares, the shares authorized under the plan increased with the additional preferred stock issuances disclosed in Note 9.

Stock Option Valuation

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

	For the years ended December 31,	
	2020	2019
Fair value of common stock	$1.44 — 5.72	$1.12
Dividend yield	—%	—%
Volatility	72.8% — 80.6%	72.4% — 72.8%
Risk-free interest rate	0.31% — 1.46%	1.43% — 2.69%
Expected term (years)	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—January 1, 2019	1,278,963	$ 1.16	9.86	$ —
Granted	380,687	0.90		
Exercised	(3,925)	0.90		
Forfeited	(119,297)	0.90		
Options outstanding—December 31, 2019	1,536,428	$ 1.12	8.96	$ 782
Granted	2,939,809	3.92		
Exercised	(1,629,276)	1.00		
Cancelled	(1,809)	0.93		
Forfeited	(99,961)	0.93		
Options outstanding—December 31, 2020	2,745,185	$ 4.20	9.40	$ 4,183
Options exercisable—December 31, 2020	378,883	$ 2.66	8.55	
Options vested and expected to vest—December 31, 2020	1,079,807	$ 1.54	8.26	

The Company utilizes a third-party valuation firm to assist in determining the grant date fair market value of its common stock. In connection with the initial audit of the Company's 2019 financial statements, the fair market value of its common stock was re-valued as of November 1, 2018 and February 7, 2020, solely for financial reporting purposes. This revaluation resulted in recognition of additional stock compensation expense. The fair value of common stock as of November 1, 2018 was determined to be $1.12 as compared to the initial $0.90 third-party fair valuation determination. The exercise price for stock options granted from November 1, 2018 through October 10, 2019 was derived from the initial valuation in November 2018. The fair value of common stock as of February 7, 2020 was determined to be $1.44 as compared to the initial $0.96 third-party fair

valuation determination. The exercise price for stock options granted from February 7, 2020 through August 19, 2020 was derived from the initial valuation in February 2020.

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

	For the years ended December 31,	
	2020	2019
Weighted-average grant-date fair value per option of total options granted	$ 2.77	$ 0.80
Aggregate intrinsic value of stock options exercised	961	—

As of December 31, 2020, total unrecognized compensation cost related to the unvested awards to employees, directors, and nonemployees is $8.0 million, which is expected to be recognized over a weighted-average period of 3.6 years.

Stock-Based Compensation

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

	For the years ended December 31,	
	2020	2019
Research and development expense	$ 357	$ 66
General and administrative expense	665	163
Total	$ 1,022	$ 229

12. Income Taxes

The Company recorded no income tax benefit for the net loss incurred for the years ended December 31, 2020 and December 31, 2019, due to its uncertainty of realizing a benefit from such losses. All of the Company's operating losses since inception have been generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective tax rate is as follows:

	For the years ended December 31,	
	2020	2019
Federal statutory rate	21.0%	21.0%
Federal research tax credit/orphan drug credit	(0.5)%	(0.2)%
Permanent items, including stock compensation	4.2%	1.4%
Change in valuation allowance	(26.8)%	(20.8)%
Other	2.2%	(1.5)%
	0.0%	0.0%

Significant components of the Company's deferred tax assets are included in the table below *(in thousands)*:

	For the years ended December 31, 2020	2019
Deferred tax assets:		
Net operating loss and capital loss carryforwards	$ 10,586	$ 4,716
Research and development credit carryforwards	1,196	862
Accrued expenses	400	317
Stock-based compensation	171	48
Total deferred tax assets	12,353	5,943
Deferred tax liabilities—depreciation	(206)	(297)
Less valuation allowance	(12,147)	(5,646)
Net deferred tax assets	$ —	$ —

The Company's management has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are composed primarily of net operating loss (NOL) carryforwards and research and development credit carryforwards. Management has considered the Company's history of net losses incurred since inception and probability of future losses to conclude it is more likely than not that the Company will not recognize the benefits of federal and state deferred tax assets. As a result, the Company has established a valuation allowance for the full amount of the net deferred tax assets as of December 31, 2020 and December 31, 2019. The valuation allowance increased by $6.5 million and $5.6 million during the years ended December 31, 2020 and December 31, 2019, respectively.

As of December 31, 2020, the Company has $39.9 million of US federal NOLs and $39.8 million of Kentucky state NOL carryforwards that have no expiration dates. The Company has $0.1 million in US federal and state capital loss carryforwards that expire in 2023. In addition, the Company had a US federal research and development tax credit carryforward of $1.2 million, which may be available to reduce future tax liabilities which start to expire in 2039.

