Vivos Inc. Issues Shareholder Update Letter

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Kennewick, WA, Nov. 06, 2025 (GLOBE NEWSWIRE) -- Vivos Inc. (OTCQB: RDGL) –The Company continues to prioritize securing FDA Investigational Device Exemption (IDE) approval to initiate human clinical studies at Mayo Clinic. Over the past several years, Vivos has successfully responded to inquiries from more than 40 unique FDA reviewers. Many items that we addressed were generated due to reviewer transitions. We are providing data and finalizing the approvable technical parameters with the FDA related to demonstrating the precision delivery of Radiogel to the treatment area and the minimal non-systemic migration of the radiopharmaceutical agent.

A Pre-Submission focused on sterilization was recently filed with the FDA, introducing the Agency to the Company's enhanced Electron Beam (E-Beam) sterilization process for the RadioGel hydrogel and confirming completion of container closure integrity testing.

To maximize the probability of IDE approval, Vivos has engaged **John Smith**, a regulatory expert with **over 25 years of direct experience** guiding brachytherapy and combination radiotherapy devices through the FDA's Center for Devices and Radiological Health (CDRH). Mr. Smith previously served in senior roles within the

FDA's Office of Device Evaluation and has led IDE approvals for multiple Class III implantable radiation devices, including several reviewed by the same Interventional Radiology and Oncology branch currently assigned to RadioGel. His intimate knowledge of this review team's expectations, historical precedents, and common deficiency patterns has been instrumental in shaping our regulatory strategy.

Based on Mr. Smith's counsel and his analysis of recurring FDA feedback on brachytherapy devices—particularly around radiation dosimetry validation, migration of therapeutic agents from the treatment site, and clinical protocol design for dose escalation—the Company is preparing a second Pre-Submission focused on these high-impact areas. This proactive step aligns with standard successful pathways for brachytherapy IDEs, allowing the Agency to provide formal written feedback prior to final IDE submission.

With the second Pre-Submission now in preparation under Mr. Smith's guidance, the Company is positioned to incorporate final FDA input and submit the complete IDE application in the near term. Mr. Smith's proven ability to present complex IDE data in a format that this specific review panel can easily digest and understand—streamlining review and reducing iterative cycles— further strengthens our confidence. This structured, reviewer-aligned approach, combined with a review pathway designed to withstand external disruptions, supports our expectation of a timely progression toward clinical studies at Mayo Clinic.

Strategic Expansion in India via Vivos Scientific India LLP (VISL)

In September 2025, the Board of Directors authorized the formation of Vivos Scientific India LLP (VISL) to establish a formal business presence in India. The entity has secured name reservation, obtained digital signatures, and received its Certificate of Incorporation. Filing of the LLP Agreement is in its final stages.

VISL will be headquartered in Mumbai under the leadership of Dr. Mike Korenko and Sandeep Bali as designated partners, supported by an Indian Advisory Board. VISL is positioned to accelerate regulatory approvals and to establish a manufacturing center for human and animal clinical studies. We intend to establish a second entity in India structured for commercial operations, subject to approvals by Indian regulators, to market RadioGel for human and Isopet for veterinary applications, providing access to India's $2 billion human oncology and $100 million veterinary therapy markets.

Phase II clinical trial approval under the Drugs Controller General of India (DCGI) is being pursued at HCG Hospital, with plans to expand RadioGel administration to Amruta Institute of Medical Science (AIMS) near New Delhi and additional strategically selected clinics across key oncology regions. These new RadioGel sites will accelerate clinical adoption, broaden intended uses, and generate diverse, high-quality data to strengthen both local commercialization and global regulatory submissions, including

the

U.S. IDE.

International Strategy – Building a Global RadioGel Platform

Beyond India, Vivos is laying the foundation for strategic expansion into select international markets with high unmet needs in oncology and veterinary care. Leveraging the international manufacturing center now in development, the Company is evaluating regulatory pathways in regions with streamlined device approvals and growing demand for precision radiotherapy. This multi-continental approach will generate additional clinical evidence, accelerate global brand recognition, and position RadioGel for broader commercialization post-U.S. IDE approval. Vivos will disclose further details as they become available and progress is achieved in these regulatory pathways.

Domestic Animal Therapy – IsoPet Demonstrates Strong Momentum

The IsoPet division reported an 800% year-over-year increase in administered therapies from 2024 to 2025, reflecting accelerating veterinary adoption nationwide. In recent months, the Company has seen a sharp rise in inbound inquiries from both veterinarians and pet owners seeking access to IsoPet therapy, signaling growing awareness and demand for this precise, cost-effective alternative to traditional radiation.

Starting in Q1 2026, the division will implement profitability-focused initiatives while continuing to expand its network of certified clinics.

Over 100 IsoPet treatments have been safely performed across dogs, cats, horses, and exotic animals.

Capital Veterinary Specialists (Tallahassee, FL) is administering IsoPet at a discounted rate for microscopic disease following tumor resection and will publish a case study on clinical outcomes.

The Company recently announced a strategic partnership with Exubrion Therapeutics, a leader in equine regenerative medicine, to co-promote IsoPet in the high-value equine oncology segment. The equine segment represents a high-growth opportunity, with five certified clinics now operational, including Brazos Valley Equine Hospital. Four equine ocular squamous cell carcinoma cases were successfully treated without ocular damage, and a clinical publication is in development with Dr. Ben Buchanan.

Manufacturing Transition Planning

The Company has proactively addressed single-source manufacturing risk previously disclosed in its SEC filings. We currently plan to discontinue the fully outsourced manufacturing in the first half of 2026. Three preferred manufacturing partners have been selected for the build out of up to two domestic and one international production

center, with equipment installation and process validation now in progress. When operational, anticipated for the second quarter of 2026, these new production centers will be managed by Vivos with production dedicated exclusively to Radiogel/Isopet and PrecisionGel.

Intellectual Property & Proprietary Technology

Vivos maintains a comprehensive IP portfolio, including four years of documented developmental data, validated Quality Management System documentation for sterile hydrogel and microparticle production, and worldwide trademark protection. Patents are actively maintained and expanded in 63 countries, covering hydrogel composition, microparticles, proprietary applicators, and future innovations

Akina Inc. recently completed rheology and resorption analysis across a broad range of hydrogel concentrations, enabling application-specific formulations (e.g., accelerated resorption post-Y-90 decay in resected tumors). A new patent describing PrecisionGel agent-release characteristics based on this developmental work is being prepared.

Leveraging our Technologies for Third Party Applications

- **PrecisionGel**: The hydrogel polymer is now commercially available via the Akina website. Resorption kinetics have been characterized and agent release data is currently being generated for three distinct therapeutic agents. Initial sales have been completed to a major university and a large pharmaceutical company for

evaluation.

- **Duncan Chiller**: A laboratory chilling prototype has been validated. Commercial refinement, patent filing, manufacturing at Applied Process Engineering Laboratory, and distribution through Akina are planned for 2026.

About Vivos Inc.

Vivos Inc. is a clinical-stage medical device company developing RadioGel®, a precision radiotherapy hydrogel for human and veterinary oncology applications. IsoPet® is commercially available for veterinary use in certified clinics nationwide.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated. These risks are detailed in the Company's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q.

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