Coeptis Therapeutics Chief Executive Officer, Dave Mehalick, Updates and Outlines Strategic Vision in Letter to Shareholders

written by Raj Shah | September 5, 2024

September 05, 2024 (Source) – Coeptis Therapeutics Holdings, Inc. (Nasdaq: COEP) (the "Company" or "Coeptis"), a biopharmaceutical company developing innovative cell therapy platforms for cancer, autoimmune, and infectious diseases, today issued a shareholder letter from its Chief Executive Officer Dave Mehalick.

Dear Coeptis Therapeutics Shareholders,

As summer comes to a close, I am pleased to share with you the latest updates and accomplishments at Coeptis Therapeutics. For the scientific and medical community, there's growing awareness, education, and acceptance for what we are achieving with our proprietary technology platform. Internally, our dedication to affecting a paradigm-shifting treatment in oncology remains stronger, more focused, and impactful as ever, with the goal of improving patient outcomes.

OUR MISSION REMAINS STEADFAST

While cell therapy is still in its early stages compared to other medical sciences, traditional autologous treatments—using

a patient’s own cells— are extremely expensive and therefore are inaccessible to many parts of the population.

At Coeptis, we’re committed to making cell therapies safe, effective, and accessible to everyone. Our focus is on allogeneic therapies, which involve creating off-the-shelf cell therapies for universal use, thereby transforming the future of cell therapy by significantly reducing treatment costs.

With the completion of our agreement with Deverra Therapeutics a year ago, Coeptis Therapeutics now owns three proprietary, innovative cell therapy platforms targeting cancer, autoimmune, and infectious diseases. These are a proprietary allogeneic NK (natural killer) cell generation platform from Deverra, the universal SNAP CAR platform from the University of Pittsburgh, and the GEAR (gene-edited antibody-resistant) engineered cell therapy platform from Karolinska Institutet.

Our clinical-phase asset, DVX201, is the first-ever allogeneic, cord-blood derived NK cell therapy generated from pooled donor CD34+ hematopoietic stem and progenitor cells (HSPC) cells. Utilizing this NK cell therapy in Phase 1 clinical trials has indicated that it is well tolerated, with no dose limiting toxicities (DLTs). We are currently preparing next steps with this exciting asset, including selecting the suitable patient population for the upcoming phase of clinical development.

Between the integration of NK cell therapies and 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, Coeptis is poised and actively working toward becoming a leader in a much-needed therapy field.

RECENT UPDATES

Despite navigating a challenging market environment, we successfully raised capital to further advance our efforts in pioneering groundbreaking treatments in cell therapy. In June, we achieved an initial closing of $4.3 million in our Series A preferred stock offering, priced at a premium to the market, and subsequently raised an additional $1.3 million in July. This financing round, led by CJC Investment Trust, demonstrates strong investor confidence in our vision and capabilities but also highlights the viability and potential of our initiative. The commitment of our investors, including significant participation from board member Christopher Calise, not only strengthens our balance sheet but also bolsters our innovative cell therapy platforms and long-term growth prospects. Under the terms of this financing, the Series A preferred stock is convertible into common stock at a price of $0.40 per share, subject to certain conditions. Additionally, investors have received an 8.40% equity interest in our newly formed subsidiaries, SNAP Biosciences Inc. and GEAR Therapeutics Inc., that demonstrates the inherent value and potential of our innovative approaches in the cell therapy landscape.

STRATEGIC PARTNERSHIPS CONTINUE TO SPEARHEAD GROWTH

Our commitment to scientific advancement through strategic partnerships continues to yield promising results. Our sponsored research agreement with the Lohmueller and Dieters labs at the University of Pittsburgh has led to significant new findings, including further characterization of the adaptor chemistry, expanding to new antibody adaptors, and performing studies with multi-antigen targeting. Meanwhile, our collaboration with the research team at Deverra has successfully extended the application of the SNAP-CAR technology to NK cells, building on prior achievements with T-cells.

These developments were highlighted at two prominent

conferences, where they sparked considerable interest. We remain focused on further optimizing transduction and cell engineering processes and are actively planning future in vivo studies to continue driving innovation in this critical area.

Earlier this year we also expanded our exclusive license agreement with the University of Pittsburgh to include autoimmune indications for the SNAP-CAR T and SNAP-CAR NK platforms, leveraging the unique abilities to target multiple antigens and autoreactive B cells.

RECENT MILESTONES

Our Phase 1 clinical trial for the treatment of COVID-19-related viral infections and enrollment in our Phase 1 clinical trial for r/r AML & High Risk MDS have been completed.

We are pleased to announce the completion of our Phase 1 clinical trial for the treatment of COVID-19-related viral infections and the successful enrollment in our Phase 1 clinical trial for relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome (HR-MDS). Our DVX201 platform, which uses natural immune cells (NK) derived from donated cord blood stem cells, is designed to target both serious viral infections, such as COVID-19, influenza, and respiratory syncytial virus (RSV), and oncological conditions like AML. This unique approach utilizes healthy immune cells to potentially enhance the body’s ability to combat serious viral infections that can lead to hospitalization, especially during “tripledemic” seasons, by directly infusing NK cells.

