# TransCode Therapeutics Reports Second Quarter 2023 Results; Provides Business Update

August 14, 2023

BOSTON, Aug. 14, 2023 (GLOBE NEWSWIRE) -- TransCode Therapeutics, Inc. (NASDAQ: RNAZ), the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today reported financial results for the second quarter ended June 30, 2023, and recent business progress.

"We continued to advance our therapeutic programs during the second quarter with the primary focus on our lead therapeutic candidate, an RNA targeted therapy for treatment of metastatic disease," said Michael Dudley, co-founder, president and CEO of TransCode. "We are excited to dose our first patients in our planned Phase 0 clinical trial with TTX-MC138 in cancer patients with advanced solid tumors for which enrollment has commenced. In addition, we successfully closed a funding round of $7M through a registered direct offering in June."

"We continued to expand our delivery platform, adding the potential for delivery of nucleases to tumors as well as to proteins in the form of nanobodies," added Dudley. "We are currently working with potential strategic partners in certain of these therapeutic areas and are in discussions with others regarding other areas."

TransCode co-founder and Chief Technology Officer, Dr. Zdravka Medarova, commented, "With our First-in-Human study with TTX-MC138 beginning, and initiation of a Phase I trial planned soon after predicated on IND-enabling studies that are well on their way to completion, TransCode expects to achieve several major value-creating milestones within months."

**Recent Business Highlights**

- In June 2023, the Company entered into a Securities Purchase Agreement under which the Company sold 99,000 shares of common stock, 1,801,000 pre-funded warrants ("PFWs"), 2,000,000 Series A-1 Warrants to purchase common stock, and 2,000,000 Series A-2 Warrants to purchase common stock in a registered direct offering at a purchase price of $3.50 per share or PFW (the "June RDO"). The purchase of each share of common stock or PFW was accompanied by one Series A-1 warrant and one Series A-2 warrant. The Series A warrants are exercisable for three years at an exercise price of $3.25 per share. Net proceeds from the June RDO, after deducting fees payable to the placement agent and other offering expenses, were approximately $6.1 million.
- On April 27th, TransCode announced that it has received written approval from the Dana Farber Cancer Institute Institutional Review Board (IRB) to proceed with its First-in-Human (FIH) Phase 0 clinical trial. The planned clinical trial is to evaluate delivery of TransCode's lead therapeutic candidate, TTX-MC138, to metastatic lesions in up to 12 cancer patients with advanced solid tumors. TTX-MC138 is designed to inhibit the pro-metastatic RNA, microRNA-10b, described as the master regulator of metastasis in a number of advanced solid tumors. TransCode believes that TTX-MC138 could become a treatment for many of these cancers.
- In April and May, TransCode also sold an aggregate of 110,000 shares to White Lion Capital LLC under a stock purchase agreement. Gross proceeds before offering expenses from the White Lion transactions were approximately $538 thousand.

TransCode completed IND-enabling toxicity studies in two animal species to support an Investigational New Drug, or IND, application for Phase I/II clinical trials with TTX-MC138. No mortality or severe/unacceptable adverse events were observed even at the highest doses tested in the studies. TransCode's contract manufacturer is in the final phase of synthesis of GMP compliant TTX-MC138 drug product for use in the Phase I/II clinical trials planned to begin in the first half 2024.

In addition, TransCode plans to file an application for an SBIR Phase IIB award from the National Cancer Institute. If awarded, the current Fast-Track SBIR funding could be increased by up to $4.5 million over two years beginning in April 2024. The award is only available to prior recipients of an SBIR. There is no assurance that any additional funding will be awarded.

**Planned Milestones**

TransCode's goals to continue to advance its portfolio include:

- TTX-MC138
  - Completion of a FIH Phase 0 clinical trial intended to demonstrate quantifiable evidence of delivery of radiolabeled TTX-MC138 to metastatic lesions in advanced solid tumors; measure pharmacokinetics and biodistribution in vital organs and other tissues; potentially inform therapeutic dose levels for future trials based on Phase O microdose results; and potentially validate delivery for the TTX pipeline more broadly, which could open-up additional relevant RNA targets that have been previously undruggable due to challenges with RNA delivery.
  - Submission to FDA by year end 2023 of an IND application for its Phase I/II clinical trial.
  - Completion of preclinical *in vivo* studies supporting the lead therapeutic candidate, TTX-MC138, in pancreatic

cancer and glioblastoma multiforme.

