Coeptis Therapeutics President and CEO Issues Letter to Shareholders Highlighting 2023 Accomplishments and Outlook for 2024

written by Raj Shah | January 4, 2024
January 4, 2024 (Source) – Coeptis Therapeutics Holdings, Inc. (NASDAQ: COEP) (the "Company" or "Coeptis"), a biopharmaceutical company developing innovative cell therapy platforms for cancer, today announced that Dave Mehalick, President and CEO of Coeptis Therapeutics Holdings, has issued a Letter to Shareholders providing a review of its 2023 achievements and anticipated milestones for 2024. The full text of the letter follows.

A MESSAGE FROM OUR PRESIDENT AND CHIEF EXECUTIVE OFFICER

To my fellow shareholders,

2023 was nothing short of transformative for Coeptis with the highlight of the year being the exclusive licensing agreement with Deverra Therapeutics Inc. With this single transaction, we gained access to a proprietary allogeneic stem cell expansion and directed differentiation platform, a clinical-stage, unmodified natural killer (NK) cell therapy, DVX201, and a team of visionary scientists led by Colleen Delaney, MD, MSc, who joined Coeptis as our Chief Scientific and Medical Officer.

Since completing the agreement in August, we have been working diligently with Dr. Delaney and her team to advance the DVX201 clinical programs, while integrating SNAP-CAR, our universal,

multi-antigen CAR technology that we licensed from the University of Pittsburgh into the Deverra allogeneic immune effector cell generation platform. Our strategy is to leverage these innovative and complementary platforms to develop powerful, personalized cell-based treatments to improve outcomes for patients with cancer. Importantly, these cell-based therapies are universal products enabling greater patient access to these medical breakthroughs. It is a bold vision, and I believe we now have under one roof the technological assets and scientific expertise to fully pursue the opportunity. As we look to 2024, we see enormous potential to advance our pipeline and achieve meaningful growth milestones.

DVX201 – Rapidly Advancing Clinical Programs; Expected, Near-Term Milestones

DVX201 is a first-ever allogeneic, cord-blood derived NK cell therapy generated from pooled donor CD34+ hematopoietic stem and progenitor cells (HSPC) cells. This product is being investigated in two Phase 1 clinical trials for the treatment of relapsed/refractory acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS) and patients hospitalized with COVID-19 infection. Interim data from both trials involving 17 patients and 25 infusions of DVX201 indicated that the NK cell therapy is well-tolerated with no dose limiting toxicities (DLTs), and with no cytokine release syndrome (CRS) or infusion toxicities observed thus far through the highest dose level.

Drilling down further, the Phase 1 clinical trial investigating DVX201 in patients with hospitalized COVID-19 infection completed the three dosing cohorts, enrolling a total of nine patients each receiving a single infusion. DVX201 was tolerated at all dosing levels, an important observation for this first-in-human allogeneic cell therapy derived from pooled donor manufacturing. Based on these favorable results, Coeptis plans

to pursue a Phase 2 clinical program investigating DVX201 as an anti-viral therapy in high-risk patients hospitalized with viral respiratory infections, allowing us to expand beyond COVID-19 related infection and into a substantially larger patient population.

Meanwhile, the Phase 1 trial investigating DVX201 in relapsed/refractory AML or high-risk MDS has now safely dosed a total of eight subjects each receiving two infusions. The trial is expected to enroll two additional patients who will be infused at the highest dosing level, with completion of dosing expected to occur in Q1 2024. This timeline is also expected to enable us to report topline safety and efficacy data from the full patient population in the first half of 2024.

An Emerging Leader in Natural Killer Cell Therapy

Our DVX201 programs represent an important value driver for Coeptis, but we believe they are the tip of the iceberg considering our expectations regarding the greater potential of our assembled technologies. The assets from Deverra along with SNAP-CAR out of the University of Pittsburgh and the GEAR platform developed at the Karolinska Institute provide Coeptis with a foundation for us to pursue one of our primary goals, which is to change the paradigm of how engineered allogeneic NK and other immune effector cell therapies are developed and administered.

CAR-T cell therapies have been transformative and curative for some, however challenges with starting material, costs and accessibility continue to persist. NK cell therapies, on the other hand, offer several key advantages compared to CAR-T. For example, NK cells have been shown to be able to target cancer through multiple broadly expressed activating ligands and can be used allogeneically without the risk of graft versus host

disease (GVHD) and cytokine release syndrome (CRS) that is associated with T cell therapies.

Coeptis sees significant potential to integrate our technology platforms to develop next-generation therapies for cancer. The team at Deverra has pioneered advances in donor selection and manufacturing approaches, including pooled donor approaches, that have made it possible to generate significant numbers of unmodified NK cells reproducibly and at scale with minimal lot to lot variability and with low cost of goods, addressing major hurdles in the allogeneic cell therapy development space. These generated unmodified NK cells can also be engineered to vastly enhance the accessibility, versatility and potential enhanced efficacy of NK cell derived therapies for a host of cancers and infectious diseases.

