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): August 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 August 12, 2021, Talaris Therapeutics, Inc. announced its financial results for the quarter ended June 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 August 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: August 12, 2021

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

Exhibit 99.1

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

On track to provide FREEDOM-1 initial clinical update, initiate FREEDOM-2 and FREEDOM-3 trials, and to disclose additional indication for FCR001 before year-end

BOSTON, MA, and LOUISVILLE, KY, August 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 six-month periods ended June 30, 2021, and provided an update on its business.

"As we enter the second half of 2021, we remain on track to provide the first clinical update on our first FREEDOM-1 patients," stated Scott Requadt, Chief Executive Officer of Talaris. "Based on what we observed in our Phase 2 trial, we believe that chimerism, as early as three months post-transplant, has the potential to be highly predictive of establishing durable tolerance to the donated organ without chronic immunosuppression. We are also continuing to advance the rest of our pipeline as we plan for two phase 2 clinical trial initiations in FCR001 in delayed tolerance induction (FREEDOM-2) and in patients with a severe form of scleroderma (FREEDOM-3). We also expect to announce an additional indication for FCR001 before the end of this year."

Corporate Highlights

- **Initial safety and chimerism data from the Phase 3 FREEDOM-1 trial to be provided later this year.** FREEDOM-1 is a randomized, controlled, open-label Phase 3 registrational trial of FCR001 in 120 adult living donor kidney transplant ("LDKT") recipients in the United States. The primary endpoint of FREEDOM-1 is the proportion of living donor kidney transplant recipients treated with FCR001 who are free from chronic immunosuppression, without proven biopsy rejection ("BPAR"), at month 24 post-transplant. The Company plans to update investors on both safety and chimerism status of evaluable patients who have been followed for at least three months since dosing. Chimerism refers to a condition whereby both the donor's and the recipient's hematopoietic stem cells ("HSCs") co-exist in the recipient's bone marrow. In the Company's Phase 2 trial, achievement and maintenance of >50% donor T-cell chimerism in the transplant recipient at three-, six- and twelve months after administration of FCR001 all correlated strongly with the transplant recipient's ability to durably discontinue chronic immunosuppression approximately one year after transplant, without subsequent graft rejection.

- **Added new clinical sites to its Phase 3 FREEDOM-1 trial.** The Company has expanded its clinical trial footprint to 14 active sites in the United States. The Company's clinical trial sites are geographically dispersed across the United States and are all recognized as transplant centers of excellence.

Program Updates and Milestones

- **FCR001 in living donor kidney transplant (LDKT).** The Company's lead product candidate, FCR001, is currently in a randomized, controlled, open-label, multi-center Phase 3 (FREEDOM-1) trial in the United States. 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.

- **FCR001 in delayed tolerance induction.** The Company remains on track to initiate a Phase 2 (FREEDOM-2) trial for FCR001 in delayed tolerance induction in the fourth quarter of 2021. In FREEDOM-2, the Company will evaluate the potential for 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.

- **FCR001 in scleroderma.** The Company remains on track to initiate its first clinical trial in autoimmune diseases with its FREEDOM-3 trial in the fourth quarter of 2021. FREEDOM-3 is a multi-center, single-arm, open-label, proof-of-concept Phase 2 trial assessing the safety and efficacy of FCR001 in adults with a severe form of scleroderma at risk for organ failure.

- **Potential applications in deceased donor organ transplant.** The Company continues to perform preclinical research to explore the feasibility of developing a product candidate similar to FCR001 from bone marrow procured from deceased organ donors, for potential administration to recipients of a deceased donor organ transplant.

- **FCR001 in non-malignant blood, immune and metabolic disorders.** The Company remains on track to announce an additional target indication for FCR001 relating to a severe non-malignant blood, immune or metabolic disorder before the end of 2021.

Second Quarter 2021 Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the second quarter of 2021 with $266.2 million in cash, cash equivalents and marketable securities compared with $149.5 million as of December 31, 2020. Current cash and cash equivalents are expected to fund pipeline development and operations into 2025.

- R&D Expenses: Research and development expenses increased to $7.6 million in the second quarter of 2021, up from $3.4 million in the second 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 $3.5 million in the second quarter of 2021, up from $1.3 million in the second quarter of 2020, primarily due to an increase in employee headcount, increased professional fees and an increase in facilities and other expenses.

- Net Loss: The Company reported a net loss of $11.4 million, or $0.41 per share, in the second quarter of 2021, compared with a net loss of $4.7 million, or $0.73 per share, in the second 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, and at 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 FCR002; expectations regarding the timing and data from the planned clinical update of FREEDOM-1; expectations regarding Talaris' use of capital, expenses and other financial results during 2021 and in the future, and its ability to fund operations into 2025. 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 initiation of FREEDOM-2 and 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 Company's expectations regarding its management hires; 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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TALARIS THERAPEUTICS, INC (TALS)
Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three months ended June 30,	
	2021	2020
	(in thousands)	
Operating expenses		
Research and development	$ 7,570	$ 3,402
General and administrative	$ 3,487	$ 1,335
Total operating expenses	11,057	4,737
Loss from operations	(11,057)	(4,737)
Interest and other income (expense), net	$ (295)	$ 74
Net loss attributable to common stockholders	$ (11,352)	$ (4,663)
Net loss per common share, basic and diluted	$ (0.41)	$ (0.73)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	$ 27,373,165	$ 6,397,025

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	As of June 30, 2021	As of December 31, 2020
Cash, cash equivalents and marketable securities	$ 266,220	$ 149,488
Working capital	265,809	147,347
Total assets	272,814	152,778
Other liabilities	800	1,369
Total liabilities	5,461	4,774
Total convertible preferred stock and stockholders' deficit	267,353	148,004