

## Breakthrough Testing with Nvidia AI Chips, Cyclomics and GEDICube; Early Cancer Detection: Renovaro: NASDAQ: RENB

Breakthrough Testing with Nvidia Al Chips: Renovaro Biosciences Inc. (Nasdaq: RENB)

LOS ANGELES , CALIFORNIA, UNITED STATES , February 22, 2024 /EINPresswire.com/ -- Breakthrough Testing with Nvidia AI Chips Emerging from Cyclomics Acquisition and GEDICube; Early Cancer Detection: Renovaro Biosciences Inc. (Nasdaq: <u>RENB</u>)



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We are committed to early cancer detection, intervening at a stage where treatment can be most effective."

RENB CEO, The Hon. Mark Dybul, MD For more information on this Exciting NASDAQ Company: RENB visit: <u>http://www.renovarobio.com</u> and <u>https://axecapitalusa.com/renb/</u>

Developing Cell, Gene & Immunotherapy Platforms to Renew Natural Tumor-Fighting Capabilities Against Cancer and Infectious Diseases.

Partnership with NVIDIA to Utilize Advanced Artificial Intelligence (AI) Chips.

Proprietary AI Platform Aims to Commercial Products to Support Clinical, Research and Pharmaceutical Organizations.

RENB Will Acquire 75% of Cyclomics with 4th Generation Liquid Biopsy Genomics Platform "Omni-Omic" Blood Test Ready for AI Application. Cyclomics' 4th generation liquid biopsy genomics platform is the first truly "Omni-Omic" blood test ready for Al application.

Achieving in Pre-Clinical Studies what Dr. Anahid Jewett, a Top Oncological Immunology Scientist at UCLA Calls "The Holy Grail of Cancer Research."

Finalized Clinical Protocol and Identified Principal Investigator from Department UCLA to Conduct First-In-Human Studies Projected for The End of 2024.

Renovaro Biosciences, <u>Inc (Nasdaq:</u> <u>RENB)</u> has developed advanced cell, gene, and immunotherapy platforms designed to renew the body's natural tumor-fighting capabilities against cancer and infectious diseases.

RENB is harnessing the power of genetic expression and gene therapy. The RENB AI platform finds correlations between genes and their expression. RENB gene therapy has the potential to teach the patient's immune system to recognize their cancer and destroy it. RENB will have the ability to inform and design clinical trials with insights from the deep learning of NVIDIA Partnered GEDiCube. RENB expects to make adjustments for their upcoming human clinical trials and test them insilico.

RENB Owned AI Company GEDiCube and Cyclomics Sign Binding LOI to Join



## \$RENB AI Healthcare

Integrated Oncology Company



Renovaro Biosciences

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## **\$RENB Strategic Partners**

Forces and Position Themselves in The Global Liquid Biopsy Marketplace

On February 15th RENB wholly owned subsidiary GEDiCube (moving forward RenovaroCube), a London and Netherlands-based advanced AI company and a wholly announced it has executed a binding Letter of Intent (LOI) to acquire 75% of Cyclomics.

Cyclomics is a Dutch company founded in 2018, winner of the Health Holland Venture Challenge (startup of the year) by scientists of the UMC Utrecht. Its ambition is to transform cancer care by enabling faster and more reliable diagnoses, particularly in the context of cancer recurrence, thanks to its proprietary circulating tumor DNA (ctDNA) detection technology. See the company website at: <u>https://www.cyclomics.com</u>.

Cyclomics has developed a groundbreaking diagnostic method for monitoring early cancer recurrence named "CyclomicsSeq"- a novel ctDNA (circulating tumor DNA is tumor-derived fragmented DNA in the bloodstream that is not associated with cells) detection assay based on Oxford Nanopore sequencing which delivers fast, low-cost, and point-of-care sequencing. In contrast to available ctDNA-based methods, "CyclomicsSeq" ensures that even a single ctDNA molecule in the blood can be detected at very high accuracy. This solution consists of a new diagnostic kit (CyclomicsSeq), which has been licensed to Oxford Nanopore (LON: ONT), an RNA/DNA next-generation sequencing platform company.