Research is underway at Coeptis to bring together Deverra's novel stem cell expansion and differentiation technology, which we have accessed through our exclusive license deal with Deverra, with our existing SNAP-CAR and GEAR technologies. Importantly, in October 2023 and with this strategy in mind, we expanded our licensing agreement with the University of Pittsburgh to include SNAP-CAR NK, adding a third NK-focused technology to Coeptis' development portfolio.

SNAP-CAR, combined with Deverra's proprietary allogeneic stem cell expansion and differentiation platform for the generation of NK cells from pooled donor cord blood CD34+ cells, has us focused on continued development efforts towards a first-in-class fully universal (no HLA matching and antigen agnostic) targeted cell therapy. Our vision is that the combination of technologies offers Coeptis the opportunity to develop cell therapies that can be engineered with off-the-shelf convenience and can target multiple antigens simultaneously while also offering greater control over toxicity.

In what I believe to be an extremely informative and visionary talk, Dr. Delaney previewed this vision at the 2023 Cell & Gene Meeting on the Mesa, which is one of the most prestigious conferences in cell therapy industry. I encourage all shareholders to view this video. Interest during her presentation and in one-on-one meetings was exceptionally strong, and we are eager to build on the momentum in 2024.

For our shareholders…
This is a very exciting time in the growth and evolution of Coeptis Therapeutics, and we are working diligently to advance our assets to become a leader in the development of next-generation cell therapy technologies for cancer and infectious diseases. I would like to thank our employees for their dedication and loyalty, and our shareholders for their ongoing support as we pursue our vision to become a leader in the cell therapy industry.

On behalf of the entire Coeptis team, I wish you all a happy and healthy 2024.

Best Regards,

Dave Mehalick
President and CEO
Coeptis Therapeutics Holdings, Inc.

About Coeptis Therapeutics Holdings, Inc.

Coeptis Therapeutics Holdings, Inc., together with its subsidiaries including Coeptis Therapeutics, Inc. and Coeptis Pharmaceuticals, Inc., (collectively “Coeptis”), is a biopharmaceutical company developing innovative cell therapy platforms for cancer and infectious diseases that have the potential to disrupt conventional treatment paradigms and improve patient outcomes. Coeptis’ product portfolio and rights

are highlighted by assets licensed from Deverra Therapeutics, including an allogeneic cellular immunotherapy platform and DVX201, a clinical-stage, unmodified natural killer cell therapy technology. Additionally, Coeptis is developing a universal, multi-antigen CAR T technology licensed from the University of Pittsburgh (SNAP-CAR), and the GEAR™ cell therapy and companion diagnostic platforms, which Coeptis is developing with VyGen-Bio and leading medical researchers at the Karolinska Institutet. Coeptis' business model is designed around maximizing the value of its current product portfolio and rights through in-license agreements, out-license agreements and co-development relationships, as well as entering into strategic partnerships to expand its product rights and offerings, specifically those targeting cancer. The Company is headquartered in Wexford, PA. For more information on Coeptis visit https://coeptistx.com/.

Cautionary Note Regarding Forward-Looking Statements

This press release and statements of our management made in connection therewith contain or may contain "forward-looking statements" (as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended). Forward-looking statements include statements concerning our plans, objectives, goals, strategies, future events or performance, and underlying assumptions, and other statements that are other than statements of historical facts. When we use words such as "may," "will," "intend," "should," "believe," "expect," "anticipate," "project," "estimate" or similar expressions that do not relate solely to historical matters, we are making forward-looking statements. Forward-looking statements are not a guarantee of future performance and involve significant risks and uncertainties that may cause the actual results to differ materially and perhaps substantially from our expectations discussed in the forward-looking statements. Factors that may cause such differences

include but are not limited to: (1) the inability to maintain the listing of the Company's securities on the Nasdaq Capital Market; (2) the risk that the integration of the Deverra licensed assets will disrupt current plans and operations of the Company; (3) the inability to recognize the anticipated benefits of the newly-licensed assets, which may be affected by, among other things, competition, the ability of the Company to grow and manage growth economically and hire and retain key employees; (4) the risks that the Company's products in development or the newly-licensed assets fail clinical trials or are not approved by the U.S. Food and Drug Administration or other applicable regulatory authorities; (5) costs related to integrating the newly-licensed Deverra assets and pursuing the contemplated asset development paths; (6) changes in applicable laws or regulations; (7) the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors; and (8) the impact of the global COVID-19 pandemic on any of the foregoing risks and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission (the "SEC"). The foregoing list of factors is not exclusive. All forward-looking statements are subject to significant uncertainties and risks including, but not limited, to those risks contained or to be contained in reports and other filings filed by the Company with the SEC. For these reasons, among others, investors are cautioned not to place undue reliance upon any forward-looking statements in this press release. Additional factors are discussed in the Company's filings made or to be made with the SEC, which are available for review at www.sec.gov. We undertake no obligation to publicly revise these forward-looking statements to reflect events or circumstances that arise after the date hereof unless required by applicable laws, regulations, or rules.

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