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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 29, 2021

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

Delaware	**001-40384**	**83-2377352**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

Talaris Therapeutics, Inc.
570 S. Preston St
Louisville, KY 40202
(Address of principal executive offices, including zip code)

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

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**TALS**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

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

Item 8.01 Other Events.

On October 29, 2021, Talaris Therapeutics, Inc. (the "Company") issued a press release announcing the initiation of its Phase 2 clinical trial of FCR001, the Company's investigational allogeneic cell therapy, in delayed tolerance induction, a copy of which is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Talaris Therapeutics, Inc. on October 29, 2021.
104	Cover Page Interactive Data File (embedded with the Inline XBRL document).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Talaris Therapeutics, Inc.

Date: November 2, 2021

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

Exhibit 99.1

Talaris Therapeutics Announces Initiation of Phase 2 Clinical Trial of FCR001 in Delayed Tolerance Induction

FREEDOM-2 trial will evaluate the potential for the company's investigational allogeneic cell therapy, FCR001, to induce durable immune tolerance in patients who have previously received a kidney from a living donor

BOSTON, Mass., October 29, 2021 – Talaris Therapeutics, Inc., (Nasdaq: TALS), a late-clinical stage cell therapy company developing therapies with 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, today announced the initiation of the company's Phase 2 FREEDOM-2 study. Northwestern University is the first FREEDOM-2 clinical site to have been activated and has now begun screening for eligible patients. Additional sites are expected to be activated in 2022. This trial will explore the safety and efficacy of the company's investigational allogeneic cell therapy, FCR001, to induce immune tolerance to a transplanted kidney in patients who received the transplant from a living donor up to a year prior to administration of FCR001.

"This trial exploring the efficacy of FCR001 in the delayed tolerance setting is an important step toward potentially offering an alternative to long-term immunosuppression as the standard of care for organ transplant recipients today," said Nancy Krieger, M.D., Chief Medical Officer at Talaris. "We believe that this innovative approach could allow us to broaden the opportunity to apply this novel therapy in larger patient populations by expanding the options for previously transplanted patients whose donor is still available."

FREEDOM-2 (NCT# NCT01649388) is a single-arm, open-label, multicenter study exploring the preliminary efficacy and evaluating the safety of FCR001, the company's investigational allogeneic cell therapy, in living donor kidney transplant recipients 3-12 months following transplantation. The study consists of a one-time treatment administered with non-myeloablative conditioning, after which patients are followed for five years, with a primary analysis performed at 24 months.

"As a physician, I believe the possibility of inducing immune tolerance to a previously-transplanted organ would be transformative," said Joseph R. Leventhal, M.D., Ph.D., Fowler McCormick Professor of Surgery at Northwestern University Feinberg School of Medicine, and the principal investigator for the FREEDOM-2 trial. "I look forward to leading this important study and to the insights it will bring to improve patient care."

About FCR001

FCR001 is an investigational, allogeneic cell therapy developed by Talaris Therapeutics to induce or restore patients' immune tolerance. FCR001 builds on over 30 years of research by the company's founder, Dr. Suzanne Ildstad, into the means by which durable immune tolerance can be induced in a patient who receives a transplanted organ or can be restored in patients

with certain immune-mediated or blood disorders. FCR001 has received both Orphan Drug Designation and Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration. A Phase 3 trial of FCR001 in living donor kidney transplant recipients, FREEDOM-1, is now enrolling patients; more information can be found at: http://freedom1study.com/

About Talaris Therapeutics

Talaris Therapeutics, Inc. is a late-clinical stage biopharmaceutical company developing investigational, one-time, allogeneic cell therapies with 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. Talaris maintains corporate offices in Boston, MA, and its cell processing facility in Louisville, KY.

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; the progress and timing of the preclinical and clinical development of Talaris' programs, including FCR001 and expectations regarding the timing and data from the planned clinical update of FREEDOM-2. 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: the timing and anticipated timing and results of its clinical trials, strategy and future operations, including the expected timing and results from FREEDOM-2,; the risk that the results of Talaris' clinical trials may not be predictive of future results in connection with future clinical trials; the Company's ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of Talaris' planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. 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 June 30, 2021, 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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