



VivoSim Labs Extends NAMkind Platform with Human Disease Models for Efficacy Testing and Mechanistic Biomarker Profiling

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Patient-derived liver and intestinal disease models are designed to help drug developers test whether a candidate reduces human disease in tissue before it reaches clinical trials

SAN DIEGO, Oct. 21, 2026 (GLOBE NEWSWIRE) -- VivoSim Labs, Inc. (Nasdaq: VIVS) (the "Company" or "VivoSim"), a provider of next-generation New Approach Methodologies (NAM) 3d human cellular models for preclinical safety and efficacy, today announced that it is extending its human tissue platform beyond toxicology, the core of its business today, with efficacy testing services built on NAMkind™ disease models of the liver and intestine. The disease models are built with cells from patient donors, so they carry features of the disease itself. Drug developers can measure whether a candidate acts on those disease features in human tissue before it enters clinical trials. VivoSim offers efficacy testing alongside toxicology on its liver and gastrointestinal (GI) models.

The move builds on demonstrated disease model excellence already demonstrated. Its intestinal efficacy platform, built in part from cells of patients with ulcerative colitis or Crohn's disease, received a "Poster of Distinction" award at Digestive Disease Week in May 2025, in work showing that the platform responds to clinically used therapeutics. VivoSim has also used its human disease models to identify new molecular targets that drive inflammatory bowel disease (IBD) and to explore how known drugs act.

Lack of efficacy is the most common reason drug candidates fail in clinical trials. In an analysis of more than 28,000 clinical trials stopped before reaching their endpoints, more than twice as many were stopped for negative results or lack of efficacy as for safety (Razuvayevskaya et al., Nature Genetics, 2024).

"Toxicology is the core of our business today, and it will remain a core service," said Keith Murphy, Executive Chairman of VivoSim Labs. "Our customers often need help with whether a candidate is likely to work, because that is where many drugs fall short in the clinic. Disease models let us address that question on the same human tissue platform we already use for safety, but leveraging patient-derived diseased cell sources so a customer can learn more before committing a program to clinical trials. We believe disease models could more than double our addressable market."

NAMkind™ Disease Models

- **Liver (MASH):** The NAMkind™ MASH disease model co-cultures healthy human liver cells with stellate, Kupffer, and endothelial cells from a donor with metabolic dysfunction-associated steatohepatitis (MASH), producing steatotic tissue with fibrosis. Compounds are dosed repeatedly over 14 or 21 days, with readouts for fibrosis and liver function. Cell-health markers measured in the same study separate an anti-fibrotic effect from cell damage.
- **Intestine (IBD):** The NAMkind™ IBD disease model is built from colon and small-intestine organoids derived from donors with ulcerative colitis and Crohn's disease, with twelve donors currently available. It measures barrier integrity, inflammation, and fibrosis in the same well and reports results donor by donor. A healthy tissue comparator arm is available.
- **Pharmacodynamic (PD) & Target Biomarker Profiling:** The platform evaluates target engagement, gene expression panels, cytokine profiling, extracellular matrix turnover markers, and other relevant biomarkers across donor tissues, enabling sponsors to map mechanism-of-action and dose-response relationships alongside functional efficacy readouts.

In both models, each study runs the client's compound alongside an approved or clinically validated reference compound in the same donor tissue, such as resmetirom in the MASH model or tofacitinib or upadacitinib in the IBD model. In results VivoSim has published for the IBD model, JAK inhibitors that look alike on paper had different effects on fibrosis, barrier function and inflammation, and methotrexate, a clinically used anti-inflammatory, reduced a fibrosis marker in a dose-dependent way in both Crohn's patient models tested.

"By leveraging patient-derived donor tissues, our disease platforms preserve the complex multiomic signatures and heterogeneous phenotypes seen in real-world clinical populations," said Amar Sethi, M.D., Ph.D., Chief Scientific Officer of VivoSim Labs. "Crucially, we can now evaluate candidate compounds not only for primary disease endpoints like fibrosis and barrier repair, but also for target-specific pharmacodynamic biomarkers. This dual capability allows drug developers to confirm both functional human efficacy and underlying drug mechanism on the exact same platform before entering clinical trials."

About VivoSim Labs

VivoSim Labs, Inc. ("VivoSim" and the "Company"), is a pharmaceutical and biotechnology services company that is focused on providing testing of drugs and drug candidates in three-dimensional ("3D") human tissue models of liver and intestine. The

Company offers partners liver and intestinal toxicology insights using its new approach methodologies ("NAM") models. The Company anticipates accelerated adoption of human tissue models following the U.S. Food and Drug Administration ("FDA") Roadmap to refine animal testing requirements in favor of these non-animal NAM methods. VivoSim Labs operates from San Diego, CA. Visit www.vivosim.ai.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations but are subject to a number of risks and uncertainties. Forward-looking statements include statements regarding the Company's cash on hand, revenue growth guidance and the Company's progress in marketing contract research services using NAMs models to pharmaceutical companies. Such forward-looking statements are not guarantees of performance and actual actions or events could differ materially from those contained in such statements. These risks and uncertainties and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on July 14, 2026, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on August 12, 2026. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events, or circumstances or to reflect the occurrence of unanticipated events.

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