TransCode Therapeutics Publishes Open Letter Outlining Company's Progress and Objectives

January 4, 2024

Despite Difficult Financial Markets, TransCode Raised New Capital and Initiated Its First Clinical Trial With Its Lead Therapeutic Candidate, A First-in-Class Compound Designed to Treat Metastatic Disease

BOSTON, Jan. 04, 2024 (GLOBE NEWSWIRE) -- **TransCode Therapeutics, Inc. ("TransCode" or the "Company") (NASDAQ: RNAZ)**, the RNA oncology company committed to more effectively treating cancer using RNA therapeutics, today announced publication of an open letter to shareholders outlining the Company's progress in 2023 and objectives in 2024. The text of the letter is below.

Dear Shareholders,

As we begin the new year, we reflect on the challenges faced by the biotech sector over the past two years. Despite those challenges, we have the pleasure to report on TransCode's progress and resilience and solicit your continued support.

Our commitment to defeating cancer remains steadfast. We are pleased to report continued progress in advancing our lead therapeutic candidate for patients with metastatic disease. Commencement of our first human clinical trial is a testament to the dedication of our team and their belief in our mission, and, as importantly, the promise of our science.

Raising capital in a highly challenging environment

The industry has experienced unprecedented challenges in obtaining the capital needed to advance development programs, exacerbated by a corresponding drop in market values. A large number of companies have had sizable lay-offs and reductions in operations; a significant number have closed completely. Many have had to make difficult decisions to survive. In this extraordinary economic environment, we have continued to weather these storms, securing approximately $18.5M in additional capital in 2023. While this capital was expensive, a sizable number of companies could not obtain new capital at any cost.

Prioritized Lead Therapeutic Development Program

The development program for our lead therapeutic candidate, TTX-MC138, continues to progress on regulatory and clinical development pathways.

We currently have an active eIND open with the FDA for our Phase 0 clinical trial in which radiolabeled TTX-MC138 may be administered to patients with advanced solid tumors. Initial data from the first patient in the trial showed that radiolabeled TTX-MC138 had pharmacokinetic behavior consistent with that expected based on earlier nonclinical IND-enabling studies. Data monitoring, analysis and enrollment are ongoing.

We plan to submit an IND to the FDA in the first quarter of 2024 to support a proposed Phase 1 clinical trial of TTX-MC138, also in patients with advanced solid tumors. Key GMP manufacturing activities are in process and IND-enabling toxicity studies in support of our IND submission have been completed.

Partnership Developments

Our ongoing conversations with industry leaders have generated increased awareness about the potential of our technologies. We are in partnership discussions with several pharma companies regarding development of several of our preclinical programs including TTX-mRNA, TTX-CRISPR, and TTX-siRNA. Initial collaborations would likely be proof-of-concept studies that could potentially lead to more significant development arrangements. We believe that these collaborations, if consummated, will expedite development of our targeted therapies through utilization of our proprietary delivery platform.

Streamlining of Operations

In response to the challenging financial landscape, we have taken decisive actions to reduce expenses without compromising our commitment to innovation and progress. We have reviewed company operations to identify areas in which we could delay or reduce expenditures including a reduction in headcount from 19 employees at the end of 2022 to 11 at the end of 2023. These steps are aimed at minimizing our cash burn and allowing us to focus substantially all our efforts into the timely initiation of a Phase I clinical trial for our lead compound, TTX-MC138.

In addition, we have implemented sizable temporary salary reductions for senior management to demonstrate our collective determination to navigate the current economic challenges while preserving the core of our organization.

Despite the headwinds, TransCode remains dedicated to innovation and collaboration.

Proposed Reverse Stock Split

Our board of directors has put a proposal before shareholders for a reverse stock split. We are not only managers of the company, but shareholders as well. A number of us worked with no cash compensation for lengthy periods prior to our IPO – something rarely, if ever, seen in biotech. Our compensation came in the form of shares of stock, so we are acutely aware of the pain that can result from reverse splits. Our reason for requesting your approval of the reverse stock split is that, based on discussions with investment bankers, our ability to raise the additional capital needed to continue funding our business plan drastically improves with a share price that is multiples above current levels. Further, capital is needed very soon as we have until January 22, 2024, to demonstrate to Nasdaq that we are on-track with our plan to regain and sustain compliance with its stockholders' equity requirement. We believe that the reverse split is essential to enabling us to achieve this objective.

It has been suggested that we seek nondilutive funding (instead of issuing new equity) – we have and we are. We have submitted applications for nondilutive government funding and are awaiting funding decisions. We are also pursuing partnering opportunities as described above. The challenge with nondilutive funding, however, is that TransCode does not control either the decision about whether such funding will be made available, nor the timing of such funding. This applies both to government grants as well as to potential collaboration arrangements with potential strategic partners.

We assure you that we do everything we possibly can to minimize the cost of obtaining the new capital needed both for company operations and to have our shares continue to trade on Nasdaq. We are streamlining operations to extend our cash runway and ensure effective use of our funds to reach our most significant and potentially valuable milestones, including further clinical development progress with our lead therapeutic candidate.

We respectfully request that you vote in favor of the reverse split proposal. If you have already voted, it is not too late to change your vote should you wish to do so. If you have any questions or need help voting, please call our proxy solicitor, Saratoga Proxy Consulting LLC, at (888) 368-0379.

Summary

We extend our heartfelt gratitude for your continued investment in TransCode. Your trust and support empower us to face challenges head-on and drive us toward a future where our innovative therapies make a meaningful impact on the lives of cancer patients. We eagerly look forward to sharing further updates on our progress in the coming months and remain optimistic about the promising future that lies ahead.

Thank you for being an essential part of our journey.

Sincerely,

Philippe Calais, PharmD, PhD	R. Michael Dudley
Executive Chairman	Chief Executive Officer and Co-Founder

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 currently-open 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, statements concerning TransCode’s development programs and TTX technology platform generally, and statements concerning TransCode’s need for additional capital. 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: 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 financial condition and its need to obtain additional funding to support its business activities, including TransCode’s ability to continue as a going concern; 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:

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