Cyclomics' Omni-Omic 4th generation technology can disrupt the cancer diagnostics market and clinical practice by enabling fast and reliable results and delivering superior performance to standard radiological and physical examination alone. The platform enables reliable, fast, and ultra-sensitive early/ recurrence detection of cancer using the next-generation whole genome sequencing. That is achieved by detecting ctDNA, a reliable biomarker for determining the presence or absence of cancer, which can be non-invasively obtained from a blood sample (liquid biopsy). The novel approach to cancer detection is based on a single vial of blood and multi-dimensional profiling. Cyclomics applies a wide multi-signal/ multi-omics approach to a very low amount of tumor ctDNA. The Omni-Omic approach is critical for early cancer detection with high accuracy.

Cyclomics has already developed an early detection technology called "CyclomicsSeq TP53", an in vitro diagnostic (IVD) kit integrating an innovative sequencing methodology and state-of-the-art analysis software. Ninety percent of Head Neck Cancer (HNC) patients carry specific oncogenic DNA mutations in the gene TP53. There are 150,000 new cases every year in the EU and nearly 70,000 in the USA. The Cyclomics solution can be applied to other cancer types harboring TP53, such as small-cell lung cancer, squamous cell lung cancer, triple-negative breast cancer, and high-grade serous ovarian cancer, and can be expanded to almost all cancer types.

RENB is committed to the early detection of cancer, to intervene at a stage where treatment can be most effective. With its award-winning AI Technology high, performing biomarker panels for 13 frequently occurring cancer types have been discovered. The technology also significantly accelerates their development and validation into diagnostic products through in-silico validation, saving valuable development time and money. The focus is on early cancer- and early recurrence detection, prediction of response to therapy, and personalized treatment, all via liquid biopsy tests. Our platform, RENB brings together proprietary artificial intelligence (AI/ML) technology and algorithms, multi-omics, multi-modal data, and the expertise of a carefully selected multidisciplinary team.

The RENB platform technology deploys next-generation AI running on NVIDIA's latest chips and stacks genetic and protein expression on top of DNA mutation for accuracy in cancer detection. RENB is focused on developing advanced diagnostic and monitoring tests that use multi-omics, integrating data from each stage of genetic expression, including genomics, epigenomics, transcriptomics, proteomics, fragmentomics, and metabolomics. As a member of the Nvidia Inception Program, RENB will integrate medical imaging into its AI engine.

Message from RENB CEO, The Hon. Mark Dybul, MD

Accelerating Healthcare With Award-Winning AI: Big Steps Forward In 2023 And The Early Days Of 2024

On January 16th RENB CEO Mark Dybul, MD issued a letter to shareholders which included the following commentary.

RENB moves from an exciting 2023, highlighted by:

Signing a definitive agreement to combine with the European-based, cutting-edge AI company GEDi Cube. GEDi Cube signed a partnership with NVIDIA to expand its multi-omic capabilities to multi-modal and has progressed toward commercialization of liquid biopsy test kits in 2024.

RENB is consistently achieving in pre-clinical studies what Dr. Anahid Jewett, an oncological immunology scientist at UCLA, recently named among the top 3% of researchers in the world by Stanford University, calls "The holy grail of cancer research."

2024 is off to a promising start:

RENB filed its definitive proxy statement for its shareholder meeting scheduled for January 25, 2024, in order to vote on matters related to the combination with GEDi Cube.

GEDi Cube has Promising AI advancements toward commercialization in 2024

In addition, since the last CEO letter, RENB has been advised by GEDi Cube that its team has substantially accelerated its multi-omic health technology while aggressively pursuing key partnerships to contribute to the commercialization of potential products and lay a solid foundation for a client base for rapid uptake when products become available. In that regard, the GEDi Cube became a formal Inception Partner of NVIDIA. This partnership gives GEDi access to their resources for infrastructure and scaling, and specific advice and guidance from their Inception Team to progress towards moving from a multi-omic to a multi-modal approach by incorporating imaging technology.

GEDi Cube also informed RENB that it aims to utilize its proprietary AI platform in the development of commercial products to support clinical, research, and pharmaceutical organizations that are trying to improve patient care through precision diagnosis, prediction of success of therapy, new drug discovery, treatment protocols, or clinical trials. Specifically, GEDi Cube specializes in developing products and services aimed at (i) early cancer characterization, (ii) personalized treatment selection, (iii) prediction and tracking response to therapies, (iv) recurrence detection and efficacy monitoring, and (v) ultimately, drug discovery.

RENB reports that GEDI Cube has progressed its efforts with a three-phase workflow for its AI platform for biomarker discovery.