Since this is a groundbreaking treatment, our priority is ensuring its safety as we test its ability to treat severe viral infections. With over 20 years of safety data backing the use of cord blood cells, and having combined multiple donations to increase effectiveness, we have administered DVX201 to patients

at escalating doses up to nearly 1 billion NK cells, with no observed cytokine release syndrome or infusion toxicities, even at the highest dose. For context, the body normally has around two billion NK cells at any given moment.

As we move forward from Phase 1 trials for COVID-19 and AML/MDS, we will be progressing the clinical development following study closeout, top-line data analysis, and completion of potential, supportive ancillary in-vitro studies.

COEPTIS EXPANDING VISIBILITY AND AWARENESS

To expand our visibility and awareness in both the capital markets and the medical industry, we have actively participated in several key conferences and meetings during the first half of this year.

Allogeneic Cell Therapies Summit 6th Annual Meeting

- In June of this year, our chief scientific and medical officer, Dr. Colleen Delaney, delivered two seminars at the 6th Annual Allogeneic Cell Therapies Summit.
- The Summit, which gathers leaders within the scientific community, provided an excellent platform to educate peers on Coeptis's progress, particularly in integrating the cell generation platform with universal SNAP-CAR technology to reshape the cancer treatment market.

Oral Presentation at ISCT 2024

- We were selected for an oral presentation titled "Developing a First-in-Class Universal Allogeneic SNAP-CAR NK Cell Therapy" at the International Society for Cell & Gene Therapy (ISCT) 2024.
- The presentation highlighted the SNAP-CAR platform

technology, which has shown potential as a “universal” CAR therapy targeting multiple antigens while potentially avoiding toxicities and relapse due to antigen loss.

- Supported by research from the University of Pittsburgh and Deverra Therapeutics, our allogeneic CAR NK cells offer a safer, more accessible, and cost-effective alternative to autologous CAR T-cells. Building on the successful use of SNAP-CAR technology in T-cells, we are developing a universal allogeneic SNAP-CAR NK cell. This innovation replaces the antigen-binding domain of a CAR with a SNAP tag enzyme, enabling the attachment of any antibody with a BG tag to create a targeted, functional CAR.
- Our presentation represents a significant and meaningful path forward in advancing our mission to develop a proprietary, allogeneic cell generation platform aimed at universalizing the treatment of many debilitating diseases.

2024 American Society of Gene and Cell Therapy (ASGCT) Annual Meeting

- Our abstract on the development of SNAP-CAR NK cells was featured as a poster presentation at the ASGCT.
- The data presented focused on the potential of the SNAP-CAR NK platform to target multiple antigens, with the aim of addressing a wide range of cancers.
- We are pioneering a first-in-class fully universal targeted cell therapy by combining a highly scalable and cost-effective cell generation platform with universal SNAP-CAR technology. The integration of these two platforms has the potential to revolutionize cancer treatment by offering fully universal, antigen-agnostic targeted cell therapies, without the need for HLA

matching.

Cord Blood Association (CBA)

- We are participating in the Cord Blood Connect Conference in September 2024.
- CBA helps raise awareness and advocates for the safe use of cord blood to benefit patients and advance medicine.

UPDATE ON NASDAQ LISTING

On July 30, we received a delisting determination letter from Nasdaq indicating that we have not regained compliance with the Minimum Bid Price Requirement. We have requested an appeal of Nasdaq's decision, and a hearing before the Panel is scheduled for September 12. According to Nasdaq Listing Rule 5815(a)(1)(B), our request for a hearing has temporarily stayed the suspension of trading and the delisting of our Common Stock, which will remain listed on the Nasdaq Capital Market at least until the Panel issues a decision following the hearing. We are actively exploring all available options to regain compliance and to maintain our listing on the Nasdaq Capital Market. As such, we will continue to keep you informed as we evaluate the best options available for enhancing the value for our shareholders.

To summarize, our key catalysts over the next few quarters include:

- Publication of Phase 1 results for DVX201 trial in hospitalized COVID-19 patients; currently under peer review.
- Phase 1 study for AML and high-risk MDS has concluded; top-line data expected soon.

- Preclinical and proof-of-concept results anticipated; initiating scale-up of manufacturing for SNAP-CAR adaptors.
- Selecting a new manufacturing partner capable of late-stage and commercial production for DVX-201
- Development of a robust Quality System that supports current clinical operations and future outsourced GMP activities.

As we reflect on our recent accomplishments, I am filled with both pride and excitement. The progress we've made—ranging from our imminent Phase 1 results for the DVX201 trial to the successful completion of our AML and high-risk MDS study—represents a significant stride forward in our mission. Our ongoing advancements in the SNAP-CAR allogeneic cell program and the strategic steps we're taking with our manufacturing processes further underscore our commitment to innovation and excellence.

Looking ahead, I am optimistic about the opportunities that lie before us. We are well-positioned for a future filled with potential. These efforts, along with other initiatives we are pursuing, will position Coeptis to expand our valuation and enhance shareholder value. We remain committed to delivering on our mission and look forward to sharing more exciting updates on our progress with you soon. Thank you for your unwavering support as we move forward into an exciting new phase of growth.

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, autoimmune, 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 and infectious diseases. 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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