



VivoSim Labs Celebrates Updated FDA Regulations Allowing Greater use of Non-Animal Testing Methods

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As the FDA opens the door to non-animal safety testing, VivoSim's human-relevant models are already helping lower drug costs

SAN DIEGO, Oct. 07, 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, today celebrated the U.S. Food and Drug Administration's (FDA) direct final rule updating its regulations to clarify that non-animal methods can be used where appropriate for testing the safety of drugs and biological products intended for human use.

The FDA's new rule replaces the term "animal tests" with "nonclinical tests" across its regulatory framework, formally opening pathways for NAMs, including human cell-based tests such as those offered by VivoSim.

VivoSim's liver tissue models are capable of flagging drug candidates likely to cause liver toxicity, side effects like diarrhea, and other issues. Liver toxicity is the leading cause of drug failures and market withdrawals. The company has the ability to meaningfully de-risk a client company's set of compounds and rule out likely failures prior to its selection of a drug to enter clinical testing.

Drug-induced liver injury (DILI) and gastrointestinal (GI) toxicity remain leading causes of drug candidate attrition. VivoSim's findings demonstrate how its long-duration, primary human cell-based models can help identify and differentiate these risks earlier in development, successfully ranking clinical safety risks for clients' drug candidates.

"VivoSim's NAMkind Models give insights that let our pharma and biotech partners make fewer major mistakes," said Keith Murphy, VivoSim's Executive Chairman. "By identifying risky molecules early on in development and moving on to better candidates, they avoid spending \$50 to \$200M only to learn deep in human clinical trials that their drug's results in animals were not representative."

By offering these kinds of insights, VivoSim also is helping with society's goal of lowering the cost of medicines for patients. The cited costs of up to \$2B per approved drug actually reflects the cost of eleven failed drugs for every one approved drug. VivoSim expects such wins to pass on to patients in lower drug costs through more approved drugs, greater competition, and lower pricing needed to recover a fair profit. "If we can help the world get from an 8% success rate in clinical trials to a 30% success rate, it would reduce the cost of drug development by 50%," Murphy noted.

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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