

**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): October 6, 2023

TALARIS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-40384
(Commission
File Number)

83-2377352
(I.R.S. 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

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 8.01 Other Events.

As previously announced, on June 22, 2023, Talaris Therapeutics, Inc., a Delaware corporation (“Talaris”), Terrain Merger Sub, Inc., a Delaware corporation and a wholly owned subsidiary of Talaris (“Merger Sub”), and Tourmaline Bio, Inc., a Delaware corporation (“Tourmaline”), entered into an Agreement and Plan of Merger (the “Merger Agreement”), pursuant to which, among other matters, and subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, Merger Sub will merge with and into Tourmaline, with Tourmaline continuing as a wholly owned subsidiary of Talaris and the surviving corporation of the merger (the “Merger”). On July 20, 2023, Talaris filed the definitive version of the proxy statement, as amended on August 25, 2023 and September 11, 2023, with the United States Securities Exchange Commission (the “SEC”) in connection with the Merger (the “Proxy Statement”).

Exchange Ratio

Pursuant to the Merger Agreement, the final Exchange Ratio (as defined in the Merger Agreement) will be 0.8055.

Litigation Matters

ImmunoFree Demand Letter

On September 22, 2023, the Company received a purported notice of material breach from ImmunoFree Inc. (“ImmunoFree”) (the “ImmunoFree Demand Letter”) alleging that the Company breached a provision of the Asset Purchase Agreement (“APA”), dated June 28, 2023, between ImmunoFree and the Company pursuant to which the Company sold certain clinical data and intellectual property related to its product candidate, FCR001, to ImmunoFree, and that the Company fraudulently induced ImmunoFree to enter into the APA. In the ImmunoFree Demand Letter, ImmunoFree alleged the Company failed to disclose certain information and costs related to a patient in the FREEDOM-1 Study and demanded that the Company indemnify ImmunoFree for the cost of treatment for this patient, which costs ImmunoFree asserted would be an estimated \$9 million over a 30-year period. On September 27, 2023, the Company sent a letter responding to the ImmunoFree Demand Letter, denying the allegations in the ImmunoFree Demand Letter. Among other things, the Company asserted that it had disclosed to ImmunoFree information related to this patient in accordance with its obligations under the APA, that the APA was clear that ImmunoFree assumed full responsibility for all remaining wind down and patient follow-up and treatment costs for the FREEDOM-1 Study, and, thus, that the Company had no obligation to indemnify ImmunoFree for the treatment costs for this patient.

On October 6, 2023, the Company and ImmunoFree executed a binding settlement agreement (the “Settlement Agreement”) pursuant to which the Company will pay ImmunoFree \$4 million and ImmunoFree and Talaris will mutually release each other from any and all claims, liabilities and/or losses relating to the APA, the FREEDOM-1 Study, and the ImmunoFree Demand Letter and the allegations therein. As set forth in the Settlement Agreement, the Company denies any and all liability with respect to this matter, and has resolved it solely to avoid the risks and costs associated with litigating this matter and any risk to the consummation of the Transaction.

Merger Litigation

Following the announcement of the proposed Merger and as of the filing of the supplemental disclosures set forth below (the “Supplemental Disclosures”), three lawsuits were filed by purported stockholders of the Company challenging the proposed Merger. These lawsuits, brought by the plaintiffs individually, are captioned *Wieder v. Talaris Therapeutics, Inc., et al.*, No. 1:23-cv-08355 (S.D.N.Y. filed Sept. 21, 2023), *Carlisle v. Talaris Therapeutics, Inc., et al.*, No. 1:23-cv-08520 (S.D.N.Y. filed Sept. 27, 2023), and *Roberts v. Talaris Therapeutics, Inc., et al.*, No. 1:23-cv-01063 (D. Del. filed Sept. 27, 2023) (collectively, the “Complaints”). The Complaints name the Company and the Company’s board of directors as defendants.

The Complaints assert claims under Section 14(a), and Rule 14a-9 promulgated thereunder, and Section 20(a) of the Securities and Exchange Act of 1934, as amended (the “Exchange Act”). The plaintiffs generally allege that the Proxy Statement omits material information with respect to the proposed Merger, which renders the Proxy Statement false and misleading. The Complaints seek preliminary and permanent injunction of the proposed Merger, and, if the Merger is consummated, rescission or rescissory damages, as well as attorneys’ fees and costs.

Additionally, between July 25 and September 20, the Company received five demand letters from purported stockholders of Talaris in connection with the Merger (the “Demands”). The allegations in the Demands are substantially similar to those in the Complaints. The Demands request that the Company disseminate corrective disclosures to cure the allegedly misleading Proxy Statement.

