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 20, 2022

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)**	**(IRS Employer Identification No.)**

93 Worcester St. **Wellesley, Massachusetts**	**02481**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 502 398-9250

(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	Trading 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 20, 2022, Talaris Therapeutics, Inc. issued a press release entitled "Talaris Therapeutics Provides Update on FREEDOM-1 Phase 3 Clinical Trial." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release entitled "Talaris Therapeutics Provides Update on FREEDOM-1 Phase 3 Clinical Trial."
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Talaris Therapeutics, Inc.

Date: October 20, 2022

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

Talaris Therapeutics Provides Update on FREEDOM-1 Phase 3 Clinical Trial

BOSTON, MA, and LOUISVILLE, KY, October 20, 2022 – 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 and severe immune and blood disorders, today announced a status update on its Phase 3 FREEDOM-1 study in living donor kidney transplant (LDKT) recipients.

On October 18, 2022, the Company received a report of a patient death, which triggered a pre-specified, temporary stopping requirement and review by the FREEDOM-1 Data Monitoring Committee (DMC). After their review of this case, the DMC determined that trial enrollment and dosing may continue. The Company has reported this event and the DMC's recommendation to the U.S. Food and Drug Administration (FDA).

"We are exceptionally saddened by this news, and patient safety remains our top priority. Kidney disease and its related effects are why we are conducting FREEDOM-1, with the goal of improving the lives of patients undergoing kidney transplantation," said Talaris CEO Scott Requadt.

The deceased patient was one of three study subjects reported in June 2022 to have been diagnosed with grade II acute graft-vs-host disease (aGvHD). As reported, this patient was also diagnosed with moderate chronic GvHD that was responding to treatment at the time of the update. The patient was recently hospitalized with grade IV GvHD that was complicated by serious infections leading to respiratory and renal failure, and ultimately death.

In June 2022, the Company provided a clinical update on its FREEDOM-1 study and summarized an amendment to the trial protocol following a review of all GvHD cases to date, spanning its Phase 2 and Phase 3 studies. The Company reported that the incidence of GvHD in FCR001 subjects was correlated with high CD34+ cell counts and high total nucleated cell counts in the FCR001 product. It also noted a correlation between the use of plerixafor as a donor mobilizing agent and an increased risk of GvHD, as plerixafor significantly increased CD34+ and total nucleated cell counts in the FCR001 product. The Company introduced two risk mitigation measures for GvHD in the amended trial protocol: (1) elimination of plerixafor as a donor mobilizing agent, and (2) addition of a second post-transplant dose of cyclophosphamide, which has been demonstrated to reduce the risk of severe GvHD in haplo-identical allogeneic hematopoietic stem cell transplants. [1]

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[1] Elmariah H, Fuchs EJ. Post-transplantation cyclophosphamide to facilitate HLA-haploidentical hematopoietic cell transplantation: Mechanisms and results. Semin Hematol. 2019 Jul;56(3):183-189.

The deceased patient had a related, same-sex donor with an HLA mismatch of 2/6. Although plerixafor was not used to mobilize this donor, the starting FCR001 material contained a high number of CD34+ cells and total nucleated cells, both of which had been identified by the Company during its review as factors that correlated with an increased risk of GvHD. The patient had not received a second post-transplant dose of cyclophosphamide as the patient was treated prior to the June 2022 protocol amendment.

At the date of this update, the other two FREEDOM-1 patients who were previously reported to have had grade II aGvHD have experienced complete resolution of their aGvHD symptoms, although one patient experienced additional flares that were also responsive to treatment.

After reviewing the facts of this case, the DMC concluded that the FREEDOM-1 protocol modifications implemented in June 2022 should be sufficient to mitigate the risk of GvHD going forward, and recommended continuation of the study without further modifications.

About the FREEDOM-1 Study

FREEDOM-1 is a randomized, controlled, open-label Phase 3 registrational study of FCR001 in 120 adult LDKT recipients in the United States. The primary endpoint of FREEDOM-1 is the proportion of kidney transplant recipients treated with FCR001 who are free from chronic IS, without biopsy-proven acute rejection (BPAR), at month 24 post-transplant. The last update on the FREEDOM-1 study was provided on June 30, 2022, at which time the protocol amendment for certain risk mitigation measures for GvHD was also announced.

About Talaris Therapeutics

Talaris Therapeutics, Inc. is a late-clinical stage cell therapy company 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, its cell processing facility in Louisville, KY, and additional research operations 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; the progress and timing of the preclinical and clinical development of Talaris' programs, including FCR001. 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-1, expectations regarding the updated mobilization protocol for FREEDOM-1, the risk that the FDA may require us to pause or discontinue FREEDOM-1, the risk that the results of Talaris' prior clinical trials may not be predictive of or consistent with future and/or final results in connection with the Company's ongoing or future clinical trials; the therapeutic benefits expected from FCR001 and the Company's ability to successfully demonstrate its safety and efficacy. 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, 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 its 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.

Media Contact

Lisa Raffensperger
Ten Bridge Communications
lisa@tenbridgecommunications.com
(617) 903-8783

Investor Contact

Chris Brinzey
ICR Westwicke
chris.brinzey@westwicke.com
(339) 970-2843