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): June 14, 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 June 14, 2021, Talaris Therapeutics, Inc. announced its financial results for the quarter ended March 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 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 June 14, 2021.

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: June 14, 2021

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

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

BOSTON, MA, and LOUISVILLE, KY, June 14, 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-month period ended March 31, 2021, and provided an update on its business.

"Following our successful IPO, we are well financed into 2025 and very focused on program execution," stated Scott Requadt, Chief Executive Officer of Talaris. "With our open-label, registrational Phase 3 trial in living donor kidney transplant, FREEDOM-1, already underway, two additional open-label Phase 2 trials initiating later this year, and multiple potential indications for FCR001 being evaluated, we anticipate several important milestones ahead of us. We appreciate our investors' confidence in Talaris and look forward to advancing our lead product candidate, FCR001, to potentially benefit patients in multiple areas of high unmet need."

Corporate Highlights

- **Presented long-term data from Phase 2 study of FCR001 at the Virtual 2021 American Transplant Congress.** The Company reported that all stably chimeric kidney transplant recipients in its Phase 2 study remained off chronic immunosuppression and rejection-free for the duration of follow up, with a minimum follow-up of four years and the longest follow-up of almost 12 years. Chimerism refers to a state whereby the recipient's and donor's blood and immune cells co-exist in the recipient, creating a reciprocal state of immune tolerance called allogeneic tolerance. The Company believes chimerism is a highly predictive marker of potential immunotolerance.
- **Successfully completed an initial public offering (IPO).** In May 2021, the Company completed its IPO, raising approximately $150.0 million in gross proceeds before deducting underwriting discounts and commissions and other offering expenses. The shares began trading on the Nasdaq Global Select Market on May 11, 2021, under the ticker symbol "TALS."
- **Talaris strengthens organization with key management hires.** Mary Kay Fenton joined as Talaris' Chief Financial Officer bringing 25 years of operational, strategic, and transactional experience in the biotechnology industry. The Company also announced several additional hires to augment its organizational strength and build out its in-house manufacturing and quality operations, advance its lead program through a Phase 3 registrational clinical trial, and expand its therapeutic pipeline.

- **Added to the Russell 2000® and Russell Microcap® Indexes.** In June 2021, it was announced that Talaris would be added to the Russell 2000 and Russell Microcap Indexes as part of Russell's annual reconstitution. The Russell U.S. Indexes are widely used by investment managers and institutional investors for passive funds and investment products and as benchmarks for active investment strategies.

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. The goal of the FREEDOM-1 trial is to assess the potential of FCR001 to induce durable immune tolerance to the transplanted kidney without the need for chronic immunosuppression to prevent graft rejection. 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. The Company will provide an initial clinical update on FREEDOM-1 in the fourth quarter of 2021.
- **FCR001 in Delayed Tolerance Induction.** In the second half of 2021, the Company plans to initiate a Phase 2 (FREEDOM-2) trial evaluating 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.** In the second half of 2021, the Company plans to initiate its first clinical trial in autoimmune diseases with the initiation of its Phase 2 (FREEDOM-3) trial evaluating the safety and clinical activity of FCR001 in patients with a severe form of scleroderma.
- **FCR001 or FCR002 in Deceased Donor Kidney Transplant.** The Company is conducting preclinical research to explore the manufacturing of FCR001 or FCR002 from bone marrow procured from deceased organ donors. If successful, the Company plans to initiate IND-enabling studies of FCR001 or FCR002 in deceased donor kidney recipients.
- **FCR001 in Non-Malignant Blood, Immune and Metabolic Disorders.** By the end of 2021, the Company expects to announce an additional target indication for FCR001 relating to a severe, non-malignant blood, immune or metabolic disorder.

First Quarter 2021 Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the first quarter of 2021 with $140.1 million in cash, cash equivalents, and marketable securities compared with $149.5 million as of December 31, 2020. Pro forma cash and equivalents at March 31, 2021, including the $139.5 million in net proceeds from the Company's IPO completed in May 2021, totaled $279.6 million.
- R&D Expenses: Research and development expenses increased to $6.5 million in the first quarter of 2021, up from $3.5 million in the first 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 increases in facilities and other expenses.
- G&A Expenses: General and administrative expenses totaled $2.5 million in the first quarter of 2021, up from $1.4 million in the first quarter of 2020, primarily due to an increase in employee headcount, increased professional fees, and an increase in facilities and other expenses.
- Net Loss: Talaris reported a net loss of $9.3 million, or $1.30 per share, in the first quarter of 2021, compared with a net loss of $4.8 million, or $0.76 per share, for the first 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 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 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 March 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)

	Three months ended March 31,	
	2021	2020
Operating expenses		
Research and development	$ 6,468	$ 3,535
General and administrative	2,537	1,439
Total operating expenses	9,005	4,974
Loss from operations	(9,005)	(4,974)
Interest and other income (expense), net	(294)	126
Net loss attributable to common stockholders	$ (9,299)	$ (4,848)
Net loss per common share, basic and diluted	$ (1.30)	$ (0.76)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	7,160,631	6,390,771

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	Three months ended March 31,	Year ended December 31,
	2021	2020
Cash, cash equivalents and marketable securities	$ 140,101	$ 149,488
Working capital	139,222	147,347
Total assets	144,900	152,778
Other liabilities	1,634	1,369
Total liabilities	5,215	4,774
Total convertible preferred stock and stockholders' deficit	139,685	148,004

Pro Forma Selected Financial Data
(Unaudited, in thousands except share amounts)

	Pro forma
	March 31, 2021
Cash, cash equivalents and marketable securities	$ 279,624
Total shares outstanding	41,310,241