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

On May 12, 2022, Talaris Therapeutics, Inc. announced its financial results for the quarter ended March 31, 2022 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 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 May 22, 2022.
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: May 12, 2022

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

Exhibit 99.1

Talaris Therapeutics Announces First Quarter Financial Results and Corporate Update

Multiple presentations pending at upcoming American Transplant Congress (ATC), as well as concurrent update on ongoing Phase 3 (FREEDOM-1) clinical trial in living donor kidney transplant (LDKT) patients

Presented data on COVID-19 outcomes among kidney transplant patients treated with FCR001

Strong $225.5 million cash balance to fund operations

BOSTON, MA, and LOUISVILLE, KY, May 12, 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 reported financial results for the three-month period ended March 31, 2022, and provided an update on its business.

"It has been a productive start to the year," stated Scott Requadt, Chief Executive Officer of Talaris. "We recently presented at the 2022 Cutting Edge of Transplantation (CEoT) meeting and are excited to present five abstracts at the upcoming American Transplant Congress annual meeting that continue to highlight the growing body of scientific evidence supporting FCR001's potential to achieve durable immune tolerance in kidney transplant patients. Alongside the meeting, we also plan to provide an interim update on our open-label FREEDOM-1 clinical study. With a strong balance sheet to support our development initiatives, we look forward to reporting on additional progress in our pipeline programs."

Corporate Highlights

- **Updated data from the Phase 3 (FREEDOM-1) clinical trial of FCR001 in living donor kidney transplant (LDKT) to be presented mid-year.** FREEDOM-1 is a randomized, controlled, open-label, multi-center Phase 3 registrational trial of FCR001 in 120 adult LDKT recipients in the United States. In November 2021, the Company announced that all three evaluable patients treated with FCR001 following kidney transplant demonstrated >50% chimerism at 3-, 6- and 12-month timepoints post-transplant, and that the two patients who were transplanted and dosed more than 12 months prior had successfully discontinued the use of chronic immunosuppressive therapies. The Company continues to enroll patients in this trial and has activated additional sites across the United States. The Company will provide a further update on this trial next month at ATC.

- **Multiple abstracts to be presented at the American Transplant Congress (ATC) taking place June 4-8, 2022.** Five abstracts will be presented including new long-term follow-up data from the successful Phase 2 study of FCR001 in LDKT patients. In addition, the Company is presenting a poster reflecting the results of a retrospective real-world evidence analysis of the long-term health outcomes of Phase 2 patients treated with FCR001 compared to a cohort of matched patients treated with standard of care.

- **Presented data on COVID-19 outcomes among kidney transplant patients treated with FCR001.** In April, the Company presented data at the 2022 Cutting Edge of Transplantation (CEoT) meeting organized by the American Society of Transplantation highlighting that a low rate of COVID-19 infection was observed in vaccinated, durably chimeric patients off immunosuppression. No evidence of acute kidney injury or impaired renal function was seen in these patients and no patients lost chimerism as a result of COVID-19 vaccination or infection. The Company will present additional updated data on COVID-19 outcomes among kidney transplant patients treated with FCR001 at ATC.

- **Phase 2 (FREEDOM-2) clinical trial of FCR001 in LDKT delayed tolerance induction.** FREEDOM-2 is evaluating the potential of FCR001 to induce durable immune tolerance in patients who have previously received a kidney from a living donor (delayed tolerance). Success in FREEDOM-2 would expand the LDKT patient population and market potential for FCR001 by an estimated 6,000-10,000 patients annually.[1] The Company recently activated its second trial site for FREEDOM-2.

- **Phase 2 (FREEDOM-3) clinical trial of FCR001 in scleroderma.** FREEDOM-3 is evaluating the safety and efficacy of FCR001 in adults with a severe form of scleroderma, a debilitating, complex and heterogeneous systemic autoimmune disease affecting multiple tissues and organs. In systemic autoimmune diseases, hematopoietic stem cell transplantation (HSCT) has already been observed to be potentially curative. The Company believes that positive proof-of-concept data from FREEDOM-3 has the potential to both support the use of FCR001 in scleroderma as well as other severe, systemic autoimmune diseases.

[1] Organ transplant population estimates based on UNOS/OPTN data for patients 1 year to 18 months delayed from incident LDKT

First Quarter 2022 Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the first quarter of 2022 with $225.5 million in cash, cash equivalents and marketable securities compared with $140.1 million as of March 31, 2021.

- R&D Expenses: Research and development expenses increased to $14.2 million in the first quarter of 2022, up from $6.5 million in the first quarter of 2021. 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 for increased enrollment and additional site activations, and increases in facilities and other expenses.

- G&A Expenses: General and administrative expenses totaled $4.2 million in the first quarter of 2022, up from $2.5 million in the first quarter of 2021, primarily due to an increase in employee headcount, increased professional fees, and an increase in executive risk insurance premiums.

- Net Loss: The The Company reported a net loss of $18.3 million, or $0.45 per share, in the first quarter of 2022, compared with a net loss of $9.3 million, or $1.30 per share, in the first quarter of 2021.

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 and FCR002; expectations regarding the timing and data from the planned clinical update of FREEDOM-1, FREEDOM-2 or FREEDOM-3; and expectations regarding Talaris' use of capital, expenses and other financial results during the first quarter ended on March 31, 2022 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, 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 any additional indications 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 March 31, 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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TALARIS THERAPEUTICS, INC (TALS)
Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	For the three months ended March 31,	
	2022	2021
	(in thousands)	
Operating expenses		
Research and development	$ 14,196	$ 6,468
General and administrative	$ 4,218	$ 2,537
Total operating expenses	18,414	9,005
Loss from operations	(18,414)	(9,005)
Interest and other income (expense), net	$ 155	$ (294)
Net loss attributable to common stockholders	$ (18,259)	$ (9,299)
Net loss per common share, basic and diluted	$ (0.45)	$ (1.30)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	$ 40,980,213	$ 7,160,631

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	March 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 225,529	$ 243,971
Working capital	220,353	238,527
Total assets	237,246	251,422
Other liabilities	3,151	626
Total liabilities	11,216	8,613
Total convertible preferred stock and stockholders' deficit	226,030	242,809