Phase I of the workflow behind GEDi Cube's AI platform primarily centers on the pivotal process of biomarker discovery. This intricate procedure unfolds through the application of data mining algorithms and statistical methodologies integrated into the AI platform. The paramount objective of Phase I is to reduce the plethora of genomic features displaying variations across samples, which is accomplished by systematically eliminating extraneous or inconsequential features while preserving those features that exhibit the greatest potential for accurately detecting cancer.

Phase II of the workflow builds upon the foundation of selected biomarkers by focusing on understanding the dynamic interplay among these chosen biomarkers, culminating in the creation of composite panels. The goal of Phase II is to pinpoint biomarker combinations that not only demonstrate robustness in detecting cancer but also maintain their efficacy across diverse contexts. GEDi Cube believes that its AI algorithms are adept at uncovering multiple combinations across a spectrum of panels, which is supported by GEDi Cube's AI-guided panel mining, a proprietary combinatorial optimization technique used by GEDi Cube's AI technology.

This approach, coupled with the capacity to explore numerous panels, significantly enhances the likelihood of discovering panels that align with specific metric criteria, such as sensitivity, specificity, precision, and recall, and allows for tailoring criteria to align with the client's unique needs, such as the number of biomarkers included per panel or the inclusion of biomarkers associated with the expression of specific genes. The performance of the top-tier panels is further fine-tuned through the application of machine learning models. Subsequently, the efficacy of these biomarker panels in detecting cancer is validated through independent data sets.

Phase III of the workflow involves GEDi Cube's collaboration with its clinical partners to validate

the performance of the biomarker panels. Through this collaboration, GEDi Cube is able to confirm the utility and accuracy of its biomarker panels in real-world clinical contexts.

The GEDi Cube and RENB teams have been actively planning for a potential multiplier effect through the combined companies. RENB and GEDi Cube have jointly engaged to design clinical studies that will collect blood and biopsy samples from leading cancer centers in the USA and Holland to help accelerate the potential commercialization of AI-powered products.

Advancing a Cancer Vaccine Toward Studies in Humans

RENB has expanded the pre-clinical validation of the effectiveness of the cancer vaccine RENB-DC11. Dr. Jewett dubbed the results "the holy grail of cancer research" based on the highly reproducible results obtained in 4 experiments of pancreatic cancer in humanized mice conducted by UCLA, including:

Rapid and significant tumor regression: an 80-90% decrease in tumor size; Effective tumor infiltration: significant infiltration of the tumor sack by effector immune cells, indicating ongoing killing of cancer cells;

Immune Cell activation predicted by the anticipated mechanism of action: significant increases in the blood of effector immune cells and key markers of cancer-killing immune activation, and; Aggressive cancer progression inhibition: no metastases.

Recently, a leading contract research organization conducted an additional animal study that was designed to examine the effects of RENB-DC11 in a more advanced stage of pancreatic cancer. In the treated group, there were no metastases, and there was a significant reduction in tumor size – down to an undetectable level. Compared with previous studies, half the dose and a non-matched pancreas tumor line lysate, rather than matching it to the specific cancer tissue biopsy, were used.

In addition, Dr. Jewett conducted a preliminary study in liver cancer with promising results, showing a reduction in cancer progression, including metastases, and apparently improved survival in mice treated with the vaccine compared to the untreated group of animals.

The results are encouraging and consistent with the strong response observed in all previous studies. In addition, RENB has made substantial progress toward manufacturing clinical-grade material under Good Manufacturing Processes (GMP), enabling both safety and toxicity studies required for the filing of an Investigational New Drug (IND) application to initiate clinical trials.

Finally, RENB finalized the design of the clinical protocol and identified the principal investigator from the Department of Oncology at UCLA to conduct the first-in-human studies, which is projected to be at the end of 2024. Because RENB Senior Vice President for Clinical Operations has 32 years of experience at Pfizer, including creating and leading teams that managed human trials of cancer cell and gene therapies, RENB will retain complete control of the study with subcontractors who have already been identified rather than outsourcing to a Clinical Research Organization. This should help ensure the combined Phase 1 and 2 trial's quality and speed and reduce the estimated cost by 50%.

Link to the deep-dive slide deck on the cancer platform: <u>https://renovarobio.com/events-and-presentations/default.aspx</u>

Structured for Success

The structure envisioned for the combined Company is a Topco, for which Dr. Mark Dybul would serve as CEO, and two subsidiaries – Renovaro Bioscience and GEDi Cube, with the intention to change the name to Renovaro AI or another appropriate name.

This approach is intended to allow each subsidiary to advance its cutting-edge technologies without introducing cultural and management challenges inherent in business combinations.

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