Through December 31, 2020, the Company has generated research and development tax credits but has not conducted a study to document the qualified activities. Such study may result in an adjustment to the Company's research and development credit carryforwards. Since a full valuation allowance has been provided against the Company's research and development credits, any reduction in the gross deferred tax asset established for the research and development credit carryforwards would not result in any net impact to the Company's financial statements.

Realization of the future tax benefits is dependent on many factors, including the Company's ability to generate taxable income within the NOL carryforward period. Under the provisions of Sections 382 and 383 of the Internal Revenue Code, and corresponding provisions of state law, certain substantial changes in the Company's ownership, including a sale of the Company or significant changes in ownership due to sales of equity, may have limited, or may limit in the future, the amount of NOL carryforwards, which could be used annually to offset future taxable income.

The Company files US federal and state tax returns in the United States. All tax years since incorporation remain open to examination by the major taxing jurisdictions (state and federal) to which the Company is subject, as carryforward attributes generated in years past may still be adjusted upon examination by the Internal Revenue Service (IRS) or other authorities if they have or will be used in a future period. The Company is not currently under examination by the IRS or any other jurisdictions for any tax year.

13. Defined Contribution Plan

The Company established a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows

participants to defer a portion of their annual compensation on a pretax basis. Company contributions to the plan are made to employees who meet minimum service requirements in the amount of 3% of gross pay, subject to certain limitations. For the years ended December 31, 2020 and December 31, 2019, the Company made contributions in the amount of $0.2 million and $0.1 million, respectively.

14. Net Loss Per Share Attributable to Common Stockholders

Net Loss Per Share

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

	For the years ended December 31,	
	2020	2019
Net loss and net loss attributable to common stockholders	$ (22,707)	$ (18,155)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.40)	$ (2.84)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	6,685,066	6,383,261

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

	For the years ended December 31,	
	2020	2019
Convertible preferred shares (as converted to common stock and non-voting common stock)	24,392,498	10,467,283
Options to purchase common stock	2,745,185	1,536,428
Restricted stock related to early exercise of options to purchase common stock	932,279	—
Contingent common stock (as converted to common stock)	65,186	65,186
	28,135,148	12,068,897

Unaudited Pro Forma Net Loss Per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 has been prepared to give effect to adjustments arising upon the completion of a qualified initial public offering. The pro forma net loss attributable to common stockholders used in the calculation of pro forma basic and diluted net loss per share attributable to common stockholders is the same as the net loss per share for the year ended December 31, 2020.

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2020 has been prepared to give effect, upon a qualified initial public offering, the automatic conversion of all outstanding shares of convertible preferred stock into common stock and non-voting common stock as if the proposed initial public offering had occurred on the later of January 1, 2020 or the issuance date of the convertible preferred shares.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Pro forma December 31, 2020
Net loss attributable to common stockholders	$ (22,707)
Pro forma net loss per share attributable to common stockholders, basic and diluted	$ (1.07)
Pro forma weighted average number of shares outstanding used in computation of net loss per common share, basic and diluted	21,192,565

15. Related Party Transactions

The Company engaged a firm managed by an executive of the company for professional services related to accounting, finance and other administrative functions. The costs incurred under this arrangement totaled $0.4 million for the years ended December 31, 2020 and 2019, which were recorded as general and administrative expense in the accompanying statements of operations. As of December 31, 2020 and 2019, amounts owed under this arrangement totaled an immaterial amount.

16. Subsequent Events

The Company has evaluated subsequent events through February 26, 2021, the date the financial statements were available to be issued, and May 3, 2021 as to the Product Interest Rights Termination Agreement, the approval of the 2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan and the reverse share split referenced below. The Company has concluded no subsequent events have occurred that require disclosure, except for those referenced below.

Product Interest Rights Termination Agreement

On March 12, 2021, the Company entered into a termination agreement with the holders of Series A and Series A-1 Convertible Preferred Stock to terminate the Product Interest Rights Agreement between the parties, pursuant to an initial public offering. The termination agreement cancels all product interest rights associated with the Series A-1 Convertible Preferred Stock. There was no value offered in exchange for the cancellation.

2021 Stock Option and Incentive Plan and 2021 Employee Stock Purchase Plan

On April 15, 2021, the Company's board of directors approved the 2021 Stock Option and Incentive Plan, terminated the 2018 Plan with respect to any unissued awards under the plan and approved the 2021 Employee Stock Purchase Plan.

Reverse Share Split

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 effective as of April 30, 2021. Accordingly, all share and per share amounts for all periods presented in the accompanying financial statements and notes have been retroactively adjusted, where applicable, to reflect the reverse share split.

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8,825,000 Shares

Common Stock

PROSPECTUS

MORGAN STANLEY

SVB LEERINK

EVERCORE ISI

GUGGENHEIM SECURITIES

Through and including May 31, 2021 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

May 6, 2021