- Publication of preclinical *in vivo* studies supporting therapeutic candidates, TTX-RIGA and TTX-siPDL1, as well as TTX-MC138 in pancreatic adenocarcinoma.
- Continuation of discussions with potential strategic partners regarding partnerships in multiple therapeutic areas.
- Filing for orphan drug designation for TTX-MC138 in additional tumor indications in the first half of 2024.

**Second Quarter 2022 Financial Highlights**

- Cash was $3.6 million at June 30, 2023, compared to $5.0 million at December 31, 2022.
- Research and development expense was $3.0 million in the second quarter of 2023, compared to $2.6 million in the second quarter of 2022.
- General and administrative expense was $2.2 million in the second quarter of 2023, compared to $2.1 million in the second quarter of 2022.
- Operating loss for the three months ended June 30, 2023, was $5.1 million, compared to an operating loss of $4.7 million in the prior year period.

**Financial Guidance**

TransCode expects that its cash of $3.6 million as of June 30, 2023, is sufficient to fund planned operations into September 2023 but not for a full 12 months from the date of its financial statements.

**About TransCode Therapeutics**

TransCode is an RNA oncology company created on the belief that cancer can be more effectively treated using RNA therapeutics. The Company has created a platform of drug candidates designed to target a variety of tumor types with the objective of significantly improving patient outcomes. The Company's lead therapeutic candidate, TTX-MC138, is focused on treating metastatic cancer, which is believed to cause approximately 90% of all cancer deaths totaling over nine million per year worldwide. The Company believes that TTX-MC138 has the potential to produce regression without recurrence in a range of cancers, including breast, pancreatic, ovarian and colon cancer, glioblastomas and others. One of the Company's other drug candidates, TTX-siPDL1, is an siRNA-based modulator of programmed death-ligand 1. TransCode also has three cancer-agnostic programs: TTX-RIGA, an RNA–based agonist of the retinoic acid-inducible gene I designed to drive an immune response in the tumor microenvironment; TTX-CRISPR, a CRISPR/Cas9–based therapy platform for the repair or elimination of cancer-causing genes inside tumor cells; and TTX-mRNA, an mRNA-based platform for the development of cancer vaccines designed to activate cytotoxic immune responses against tumor cells.

**Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements concerning expected clinical results of TransCode's therapeutic candidates, statements concerning the results of RNA research, statements concerning the potential for treating cancer with RNA therapeutics, statements concerning the timing and outcome of expected regulatory filings and clinical trials, including the planned First-in-Human study of TTX-MC138, statements concerning the timing and outcome of this study, including whether this study will demonstrate proof-of-mechanism, and statements concerning TransCode's development programs and TTX technology platform generally. Of note, a Phase 0 clinical trial is an exploratory study, conducted under an exploratory Investigational New Drug (eIND) application. Exploratory IND studies usually involve very limited human exposure to a therapeutic candidate to evaluate mechanism of action in order to inform potential clinical evaluation in future clinical studies, but otherwise have no therapeutic intent. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: risks associated with TransCode's financial condition and its need to obtain additional funding to support its business activities, including TransCode's ability to continue as a going concern; the risk associated with drug discovery and development; the risk that the results of our planned clinical trials will not be consistent with our pre-clinical studies or expectations; risks associated with the timing and outcome of TransCode's planned regulatory submissions; risks associated with TransCode's planned clinical trials for its product candidates; risks associated with obtaining, maintaining and protecting intellectual property; risks associated with TransCode's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risks associated with TransCode's dependence on third parties; and risks associated with the COVID-19 coronavirus. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause TransCode's actual results to differ from those contained in or implied by the forward-looking statements, see the section entitled "Risk Factors" in TransCode's Annual Report on Form 10-K for the year ended December 31, 2022, as well as discussions of potential risks, uncertainties and other important factors in any subsequent TransCode filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release; TransCode undertakes no duty to update this information unless required by law.

**For more information, please contact:**

TransCode Therapeutics, Inc.
Alan Freidman, VP Investor Relations
alan.freidman@transcodetherapeutics.com