While the Company believes that the disclosures set forth in the Proxy Statement comply fully with all applicable law and denies the allegations in the pending actions described above, in order to moot plaintiffs' disclosure claims, avoid nuisance and possible expense and business delays, and provide additional information to its stockholders, the Company has determined voluntarily to supplement certain disclosures in the Proxy Statement related to plaintiffs' claims with the Supplemental Disclosures. Nothing in the Supplemental Disclosures shall be deemed an admission of the legal merit, necessity or materiality under applicable laws of any of the disclosures set forth herein. To the contrary, the Company specifically denies all allegations in the complaints described above that any additional disclosure was or is required or material.

Supplemental Disclosures

These Supplemental Disclosures should be read in conjunction with the Proxy Statement, which should be read in its entirety. All page references in the information below are to pages in the Proxy Statement, and all terms used but not defined below shall have the meanings set forth in the Proxy Statement. The information contained in this Form 8-K is incorporated by reference into the Proxy Statement. To the extent the following information differs from or conflicts with the information contained in the Proxy Statement, the information set forth below shall be deemed to supersede the respective information in the Proxy Statement. New text within the amended and supplemented language from the Proxy Statement is indicated in bold and underlined text (e.g., **bold, underlined text**), and deleted text within the amended and supplemented language from the Definitive Proxy Statement is indicated in bold and strikethrough text (e.g., **~~bold, strikethrough text~~**).

The disclosure under the heading “Background of the Merger” is hereby amended and supplemented by replacing the final paragraph on page 158 of the Proxy Statement in its entirety with the following:

On March 3, 2023, the S&T Committee held a meeting by videoconference, at which members of Talaris management and representatives of Leerink Partners and Goodwin were present. During this meeting, Leerink Partners and Talaris management provided an update on outreach efforts in the Reverse Merger Process. Talaris management also discussed Talaris' cash burn and cash position. Talaris management provided the S&T Committee with an updated analysis prepared by Talaris management regarding a potential liquidation of the company, including the potential timeline for liquidation and an estimate of the amount that would be distributable to Talaris stockholders in such liquidation scenario. Key assumptions included a liquidation completion date of March 31, 2023 and a Talaris net cash amount of approximately \$165 million as of March 31, 2023. In this liquidation scenario, Talaris management estimated that the cash distribution would be about \$3.37 per share. In the context of reviewing this liquidation scenario, the Talaris board discussed the risks, challenges, and strategic opportunities facing Talaris. Following this discussion, the S&T Committee instructed Talaris management and Leerink Partners to continue with the Reverse Merger Process. **Talaris management did not update the liquidation scenario or prepare any other liquidation analysis after March 3, 2023.**

The disclosure under the heading “Valuation Analysis—Discounted Cash Flow” is hereby amended and supplemented by replacing the final paragraph beginning on page 179 of the Proxy Statement in its entirety with the following:

A discounted cash flow analysis is a traditional valuation methodology used to derive a valuation of an asset or set of assets by calculating the “present value” of estimated future cash flows of the asset or set of assets. “Present value” refers to the current value of future cash flows or amounts and is obtained by discounting those future cash flows or amounts by a discount rate that takes into account assumptions and estimates of risk, the opportunity cost of capital, expected returns and other appropriate factors, and then adding the present value equivalent of the terminal value of the business at the end of the applicable projection period. A discounted cash flow analysis is a widely accepted valuation methodology for development stage biotechnology companies, including valuations of companies whose primary product candidate is still in development and for which regulatory authorization to market the applicable product candidate may not be obtained, if at all, until several years into the future. For purposes of its discounted cash flow analysis, at the direction of Talaris, Leerink Partners relied upon the Financial Projections. Leerink Partners was advised by Talaris, and assumed, at Talaris' direction, that the Financial Projections were

reasonably prepared on bases reflecting the best currently available estimates and judgments of the management of Talaris as to the matters covered thereby. Leerink Partners was advised by Talaris that the Financial Projections included assumptions regarding competitive market entrants. Talaris advised Leerink Partners that it believed these probabilities of success were reasonable, based on a review of publicly available studies and industry practice and Talaris management's professional experience. The Financial Projections, which Talaris management directed Leerink Partners to use in deriving its financial analyses, include cash flows through 2043, which is the year that patent protections for TOUR006 expire. Talaris advised Leerink Partners that it believed it was reasonable to forecast revenues through the patent life of TOUR006. **The Financial Projections assume that Tourmaline will have no terminal value after 2043 due to the potential expiration of patent protections for TOUR006 as early as 2043.**

The disclosure under the heading "General" is hereby amended and supplemented by replacing the first full paragraph on page 182 of the Proxy Statement in its entirety with the following:

