Talaris Therapeutics Announces Third Quarter Financial Results and Corporate Update

November 10, 2022

Enrollment and dosing continue in the Phase 3 FREEDOM-1 trial of FCR001 in living donor kidney transplant (LDKT) patients

Two presentations at the 2022 American Society of Nephrology (ASN) Annual Meeting

Strong cash balance with expected runway through 2024

BOSTON and LOUISVILLE, Ky., Nov. 10, 2022 (GLOBE NEWSWIRE) -- 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 nine-month periods ended September 30, 2022 and provided an update on its business.

“Patient safety remains our top priority and we continue to maintain rigorous oversight of patients participating in our clinical trials,” stated Scott Requadt, Chief Executive Officer of Talaris. “Our Scientific Advisory Board and the FREEDOM-1 Data Monitoring Committee (DMC) have endorsed modifications to the FREEDOM-1 protocol that were triggered by the higher incidence of graft-versus-host disease (GvHD) that was reported in June 2022. Our investigators continue to remain committed to our programs and we continue to enroll patients in our FCR001 clinical studies.”

Corporate & Pipeline Highlights

- **Presented data on FCR001 at the 2022 American Society of Nephrology (ASN) Annual Meeting.** In November, the Company presented data on mRNA transcriptional changes following successful tolerization with FCR001. This urinary cell mRNA signature may help identify patients who could safely discontinue chronic immunosuppression. In addition, the Company reported data on the immune landscape of patients’ peripheral blood mononuclear cells (PBMCs) following treatment with FCR001 in a small cohort of patients enrolled in the Company’s Phase 3 FREEDOM-1 trial. The analysis found unique patterns of immune cell types, cell states, and transcriptional activity that may underlie FCR001’s mechanisms of inducing immune tolerance.

- **Expanded management team with the addition of Senior Vice President of Clinical Operations.** In October, the Company added a key executive to the Talaris clinical team. Courtney Wells brings over 20 years of clinical operations experience at several biotech companies including AveXis, Avadel Pharmaceuticals, and mostly recently at Jaguar Gene Therapy. Ms. Wells will oversee clinical operations including patient recruitment and trial management.

- **Three clinical trials continue enrollment.** Talaris continues to study its investigational product FCR001 in three clinical trials including FREEDOM-1, a Phase 3 clinical trial in LDKT patients, FREEDOM-2, a Phase 2 clinical trial in LDKT delayed tolerance induction, and FREEDOM-3, a Phase 2 clinical trial evaluating the safety and efficacy of FCR001 in adults with a severe form of scleroderma, a systemic autoimmune disease.

  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. The primary endpoint of FREEDOM-1 is the proportion of kidney transplant recipients treated with FCR001 who are free from chronic immunosuppression, without biopsy-proven acute rejection (BPAR), at month 24 post-transplant. The Company is enrolling and dosing patients in this trial. On October 20, 2022, the Company reported the death of a patient in the FREEDOM-1 clinical trial. In light of modifications to the study protocol that were already implemented in June 2022 to mitigate the risk of GvHD, the FREEDOM-1 DMC recommended the study may continue without further modifications.

Third Quarter Financial Results

- Cash, Cash Equivalents and Marketable Securities: Talaris finished the third quarter of 2022 with $193.9 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 $15.0 million in the third quarter of 2022, up from $9.2 million in the third 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 $4.8 million in the third quarter of 2022, up from $3.9 million in the third quarter of 2021, primarily due to an increase in employee headcount and increased professional fees.

- Net Loss: The Company reported a net loss of $19.0 million, or $0.46 per share, in the third quarter of 2022, compared with a net loss of $12.9 million, or $0.32 per share, in the third 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, 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; 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 therapeutics 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 third quarter ended on September 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 future safety and efficacy following the implementation of a protocol amendment in FREEDOM-1 and the Company's ability to successfully demonstrate the safety and efficacy of its drug candidates more generally; 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 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.

TALARIS THERAPEUTICS, INC (TALS)
Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended September 30,	
	2022	**2021**
Operating expenses		
Research and development	$ 14,981	$ 9,183
General and administrative	4,842	3,874
Total operating expenses	19,823	13,057
Loss from operations	(19,823)	(13,057)
Interest and other income (expense), net	812	116
Net loss	$ (19,011)	$ (12,941)
Net loss per common share, basic and diluted	$ (0.46)	$ (0.32)
Weighted average number of common shares outstanding used in computation of net loss per common share, basic and diluted	41,375,537	40,669,412

Balance Sheets Selected Financial Data
(Unaudited, in thousands)

	As of September 30,	As of December 31,

	2022	2021
Cash, cash equivalents and marketable securities	$ 193,869	$ 243,971
Working capital	188,959	238,527
Total assets	206,544	251,422
Other liabilities	2,509	626
Total liabilities	11,677	8,613
Total stockholders' equity	194,867	242,809

Media Contact
Lisa Raffensperger
Ten Bridge Communications
lisa@tenbridgecommunications.com
(617) 903-8783

Investor Contact
Chris Brinzey
ICR Westwicke
chris.brinzey@westwicke.com
(339) 970-2843