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): November 12, 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 2.02 Results of Operations and Financial Condition.

On November 12, 2021, Talaris Therapeutics, Inc. announced its financial results for the quarter ended September 30, 2021 and other corporate updates. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 2.02 of this Form 8-K shall be deemed to be furnished and not filed:

Exhibit No.	Description
99.1	Press Release issued by Talaris Therapeutics, Inc. on November 12, 2021.
104	Cover Page Interactive Data File (embedded within 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 12, 2021

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

Talaris Therapeutics Announces Third Quarter 2021 Financial Results and Provides Business Update

Provided initial clinical update from its Phase 3 (FREEDOM-1) clinical trial evaluating FCR001 in living donor kidney transplant patients

Initiated Phase 2 (FREEDOM-2) clinical trial for FCR001 in delayed tolerance induction patients

BOSTON, MA, and LOUISVILLE, KY, November 12, 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 reported financial results for the three- and nine-month periods ended September 30, 2021, and provided an update on its business.

"We made significant progress in the quarter, providing our first Phase 3 clinical update in living donor kidney transplant (LDKT) patients, and presenting additional long-term follow-up data from our Phase 2 trial in the same patient population at the 2021 American Society of Nephrology meeting," stated Scott Requadt, Chief Executive Officer of Talaris. "Our clinical evidence to date suggests that those patients who achieve >50% T cell chimerism at 3, 6 and 12 months after the administration of FCR001 are likely to be able to be durably weaned from chronic immunosuppression at one year after transplant. We were pleased to report, in our first clinical update from the Phase 3 FREEDOM-1 trial, that all patients who have reached the three-month time point post-transplant have achieved sustained chimerism. These results continue to give us confidence that FCR001 has the potential to transform the standard of care in solid organ transplantation."

Mr. Requadt continued: "In addition, we are advancing our pipeline with the initiation of our FREEDOM-2 Phase 2 trial of FCR001 to assess its potential to induce durable immune tolerance in LDKT patients who received their kidney transplant up to 12 months prior to administration of our investigational therapy. We also remain on track to initiate another Phase 2 trial in our first severe autoimmune disease indication, scleroderma, before year-end."

Corporate Highlights

- **Presented initial clinical update on safety and chimerism data from the Phase 3 FREEDOM-1 trial with living donor kidney transplant (LDKT) patients.**
  - FREEDOM-1 is a randomized, controlled, open-label Phase 3 registrational trial of FCR001 in 120 adult LDKT recipients in the United States. The primary endpoint of FREEDOM-1 is the proportion of LDKT recipients treated with FCR001 who are free from chronic immunosuppression (IS), without proven biopsy rejection (BPAR), at month 24 post-transplant.
  - The initial data presented includes a total of 11 LDKT donor-recipient pairs enrolled from a total of 5 clinical sites. Five of the seven patients randomized to receive FCR001 had been dosed as of the data cut-off date and three patients were dosed at least three months prior to the data cut-off date and were evaluated for safety, chimerism, and ability to wean patients off chronic IS.
  - All three patients dosed at least three months prior to the data cut-off date successfully achieved >50% chimerism. Chimerism is a condition whereby both the donor's and the recipient's hematopoietic stem cells co-exist in the recipient's bone marrow and was correlated strongly in the Company's Phase 2 trial with the transplant recipient's ability to be durably weaned from chronic IS approximately one year after transplant, without subsequent graft rejection in the Company's Phase 2 trial.
  - Both patients dosed at least 12 months prior to the data cut-off date achieved and maintained >50% T-cell chimerism at each of the 3-, 6- and 12-month timepoints and have discontinued their use of chronic IS.
  - The adverse events (AEs) and serious adverse events (SAEs) observed to date in the FREEDOM-1 study were consistent with kidney and stem cell transplantation involving non-myeloablative conditioning and what was observed in the Phase 2 study. No events occurred to cause the Data Safety Monitoring Board (DSMB) to stop or modify the study protocol, nor was any stopping rule triggered. Furthermore, no FCR001-dosed patients in the Phase 3 study experienced BPAR or developed donor-specific antibodies (DSA), the presence of which post-transplant predicts an increased risk for antibody-mediated rejection of the donated organ.

