



Talaris Therapeutics Announces Plans to Explore Strategic Alternatives and Implements Restructuring Plan

BOSTON, MA, and LOUISVILLE, KY, February 16, 2023 – Talaris Therapeutics, Inc. ([Nasdaq: TALS](#)), today announced that it has completed a review of its business and program prospects. Based on this review, Talaris has decided to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001’s ability to induce durable tolerance in living donor kidney transplant recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. The company will continue to enroll its FREEDOM-3 Phase 2 clinical trial evaluating FCR001’s ability to induce tolerance in scleroderma.

The Company has initiated a comprehensive review of strategic alternatives focused on maximizing shareholder value, including possible business combinations and/or a divestiture of the Company’s cell therapy CMC capabilities. The Company has not set a timetable for completion of this strategic review and does not intend to comment further on the status of this process unless or until its Board of Directors has approved a definitive course of action, or it is determined that other disclosure is appropriate. There can be no assurance that this strategic review will result in Talaris pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms.

In connection with the evaluation of strategic alternatives and in order to extend its resources, Talaris is implementing a restructuring plan that includes reducing its workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company’s cell therapy CMC capabilities and executing FREEDOM-3.

“It was an exceptionally difficult decision to discontinue further development of FCR001 in kidney transplantation tolerance despite the promising early data,” said Scott Requadt, Chief Executive Officer of Talaris. “I want to express our sincere thanks, first and foremost, to our patients and their donors, as well as to our investigators and collaborators for their participation in this effort, and hope to see continued improvements in kidney disease care in the future. We also want to sincerely thank all our employees, who have been supporting our mission to transform patients’ lives.” Requadt continued, “While we are disappointed that our work in kidney transplantation will not continue, given the potential of FCR001 to induce durable tolerance, we intend to continue its evaluation for scleroderma, which remains a very high unmet medical need for which there are limited treatment options.”

As the Company assesses strategic alternatives, it will suspend further guidance on the status of its programs. As of December 31, 2022, the Company’s cash, cash equivalents and short- and long-term marketable securities were approximately \$181.3 million.



About FREEDOM-3

FREEDOM-3 is a Phase 2 trial exploring the safety and clinical activity of FCR001 in patients with a severe form of scleroderma. Scleroderma is a complex and heterogeneous systemic autoimmune disease affecting multiple tissues and organs. Talaris believes that FCR001 has the potential to restore self-tolerance in patients suffering from scleroderma and other severe autoimmune diseases by eradicating diseased autoreactive cells and regenerating a new and healthy supply of immune cells, thereby halting the autoreactive cells' attack on one's own body.

About Talaris Therapeutics

Talaris Therapeutics, Inc. is developing therapies with the potential to transform the standard of care in solid organ transplantation and severe immune and blood disorders. Talaris maintains corporate offices in Boston, MA, a GMP cell processing facility in Louisville, KY, and research and development laboratories in Houston, TX.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Talaris Therapeutics, Inc.'s ("Talaris," the "Company," "we," or "our") strategy, business plans and focus; statements regarding Talaris' plans to explore and evaluate strategic options and take other actions to extend and maximize its resources; Talaris' plans to continue the clinical development of FREEDOM-3; the potential of FCR001 to induce durable tolerance; Talaris' cash, cash equivalents and short- and long-term marketable securities at December 31, 2022; expectations regarding the intended benefit and cost savings from its planned restructuring and expectations regarding Talaris' use of capital, expenses and other financial results. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" or the negative of these terms and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: volatility and uncertainty in the capital markets for biotechnology companies; Talaris' ability to execute its planned exploration and evaluation of strategic alternatives; availability of suitable third parties with which to conduct contemplated strategic transactions; whether Talaris will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed on attractive terms; whether Talaris' restructuring plans will provided the intended benefit and cost savings; Talaris' ability to successfully continue the clinical development of FREEDOM-3 and unexpected demands on Talaris' cash resources. These and other risks and uncertainties



are described in greater detail in the section entitled “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Talaris’ views only as of today and should not be relied upon as representing our views as of any subsequent date. Talaris explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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