Leerink Partners LLC is a full-service securities firm engaged in securities trading and brokerage activities as well as investment banking and financial advisory services. Leerink Partners has provided certain investment banking services to Talaris from time to time, for which it has received compensation. In the past two years, Leerink Partners served as the sales agent under Talaris' at-the-market sales agreement, for which it did not receive any fees, or commissions, or other compensation. **Other than as described in the preceding sentence or in connection with Leerink Partners' current engagement by Talaris, in the past two years, Leerink Partners has not provided investment banking services to Talaris or Tourmaline.** In the ordinary course of business, Leerink Partners may in the future provide investment banking services to Talaris, Tourmaline or their respective affiliates and would expect to receive customary fees for the rendering of such services. In the ordinary course of its trading and brokerage activities, Leerink Partners has in the past and may in the future hold positions, for its own account or the accounts of its customers, in equity, debt or other securities of Talaris, Tourmaline or their respective affiliates.

The disclosure under the heading "Certain Unaudited Prospective Financial Information" is hereby amended and supplemented by replacing the table on page 185 of the Proxy Statement in its entirety with the following:

(\$ in millions)	Q4 23	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Net Sales	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0	\$ 234	\$ 480	\$ 739	\$ 1,011	\$ 1,297	\$ 1,593
Net Income ¹	(\$ 9)	(\$ 52)	(\$ 73)	(\$ 75)	(\$ 110)	\$ 12	\$ 185	\$ 313	\$ 315	\$ 500	\$ 539
<u>Δ Net Working Capital</u>	<u>\$ 0</u>	<u>\$ 0</u>	<u>\$ 0</u>	<u>\$ 0</u>	<u>\$ 0</u>	<u>(\$ 23)</u>	<u>(\$ 25)</u>	<u>(\$ 26)</u>	<u>(\$ 27)</u>	<u>(\$ 28)</u>	<u>(\$ 39)</u>
Unlevered Free Cash Flow ²	(\$ 9)	(\$ 52)	(\$ 73)	(\$ 75)	(\$ 110)	(\$ 11)	\$ 160	\$ 287	\$ 288	\$ 472	\$ 509

	2034	2035	2036	2037	2038	2039	2040	2041	2042	2043
Net Sales	\$ 1,633	\$ 1,674	\$ 1,716	\$ 1,759	\$ 1,803	\$ 1,847	\$ 1,652	\$ 1,480	\$ 1,159	\$ 911
Net Income ¹	\$ 627	\$ 642	\$ 658	\$ 674	\$ 690	\$ 707	\$ 634	\$ 570	\$ 448	\$ 354
<u>Δ Net Working Capital</u>	<u>(\$ 4)</u>	<u>(\$ 4)</u>	<u>(\$ 4)</u>	<u>(\$ 4)</u>	<u>(\$ 16)</u>	<u>(\$ 5)</u>	<u>\$ 19</u>	<u>\$ 17</u>	<u>\$ 32</u>	<u>\$ 25</u>
Unlevered Free Cash Flow ²	\$ 623	\$ 638	\$ 654	\$ 670	\$ 686	\$ 702	\$ 653	\$ 587	\$ 480	\$ 379

(1) Net income is defined as gross profit less operating expenses and taxes.

(2) Unlevered free cash flow is defined as net income less changes in net working capital.

The disclosure under the heading "Interests of Talaris' Directors and Executive Officers in the Merger" is hereby amended and supplemented by replacing the first bullet point on page 185 of the Proxy Statement in its entirety with the following:

On September 2, 2023, the Talaris Board designated Each of Mark D. McDade and Sapna Srivastava to will continue as directors of the combined company after the effective time, and following the closing of the Merger, **they** will be compensated as a non-employee director of the combined company pursuant to the non-employee director compensation policy in place following the effective time;

The disclosure under the heading “*Management Following the Merger*” is hereby amended and supplemented by inserting the following paragraph after the fourth paragraph on page 365 of the Proxy Statement:

There have been no discussions with Talaris executive officers regarding post-transaction employment.

