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): February 15, 2023

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** **(Address of Principal Executive Offices)**		**02481** **(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 February 16, 2023, Talaris Therapeutics, Inc. (the "Company") announced that as of December 31, 2022, the Company had cash, cash equivalents and short- and long-term marketable securities of approximately $181.3 million.

The cash, cash equivalents and short- and long-term marketable securities information above is based on preliminary unaudited information and management estimates for the year ended December 31, 2022, is not a comprehensive statement of the Company's financial results as of and for the fiscal year ended December 31, 2022 and is subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, this preliminary estimate.

The information contained in this item is being 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 2.05. Costs Associated with Exit or Disposal Activities.

On February 15, 2023, in connection with the evaluation of strategic alternatives and in order to extend its resources, the Board of Directors of the Company approved a restructuring plan (the "Plan") that includes reducing the Company's workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3. The Company estimates that the reduction in force will be substantially completed by February 28, 2023. In addition, the Plan includes a discontinuation of the Company's FREEDOM-1 and FREEDOM-2 clinical development programs and further prioritization of the Company's resources as it assesses strategic alternatives. The Company estimates that it will incur approximately $2.9 million for retention, severance and other employee termination-related costs in the first and second quarters of 2023.

The estimate of costs that the Company expects to incur and the timing thereof are subject to a number of assumptions, and actual results may differ. As the Plan is implemented, the Company's management will re-evaluate the estimated costs and expenses set forth above and may revise the estimated restructuring charge as appropriate, consistent with generally accepted accounting principles. The Company may also incur other cash or non-cash charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the Plan.

Item 8.01. Other Events.

On February 16, 2023, the Company announced that it has completed a review of its business and program prospects. Based on this review, the Company has decided to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. The Company will continue to enroll its FREEDOM-3 Phase 2 clinical trial evaluating FCR001's ability to induce tolerance in scleroderma.

The Company has initiated a comprehensive review of strategic alternatives focused on maximizing shareholder value, including possible business combinations and/or a divestiture of the Company's cell therapy CMC capabilities. The Company has not set a timetable for completion of this strategic review and does not intend to comment further on the status of this process unless or until its Board of Directors has approved a definitive course of action, or it is determined that other disclosure is appropriate. There can be no assurance that this strategic review will result in the Company pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms.

In connection with the evaluation of strategic alternatives and in order to extend its resources, the Company is implementing a restructuring plan that includes reducing its workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3.

On February 16, 2023, the Company issued a press release announcing its plans to explore strategic alternatives and implement a restructuring plan. The full text of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Talaris Therapeutics, Inc. on February 16, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Forward-Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans and prospects for the Company, including but not limited to, statements about its ability to identify, assess and execute a strategic transaction or realize any value from its existing assets, its ability to preserve cash and continue the clinical development of FREEDOM-3, its planned workforce reduction and costs expected to be incurred in connection therewith, the adequacy or sufficiency of the Company's existing cash resources and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the risk that the restructuring costs and charges may be greater than anticipated or incurred in different periods than anticipated; the risk that the Company's restructuring efforts may adversely affect the Company's internal programs and the Company's ability to retain key personnel; risks associated with the Company's ability to continue the clinical development of FREEDOM-3; the risk that the Company may not execute its planned exploration and evaluation of strategic alternatives; the availability of suitable third parties with which to conduct contemplated strategic transactions; the risk that the Company's restructuring efforts may not generate their intended benefits to the extent or as quickly as anticipated; the risk that the Company's restructuring efforts may negatively impact the Company's business operations and reputation; and such other important factors as are set forth in the Company's Annual Report on Form 10-Q for the quarter ended September 30, 2022 and other filings on file thereafter with the U.S. Securities and Exchange Commission. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company's views as of the date of this Current Report on Form 8-K. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this Current Report on Form 8-K.

