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): March 17, 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.)**

570 S. Preston St Louisville, Kentucky	**40202**
(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, $0.0001par 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 March 17, 2022, Talaris Therapeutics, Inc. announced its financial results for the quarter and year December 31, 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 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 March 17, 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: March 17, 2022

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

Exhibit 99.1

Talaris Therapeutics Announces Fourth Quarter and Year-End Financial Results and Provides Business Update

Phase 3 (FREEDOM-1) clinical trial in living donor kidney transplant (LDKT) patients continues; additional data update expected mid-year 2022

Two Phase 2 (FREEDOM-2 and FREEDOM-3) clinical trials of FCR001 initiated in delayed tolerance and scleroderma

Robust $244 million cash balance to fund operations through multiple milestones

BOSTON, MA, and LOUISVILLE, KY, March 17, 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 disorders, today reported financial results for the quarter and year ended December 31, 2021, and provided an update on its business.

"We are excited by what we were able to achieve in 2021 at Talaris," stated Scott Requadt, Chief Executive Officer of Talaris. "The initial positive data update from our Phase 3 (FREEDOM-1) clinical trial that we provided late last year was a critical step that builds on years of research and development, and provides encouraging signs of FCR001's potential to induce durable, drug-free immune tolerance in kidney transplant recipients. Inducing immune tolerance for patients without the challenges of taking life-long immunosuppressive drugs is widely seen as the "holy grail" in the transplant field. Taken together with the data from our Phase 2 study, we are encouraged by the body of supportive data that we have produced to date. We are keen to explore the extensibility of our therapy to additional patient populations, starting with our Phase 2 (FREEDOM-2) clinical trial of FCR001 in LDKT delayed tolerance induction and our Phase 2 (FREEDOM-3) clinical trial in our first severe autoimmune disease indication, scleroderma. We look forward to advancing all of our programs and providing additional updates on FREEDOM-1 in 2022."

Recent Corporate Highlights

- **Presented initial positive data update from the ongoing Phase 3 (FREEDOM-1) clinical trial of FCR001 in LDKT.** 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.

- **Presented confirmatory data analysis from the Phase 2 trial demonstrating FCR001 induced durable tolerance in highly mismatched related and unrelated recipients with living donor kidney transplant (LDKT) at the American Society of Hematology (ASH) Annual Meeting in December 2021.** High-resolution allele typing at twelve loci found that FCR001 induced durable immune tolerance in highly mismatched related and unrelated recipients based on DNA samples collected in the Phase 2 trial of FCR001 in LDKT recipients. The focus of the analysis was to evaluate the degree of donor/recipient HLA mismatching using high-resolution allele typing and to understand its correlation with the ability to establish durable chimerism in this patient sample. The data analyzed demonstrated that even with a high degree of mismatch, durable chimerism induced by FCR001 allowed for full withdrawal of immunosuppression (IS) in 25 of the 32 subjects evaluated, with time off IS ranging from 3.5 to 11 years.

- **Initiated Phase 2 (FREEDOM-3) clinical trial of FCR001 in scleroderma, its first severe autoimmune disease.** 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.

- **Initiated 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]

- **Expanded management team with the addition of Andrew Farnsworth as the Chief Human Resources Officer.** Mr. Farnsworth has over twenty years of human resource experience in fast-growing private and public companies, bringing with him expertise in leadership development, HR strategy and operations, talent acquisition and retention.

- **Added to the NASDAQ Biotechnology Index (NASDAQ: NBI).** The Company was added to the NASDAQ Biotechnology Index, designed to track the performance of a set of securities listed on the NASDAQ Stock Market® (NASDAQ®) that are classified according to the Industry Classification Benchmark as biotechnology or pharmaceutical companies, in December 2021.

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

Fourth Quarter and Year-End 2021 Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the fourth quarter of 2021 with $244.0 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 $10.6 million in the fourth quarter of 2021, and $34.3 million for the year ended 2021, compared to $4.4 million and $15.3 million for comparable periods in 2020, respectively. 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, increased patient advocacy efforts and an increase in facilities and other expenses.

- G&A Expenses: General and administrative expenses totaled $3.8 million in the fourth quarter of 2021, and $13.3 million for the year ended 2021, compared to $2.5 million and $7.4 million for comparable periods in 2020, respectively, 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 $14.2 million, or $0.35 per share, in the fourth quarter of 2021, and $47.8 million, or $1.64 per share, for the year ended 2021, compared to $6.8 million, or $0.96 per share, and $22.7 million, or $3.40 per share, for comparable periods in 2020, respectively.

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; as well as expectations around timing and completion of clinical trial enrollment; expectations regarding the timing and data from the planned clinical update of FREEDOM-1, FREEDOM-2 or FREEDOM-3, including upcoming milestones and therapeutic effects; 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, 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 Annual Report on Form 10-K for the quarter and year ended December 31, 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)

	For the year ended December 31,	
	2021	2020
	(in thousands)	
Operating expenses		
Research and development	$ 34,245	$ 15,278
General and administrative	$ 13,262	$ 7,406
Total operating expenses	47,507	22,684
Loss from operations	(47,507)	(22,684)
Interest and other income (expense), net	$ (326)	$ (23)
Net loss attributable to common stockholders	$ (47,833)	$ (22,707)
Net loss per common share, basic and diluted	$ (1.64)	$ (3.40)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	$ 29,126,373	$ 6,685,066

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	As of December 31,	
	2021	2020
Cash, cash equivalents and marketable securities	$ 243,971	$ 149,488
Working capital	238,527	147,347
Total assets	251,422	152,778
Other liabilities	626	1,369
Total liabilities	8,613	4,774
Total convertible preferred stock and stockholders' deficit	242,809	148,004