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 15, 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

N/A
(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 August 15, 2022, Talaris Therapeutics, Inc. announced its financial results for the quarter ended June 30, 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 August 15, 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: August 15, 2022

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

Exhibit 99.1

Talaris Therapeutics Announces Second Quarter Financial Results and Corporate Update

All FREEDOM-1 patients who received FCR001 at least three months prior to the data cutoff date of June 15, 2022 had achieved and maintained >50% T-cell chimerism, and all three patients who were dosed at least 12 months post-transplant have discontinued their chronic anti-rejection drugs

Multiple oral and poster presentations at the American Transplant Congress (ATC) 2022 highlighted key research findings and long-term Phase 2 follow up

Strong cash balance with expected runway through 2024

BOSTON, MA, and LOUISVILLE, KY, August 15, 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- and six-month periods ended June 30, 2022, and provided an update on its business.

"The interim data from our Phase 3 FREEDOM-1 trial update this quarter highlighted that all patients treated with FCR001 at least three months prior to the data cutoff date had achieved and maintained chimerism at all measured timepoints post-transplant," stated Scott Requadt, Chief Executive Officer of Talaris. "In addition, all patients 12-months post-transplant, including the first patient now 24 months out, had been successfully weaned off chronic anti-rejection drugs and continue to remain off these drugs. With 17 centers actively recruiting patients, we are building momentum as we look forward to the continued enrollment of our Phase 3 FREEDOM-1 trial."

Mr. Requadt added: "I also would like to take a moment to acknowledge the extraordinary contributions of Dr. Suzanne Ildstad, who will be stepping into the newly created role of Senior Scientific Advisor at the end of the month. On behalf of the Board and the entire Talaris Team, I want to thank Suzanne for her contributions in advancing the field of immune tolerance, for her entrepreneurialism in forming what has become Talaris today, and most notably, for her vision and compassion for patients who want to live a life free of immunosuppression."

Corporate Highlights

- **Dr. Suzanne Ildstad, Chief Scientific Officer and Founder, to become Senior Scientific Advisor.** Effective August 31, 2022, Dr. Ildstad will transition from her current role as CSO to being a Senior Scientific Advisor to Talaris. Dr. Ildstad will continue to advise the company on key scientific matters, remain on Talaris' Scientific Advisory Board and continue as a member of Talaris' Board of Directors.

- **Further strengthened Board of Directors with the appointment of Karen Smith, M.D., Ph.D., MBA, LLM.** Dr. Smith joined the Board following the resignation of Nicholas Galakatos, Ph.D., in May. Dr. Smith brings with her over 20 years of experience in the biopharmaceutical industry overseeing more than 50 clinical trials and more than 20 regulatory approvals leading to global product launches of small molecules, biologics and devices.

Pipeline Highlights

- **Provided update as of the June 15th data cut-off date from Phase 3 (FREEDOM-1) clinical trial evaluating FCR001 in living donor kidney transplant (LDKT) recipients.** 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 June 2022, the Company announced that all of the evaluable patients treated with FCR001 following kidney transplant had achieved and maintained >50% chimerism levels at each of the 3-, 6- and 12-month timepoints post-transplant, and that the three patients who were transplanted and dosed more than 12 months prior, with the first patient dosed 24 months prior, had successfully discontinued the use of chronic anti-rejection drugs. The safety profile observed was generally consistent with that expected in patients receiving a kidney transplant and an allogeneic hematopoietic stem cell transplant (HSCT). Three cases of low-grade, acute graft-versus-host disease were reported, all of which were treatment-responsive and had since resolved. One of these patients subsequently developed chronic graft-versus-host disease, which had responded to treatment. The Company continues to enroll patients and is in the process of expanding its eligibility criteria to certain additional patient groups to accelerate patient recruitment. The Company has 17 active sites across the United States.

- **Presented multiple oral presentations and posters at the American Transplant Congress 2022.** Data from a real-world, retrospective analysis of Phase 2 patients dosed with FCR001 versus matched controls found that FCR001-treated patients had improved kidney function and fewer cardiometabolic complications than patients on immunosuppression after five years. Additionally, an oral presentation highlighted long-term follow up data from the Company's Phase 2 trial showing that all patients who were originally weaned off chronic anti-rejection drugs continued to remain off without rejecting their donated kidney.

- **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). Positive results from FREEDOM-2 could potentially expand the LDKT patient population and market 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, HSCT has already been observed to be potentially curative, albeit with significant risks. 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

Second Quarter Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the second quarter of 2022 with $207.1 million in cash, cash equivalents and marketable securities compared with $244.0 million as of December 31, 2021.

- R&D Expenses: Research and development expenses increased to $13.2 million in the second quarter of 2022, up from $7.6 million in the second 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, increased patient advocacy and recruitment efforts, and increases in facilities and other expenses.

- G&A Expenses: General and administrative expenses totaled $5.2 million in the second quarter of 2022, up from $3.5 million in the second 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 Company reported a net loss of $18.1 million, or $0.44 per share, in the second quarter of 2022, compared with a net loss of $11.4 million, or $0.41 per share, in the second 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 the rate of enrollment for its clinical trials; expectations regarding the timing and data from the planned clinical update of FREEDOM-1, FREEDOM-2 or FREEDOM-3, including potential safety, tolerability and therapeutic effects; expectations around the anticipated contribution of the members of Talaris' board of directors and executives to its operations and progress; and expectations regarding Talaris' growth as a company and use of capital, expenses and other financial results during the second quarter ended on June 30, 2022 and in the future as well as Talaris' expected cash runway through 2024. 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 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 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 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,	
	2022	2021
	(in thousands)	
Operating expenses		
Research and development	$ 13,187	$ 7,570
General and administrative	$ 5,228	$ 3,487
Total operating expenses	18,415	11,057
Loss from operations	(18,415)	(11,057)
Interest and other income (expense), net	$ 319	$ (295)
Net loss attributable to common stockholders	$ (18,096)	$ (11,352)
Net loss per common share, basic and diluted	$ (0.44)	$ (0.41)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	$ 41,088,085	$ 27,373,165

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	June 30,	December 31,
	2022	2021
Cash, cash equivalents and marketable securities	$ 207,112	$ 243,971
Working capital	204,706	238,527
Total assets	220,916	251,422
Other liabilities	2,822	626
Total liabilities	10,174	8,613
Total convertible preferred stock and stockholders' deficit	210,742	242,809