

# Quarterly Progress Review Q1 2024



Next-Generation injectable yttrium-90  
therapy for solid cancer tumors.

VIVOS  
PRECISION BRACHYTHERAPY

*"If we can reach the tumor, we can kill it."*

Precision Radionuclide Therapy™ (PRnT)





# Executive Summary of Q1 2024

- **Market Analysis**

The latest Market Analysis Report

“The global brachytherapy market size was estimated at USD 907.76 million in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 7.1% from 2023 to 2030.

The increasing prevalence of cancer, technological advancements, and a significant rise in the adoption of brachytherapy are expected to drive the growth of the market during the forecast period.”

- The physical testing phase for genotoxicity is completed. This will be followed by measurement phase and final analysis.
- The Johns Hopkins VX2 testing was completed previously. Now the draft report is near completion. The hydrogel shelf-life study for the IDE is 80% completed.
- A contract was signed with Benzinga to formally communicate to the investment community. The contract consists of 4 articles, 10 newsletters and 2 webinars posted on their platform with a reach of 25,000 followers. The first article is due out mid April.

# Quality Management System

## QUALITY MANAGEMENT SYSTEM DOCUMENTS

SOP-030 Design Documents

SOP 100 R01 Corrective and Preventative Actions

QP-001 R01 Vivos Quality Policy

SOP-812 Monitoring of Clinical Investigations

## BATCH RECORDS

MRB-003 Production Procedure and Batch Record – Preparation of RadioGel™/IsoPet® in 10 ml & 20 ml Vials

## TEST REPORTS

TR-003 Microbiological Testing of PLGA-g-PEG Polymer and Hydrogel

TR-004 Yttrium Particles Sterilization Validation Study

TR-005 Feasibility Study for the Use of Mesa Labs ProSpore BIs

## OTHER

10K – The 1QK was submitted on schedule on 3/18/24.

On 3/24/24 Rebecca Krimmins submitted an abstract 2024 European Congress of Medical Physics that is scheduled for September of this year in Munich on our rabbit work.





## **CONFERENCES IN 2024**

ACVIM (American College of Veterinary Internal Medicine) June 6-8, 2024 – Minneapolis, MN

PacVet (Pacific Veterinary Conference) – July 11-14, 2024 – San Francisco, CA

IRPA (International Radiation Protection Association) Darrell Fisher will be presenting “Direct Interstitial Injection: An Approach to Optimizing Therapeutic Ratios for Safe and Effective Delivery of High-dose Radionuclide Therapy in Treating Solid Tumors” – July 7-12, 2024 – Orlando, FL

VCS (Cancer Society) – October 17-19 in Orlando. FL

AAEP (Association of Equine Practitioners), – December 7 -11 – Orlando, FL

## **CONFERENCES IN 2025**

VMX (the world’s premier veterinary expo) – Jan 25-29 – Orlando, FL

97th Annual WVS Conference (the largest and oldest veterinary conference in the USA) March 2-5 – Las Vegas, NV

ACVIM (American College of Veterinary Internal Medicine) – June 2-14 – Louisville, KY

VCS (Veterinary Cancer Society) – Sept 25-27 – Salt Lake City, UT



# MARKETING REVIEW

## SOCIAL MEDIA

- IsoPet blogs have been written and 4 have posted to increase awareness.
- Revised Facebook, created an Instagram page to post the blogs
- The new VivosIncUSA.com website is live, a landing page for the new RadioGelUSA.com site for future updating has went live and blogs geared to pet parents have been posted on social media and [www.isopet.com](http://www.isopet.com).
- Social media posts go out daily Monday - Friday across 4 social platforms instead of just 2, we now post to Twitter (X), LinkedIn, Facebook, and Instagram.

## MARKETING MATERIALS

- Created a "Steps To Becoming A Certified IsoPet® Clinic - including RAM training
- Created new custom and generic brochures, posters, flyers, mailouts and equine magazine ads to bring awareness to our IsoPet® division
- Custom brochures were designed for Vista Veterinary Hospital, Myhre Equine Clinic and Johns Hopkins University.





# MARKETING REVIEW

## WEBSITE

Our current domains:

[www.IsoPet.com](http://www.IsoPet.com)

[www.VivosIncUSA.com](http://www.VivosIncUSA.com)

[www.RadioGelUSA.com](http://www.RadioGelUSA.com)

Q1 saw a ramp-up of IsoPet marketing, with regional campaigns around certified clinics across the US. 2024 will see an expansion through magazine features, veterinary conference participation, and clinic certification to reach more pets geographically.

Digital engagement also rose 310% in Q1, a trend poised to continue.

Q1 focused on expanding IsoPet's clinical reach through collaboration with regional clinics, treating various pet cancers and exploring potential new applications like Dr. Bradley's caudal heel pain therapy.





# ISOPET® REVIEW

- Having demonstrated safety and effectiveness of IsoPet®, the emphasis is now on certifying new clinics for IsoPet® Precision Radionuclide Therapy (PRnT)™ in household pets and horses.
- There was a significant increase in our marketing to communicate to the pet parents and veterinarians on our IsoPet® treatment in an effort to increase the number of therapies.
- New potential pet patients are currently being screened to see if they are candidates for our treatment.
- The equine study to determine if IsoPet® can treat equine caudal heel pain syndrome is showing signs of effectiveness. If successful this will be a great new market.
- One of our newest pet patients, Maximus was treated on Feb 20, 2024 and the tumor is shrinking. Maximus is doing well and more updates will follow on his cancer journey.





# RADIOGEL™ REVIEW

- Complete the testing required to submit the amended Investigational Device Exemption necessary to obtain FDA approval to initiate clinical trials. The IDE request to the FDA will be submitted in Q2. The genotoxicity and V2 reports are critical.
- Continue to improve the Quality Management System to prepare for the FDA audit prior to initiating human clinical trials.
- The physical testing phase for genotoxicity is completed. This will be followed by measurement phase and final analysis.
- The Johns Hopkins VX2 testing was completed previously. Now the draft report is near completion. The hydrogel shelf-life study for the IDE is 80% completed.







### Partnership

Vivos partners with Mayo Clinic and Initiates RadioGel Pre-Submission for an Early Feasibility IDE Application



### FDA Meeting

Vivos meets with FDA to agree on additional requirements needed for the IDE Submission



### Action Plan

Vivos initiates action plan execution based on FDA-approved activities.



### Major Milestone

RadioGel and the proposed indication for use is granted designation as a Breakthrough Device by the FDA.



### The Final Stages

Vivos is in the final stages of completing all FDA requirements in preparation of IDE Submittal.



### IDE Submittal

Vivos scheduled to submit RadioGel as an Early Feasibility IDE Application in the second quarter.

# THE ROAD TO IDE SUBMISSION