VivoSim Labs to Showcase Breakthrough Multiparametric NAMkind™ Liver and Intestine Data at the 2026 American College of Toxicology (ACT) Annual Meeting

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New data on 10 compounds pulled due to unforeseen liver tox highlight how VivoSim's models often easily catch clinical failure risk missed by animal models, using a complex approach that leverages several parameters studied simultaneously

SAN DIEGO, Nov. 16, 2026 (GLOBE NEWSWIRE) -- VivoSim Labs, Inc., (Nasdaq: VIVS) (the "Company" or "VivoSim"), a leader and pioneer in next generation human-relevant New Approach Methodologies (NAMs) 3d human cellular models for preclinical safety and translational efficacy, announced today that its scientific team is presenting two landmark studies at the 2026 American College of Toxicology (ACT) Annual Meeting, taking place November 15–18 in San Antonio, Texas.

The presentations underscore the transformative power of VivoSim's multiparametric approach across its proprietary NAMkind™ Liver and NAMkind™ Intestine platforms. Instead of measuring solely cell death, VivoSim sets a new standard by integrating multiple complementary endpoints with extended repeat-dose experimentation.

VivoSim's models successfully characterized complex mechanisms of drug-induced liver injury (DILI) and gastrointestinal toxicity, including compounds discontinued in clinical development and advanced modalities such as antibody-drug conjugates (ADCs) and CDK inhibitors.

Previously, VivoSim provided data from older, classic liver toxicity benchmark compounds, but in San Antonio the company is presenting data on 10 newly tested compounds. Each of these compounds was a drug candidate that passed its nonclinical safety package, including conventional animal studies—the standard, commonly used route to first-in-human trials. These compounds were therefore cleared to enter human trials, where liver safety signals later emerged and development was halted in mid- to late-stage clinical trials. Conventional preclinical methods missed these liabilities, yet VivoSim's 3D human model and multiparametric methodology in this experiment clearly flag all 10. This work demonstrates the immediate, real-world value of our platform in preventing costly clinical attrition today. Used ahead of first-in-human studies, testing in NAMkind™ Liver can flag liver liabilities while there is still time to redesign or drop a candidate, and help reduce costly liver-related clinical failures.

Multiparametric Resolution of Clinical Attrition in Liver Spheroids

In the first study (*Poster #P419: NAMkind™ Liver Multiparametric Analysis Detects Liver Injury Signals in Drug Candidates Discontinued During Early Clinical Development*), VivoSim evaluated 10 clinical drug candidates that successfully cleared conventional nonclinical animal safety studies but were later discontinued due to human hepatotoxicity.

Using the 3D human primary liver spheroid platform under 17-day repeated dosing, researchers tracked four complementary endpoints: ATP (metabolic/mitochondrial stress), albumin (hepatocyte function), total glutathione (GSH; oxidative stress), and lactate dehydrogenase (LDH; membrane lysis).

Cmax-normalized margin of safety (MOS) radar profiles successfully identified injury-related signals across all 10 discontinued candidates, spanning metabolic/lipid handling, aldehyde oxidase biotransformation, mitochondrial disruption, and undefined mechanisms.

"Traditional single-endpoint assays and animal models frequently fail to capture delayed or human-specific metabolic liabilities," said Dr. Amar A. Sethi, Chief Scientific Officer at VivoSim Labs. *"By applying a rigorous multiparametric approach in NAMkind™ Liver, we are able to look beyond basic cell viability and map out the exact convergence of various tissue stresses (functional, oxidative, and metabolic). This gives sponsors actionable mechanistic insight into liver toxicity risk margins long before clinical trials begin."*

Decoding Regional and Culture-State Intestinal Vulnerabilities

In the second study (*Poster #P421: NAMkind™ Intestine Profiles Region- and Culture-State-Dependent Epithelial Liabilities of CDK Inhibitors and Tubulin Inhibitor-Linked ADCs*), VivoSim demonstrated how polarized human colon and ileum models in both proliferative and differentiated states capture complex gastrointestinal toxicities.

Evaluating five cyclin-dependent kinase (CDK) inhibitors and deruxtecan and vedotin-linked ADCs across transepithelial electrical resistance (TEER), Alamar Blue (metabolic competence), and CTG ATP (viability), the study revealed:

- Despite sharing cell-cycle pharmacology, CDK inhibitors exhibited highly diverse regional and endpoint-specific MOS profiles that mirrored clinical diarrhea incidence and severity.
- Proliferative cultures demonstrated heightened barrier susceptibility (TEER), whereas differentiated cultures highlighted distinct metabolic-competence sensitivities, proving that epithelial cellular state profoundly influences toxicity manifestation.
- Histological and functional readouts confirmed concentration-dependent architectural disruption and severe barrier breakdown caused by vedotin payloads in differentiated colon epithelium.

"Gastrointestinal toxicity is a major hurdle in oncology and targeted therapeutics, yet conventional systems struggle to differentiate regional and cellular-state sensitivities," noted Keith Murphy, Executive Chairman at VivoSim Labs. *"Our latest intestinal data show that NAMKind Intestine regional tissue architecture with multiparametric readouts provides close correlation with known clinical outcomes. This system provides biopharma developers with an unprecedented lens to evaluate epithelial barrier integrity, optimize lead candidates, and align with modern regulatory frameworks like the FDA Modernization Act 2.0."*

Presentation Details

- **Poster #P419 (Liver):** *NAMkind™ Liver Multiparametric Analysis Detects Liver Injury Signals in Drug Candidates Discontinued During Early Clinical Development*
- **Poster #P421 (Intestine):** *NAMkind™ Intestine Profiles Region- and Culture-State-Dependent Epithelial Liabilities of CDK Inhibitors and Tubulin Inhibitor-Linked ADCs*
- **Conference:** American College of Toxicology (ACT) Annual Meeting, San Antonio, TX

About VivoSim Labs, Inc.

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 November 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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