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: February 16, 2023

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

Talaris Therapeutics Announces Plans to Explore Strategic Alternatives and Implements Restructuring Plan

BOSTON, MA, and LOUISVILLE, KY, February 16, 2023 – Talaris Therapeutics, Inc. (Nasdaq: TALS), today announced that it has completed a review of its business and program prospects. Based on this review, Talaris has decided to discontinue its FREEDOM-1 and FREEDOM-2 clinical trials evaluating FCR001's ability to induce durable tolerance in living donor kidney transplant recipients. This decision was primarily attributable to the pace of enrollment and the associated timeline to critical milestones. The company will continue to enroll its FREEDOM-3 Phase 2 clinical trial evaluating FCR001's ability to induce tolerance in scleroderma.

The Company has initiated a comprehensive review of strategic alternatives focused on maximizing shareholder value, including possible business combinations and/or a divestiture of the Company's cell therapy CMC capabilities. The Company has not set a timetable for completion of this strategic review and does not intend to comment further on the status of this process unless or until its Board of Directors has approved a definitive course of action, or it is determined that other disclosure is appropriate. There can be no assurance that this strategic review will result in Talaris pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms.

In connection with the evaluation of strategic alternatives and in order to extend its resources, Talaris is implementing a restructuring plan that includes reducing its workforce by approximately one-third, with remaining employees primarily focused on maintaining the Company's cell therapy CMC capabilities and executing FREEDOM-3.

"It was an exceptionally difficult decision to discontinue further development of FCR001 in kidney transplantation tolerance despite the promising early data," said Scott Requadt, Chief Executive Officer of Talaris. "I want to express our sincere thanks, first and foremost, to our patients and their donors, as well as to our investigators and collaborators for their participation in this effort, and hope to see continued improvements in kidney disease care in the future. We also want to sincerely thank all our employees, who have been supporting our mission to transform patients' lives." Requadt continued, "While we are disappointed that our work in kidney transplantation will not continue, given the potential of FCR001 to induce durable tolerance, we intend to continue its evaluation for scleroderma, which remains a very high unmet medical need for which there are limited treatment options."

As the Company assesses strategic alternatives, it will suspend further guidance on the status of its programs. As of December 31, 2022, the Company's cash, cash equivalents and short- and long-term marketable securities were approximately $181.3 million.

About FREEDOM-3

FREEDOM-3 is a Phase 2 trial exploring the safety and clinical activity of FCR001 in patients with a severe form of scleroderma. Scleroderma is a complex and heterogeneous systemic autoimmune disease affecting multiple tissues and organs. Talaris believes that FCR001 has the potential to restore self-tolerance in patients suffering from scleroderma and other severe autoimmune diseases by eradicating diseased autoreactive cells and regenerating a new and healthy supply of immune cells, thereby halting the autoreactive cells' attack on one's own body.

About Talaris Therapeutics

Talaris Therapeutics, Inc. is 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, a GMP cell processing facility in Louisville, KY, and research and development laboratories 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; statements regarding Talaris' plans to explore and evaluate strategic options and take other actions to extend and maximize its resources; Talaris' plans to continue the clinical development of FREEDOM-3; the potential of FCR001 to induce durable tolerance; Talaris' cash, cash equivalents and short- and long-term marketable securities at December 31, 2022; expectations regarding the intended benefit and cost savings from its planned restructuring and expectations regarding Talaris' use of capital, expenses and other financial results. 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: volatility and uncertainty in the capital markets for biotechnology companies; Talaris' ability to execute its planned exploration and evaluation of strategic alternatives; availability of suitable third parties with which to conduct contemplated strategic transactions; whether Talaris will be able to pursue a strategic transaction, or whether any transaction, if pursued, will be completed on attractive terms; whether Talaris' restructuring plans will provided the intended benefit and cost savings; Talaris' ability to successfully continue the clinical development of FREEDOM-3 and unexpected demands on Talaris' cash resources. 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 September 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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