- **Presented updated long-term follow-up data from its Phase 2 LKDT study at the 2021 American Society of Nephrology meeting (ASN).** At ASN, the Company presented updated long-term follow-up data from patients in its Phase 2 LDKT study. Data presented showed that 26 of 26 patients (100%) weaned off IS had continued to remain off chronic IS for the duration of their follow-up (a median >6 years and the longest >12 years post-treatment) without rejection of their donated kidney. Six of these transplant recipients have now exceeded 10 years off all chronic IS without BPAR at the time of the presentation. Through June 11, 2021, the date of the most recent DSMB meeting for the Phase 2 study, there have been no additional AEs or SAEs reported since the prior Phase 2 data cut-off date that were determined to be related to FCR001.

- **Presented potential urinary biomarker of immune quiescence at ASN.** Talaris presented findings of urinary mRNA profiling performed in a subgroup of Phase 2 LDKT patients who were tolerized to their donated kidney and a cohort of biopsy-matched, standard of care, LDKT recipients on chronic IS. These data may provide further support that these patients may have been tolerized to their donated kidney due to potential signals of greater immune quiescence in the kidneys of tolerized patients, as compared to the cohort of the biopsy-matched standard of care kidney transplant patients.

- **Initiated patient screening of Phase 2 (FREEDOM-2) clinical trial of FCR001 in delayed tolerance induction.** 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 FCR001 to induce immune tolerance to a transplanted kidney in patients who received a kidney transplant from a living donor up to a year prior to administration of FCR001.

Third Quarter 2021 Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the third quarter of 2021 with $254.7 million in cash, cash equivalents and marketable securities compared with $149.5 million as of December 31, 2020.

- R&D Expenses: Research and development expenses increased to $9.2 million in the third quarter of 2021, from $4.0 million in the third quarter of 2020. The increase in research and development expenses was primarily due to an increase in employee headcount necessary to support the growth of the Company’s research and development efforts, increased clinical trials costs and an increase in facilities and other expenses.

- G&A Expenses: General and administrative expenses totaled $3.9 million in the third quarter of 2021, up from $2.2 million in the third quarter of 2020, primarily due to an increase in employee headcount, increased professional fees and an increase in executive risk insurance premiums.

- Net Loss: The Company reported a net loss of $12.9 million, or $0.32 per share, in the third quarter of 2021, compared with a net loss of $6.4 million, or $0.94 per share, in the third quarter of 2020.

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, 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 and FCR002; expectations regarding the timing and data from the planned clinical update of FREEDOM-1; and expectations regarding Talaris' use of capital, expenses and other financial results during 2021 and in the future. 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 impact of COVID-19 on countries or regions in which the Company has operations or does business, as well as on the timing and anticipated timing and results of its clinical trials, strategy and future operations, including the expected timing and results from FREEDOM-1, the planned dosing of the first patient in FREEDOM-2 and the planned initiation and dosing of the first patient in FREEDOM-3, the planned initiation and timing of IND-enabling studies of FCR001 and FCR002 in deceased donor transplants and the announcement of an additional indication for FCR001; the risk that the results of Talaris' clinical trials, including the early data from the FREEDOM-1 study, may not be predictive of future results in connection with future clinical trials; the Company's expectations regarding the potential urinary biomarker of immune quiescence, 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 September 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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TALARIS THERAPEUTICS, INC (TALS)
Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three months ended September 30,	
	2021	2020
	(in thousands)	
Operating expenses		
Research and development	$ 9,183	$ 3,956
General and administrative	$ 3,874	$ 2,182
Total operating expenses	13,057	6,138
Loss from operations	(13,057)	(6,138)
Interest and other income (expense), net	$ 116	$ (279)
Net loss attributable to common stockholders	$ (12,941)	$ (6,417)
Net loss per common share, basic and diluted	$ (0.32)	$ (0.94)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	$ 40,669,412	$ 6,823,163

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	As of September 30, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 254,734	$ 149,488
Working capital	253,245	147,347
Total assets	261,325	152,778
Other liabilities	694	1,369
Total liabilities	5,676	4,774
Total convertible preferred stock and stockholders' deficit	255,649	148,004