Forward-Looking Statements

This Current Report on Form 8-K and the exhibit furnished herewith contain “forward-looking statements” within the meaning of the Exchange Act, and the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995, including but not limited to, express or implied statements regarding the structure, timing and completion of the proposed Merger; the combined company’s listing on Nasdaq Global Market after closing of the proposed Merger; expectations regarding the ownership structure of the combined company; the anticipated timing of the closing of the Merger; each company’s and the combined company’s expected cash position at the closing of the proposed Merger and cash runway of the combined company; the future operations of the combined company; the nature, strategy and focus of the combined company; the development and commercial potential and potential benefits of any product candidates or platform technologies of the combined company; anticipated preclinical and clinical drug development activities and related timelines, including the expected timing for data and other clinical results; the competitive landscape of the combined company; anticipated intellectual property timelines; the expected Exchange Ratio and other statements that are not historical fact. All statements other than statements of historical fact contained in this Current Report on Form 8-K are forward-looking statements. These forward-looking statements are made as of the date they were first issued, and were based on the then-current expectations, estimates, forecasts, and projections, as well as the beliefs and assumptions of management. There can be no assurance that future developments affecting Talaris, Tourmaline or the proposed Merger will be those that have been anticipated.

Forward-looking statements are subject to a number of risks and uncertainties, many of which involve factors or circumstances that are beyond Talaris’ control. Talaris’ actual results could differ materially from those stated or implied in forward-looking statements due to a number of factors, including but not limited to (i) the risk that the conditions to the closing of the proposed Merger are not satisfied, including the failure to timely obtain shareholder approval for the transaction, if at all; (ii) uncertainties as to the timing of the consummation of the proposed Merger and the ability of each of Talaris and Tourmaline to consummate the proposed Merger; (iii) risks related to Talaris’ ability to manage its operating expenses and its expenses associated with the proposed Merger pending closing; (iv) the risk that as a result of adjustments to the Exchange Ratio, Talaris shareholders and Tourmaline stockholders could own more or less of the combined company than is currently anticipated; (v) risks related to the market price of Talaris’ common stock relative to the value suggested by the Exchange Ratio; (vi) unexpected costs, charges or expenses resulting from the transaction; (vii) potential adverse reactions or changes to business relationships resulting from the announcement or completion of the proposed Merger; (viii) the uncertainties associated with Tourmaline’s platform technologies, as well as risks associated with the clinical development and regulatory approval of product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; (ix) risks related to the inability of the combined company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (x) uncertainties in obtaining successful clinical results for product candidates and unexpected costs that may result therefrom; (xi) risks associated with the possible failure to realize certain anticipated benefits of the proposed Merger, including with respect to future financial and operating results; (xii) risks associated with Talaris’ financial close process; (xiii) the risk that the pre-closing financing is not consummated; and (xiv) the risk that Talaris shareholders receive more or less of the cash dividend than is currently anticipated, among others. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section titled “Risk Factors” in Talaris’ Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC, and in other filings that Talaris makes and will make with the SEC in connection with the proposed Merger, including the Proxy Statement described below under “Additional Information and Where to Find It.” You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. Talaris expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based, except to the extent required by law. This Current Report on Form 8-K does not purport to summarize all of the conditions, risks and other attributes of an investment in Talaris or Tourmaline.

Participants in the Solicitation

This Current Report on Form 8-K and the exhibit filed or furnished herewith relate to the proposed Merger involving Talaris and Tourmaline and may be deemed to be solicitation material in respect of the proposed Merger. In connection with the proposed Merger, Talaris has filed relevant materials with the SEC, including a registration statement on Form S-4 (the "Form S-4") that contains a proxy statement (the "Proxy Statement") and prospectus. This Current Report on Form 8-K is not a substitute for the Form S-4, the Proxy Statement or for any other document that Talaris may file with the SEC and or send to Talaris' shareholders in connection with the proposed Merger. **BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS OF TALARIS ARE URGED TO READ THE FORM S-4, THE PROXY STATEMENT AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT TALARIS, THE PROPOSED MERGER TRANSACTION AND RELATED MATTERS.**

No Offer or Solicitation

This Current Report on Form 8-K and the exhibit furnished herewith do not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed Merger or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Additional Information and Where to Find It

Investors and security holders may obtain free copies of the Form S-4, the Proxy Statement and other documents filed by Talaris with the SEC through the website maintained by the SEC at <http://www.sec.gov>. Copies of the documents filed by Talaris with the SEC are also available free of charge on Talaris' website at www.talaristx.com, or by contacting Talaris' Investor Relations at investors@talaristx.com. Talaris, Tourmaline, and their respective directors and certain of their executive officers may be considered participants in the solicitation of proxies from Talaris' shareholders with respect to the proposed Merger under the rules of the SEC. Information about the directors and executive officers of Talaris is set forth in its Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 31, 2023, and in subsequent documents filed with the SEC. Additional information regarding the persons who may be deemed participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, are also included in the Form S-4, the Proxy Statement and other relevant materials to be filed with the SEC when they become available. You may obtain free copies of this document as described above.

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: October 6, 2023

By: /s/ Mary Kay Fenton
Mary Kay Fenton
Chief Financial Officer and Interim Chief Executive Officer and
President