Anivive Shareholder Letter

December 2025

Vaccine at front of USDA queue. $30M+ Zoetis facility secured. $37.5M non-dilutive revenue through 2026. Anivive 2.0 executing.

Dear Shareholders,

Over the past year we rebuilt Anivive around one mandate: get the Valley Fever vaccine approved and launched, and make sure every part of the business exists to support that goal.

We call this Anivive 2.0. It's a vaccine-first company with a software backbone, a capital plan built around non-dilutive revenue, and a small, high-talent team systematically taking risk off the table while hitting value-creating milestones.

Executive Summary: All Roads Lead to the Vaccine

• **Vaccine in final regulatory stage.** All major data are submitted. USDA has confirmed we are at the front of the line for review once they clear their shutdown backlog, with our strategy led by the former Director of the USDA Center for Veterinary Biologics (CVB), Dr. Paul Hauer.

• **Manufacturing & facilities de-risked and now an asset.** We secured both a primary supply agreement with HRA/Kemin and a $30M+ Zoetis BSL-2 facility in Texas. That Texas site is now registered, we've begun moving equipment, and three companies have already approached us to contract for its capabilities.

• **Commercial engine proven at scale.** Our software platform has quietly processed over 7,500 orders from ~400 hospitals, coordinating more than 15,000 shipments across 38 states—handling ~600 diagnostic orders and close to 1,000 individual packages and shipments every month—without a sales force.

• **Laverdia + NIH + diagnostics fund the plan.** We have clear line-of-sight to $37.5M in contracted and recurring non-vaccine revenue across 2025–2026 from Laverdia milestones, NIH biodefense contracts, and cancer diagnostics.

• **CFO hired to optimize our self-funding model.** Chip Dorsey has joined Anivive as Chief Financial Officer, effective January 5. His mandate: Build the financial infrastructure for commercial launch, lead investor relations, refinance the Leonid loan, and model optimal debt paydown.

1. Vaccine Pathway: Final Chapter, Ruthless Risk Reduction

A complete, overbuilt data package: We deliberately over-delivered on our USDA submission. The Valley Fever vaccine dossier includes mouse, rabbit, cat, and dog studies; subcutaneous and intramuscular routes; both liquid and lyophilized formulations; stability at room temperature, refrigerated, and frozen conditions; environmental safety studies; full genetic sequencing of master seed stock; and environmental assessment documentation.

Top-tier regulatory leadership: Dr. Paul Hauer, former Director of USDA CVB, now leads our vaccine regulatory strategy. Kevin McCarthy, former Speaker of the U.S. House and Anivive board member, coordinated cross-agency support spanning USDA, FDA, CDC, and NIH.

Three synchronized regulatory tracks: (1) Full approval for dogs, (2) Conditional approval in Arizona and other highly endemic areas, (3) Zoo authorization for susceptible species in endemic regions. Each path uses the same core dataset.

Commitment Type	Amount
NIH Biodefense Contract	$33M
Hospital Pre-orders (600+ hospitals)	$18M
Total Vaccine Commitments	**$50M+**

2. Manufacturing & Facilities: From Single-Point Failure to Strategic Asset

Primary supply: HRA/Kemin commercial agreement. We signed the first-ever commercial supply agreement for a fungal vaccine with HRA, now part of Kemin Industries, securing long-term capacity at a USDA-licensed facility. The agreement includes contracted production capacity, performance guarantees, and penalty clauses for failure to supply.

Backup manufacturing: the Zoetis Texas facility. A 16,237 sq ft USDA-licensed BSL-2 biomanufacturing facility in College Station, Texas. Cleanrooms, fill-finish lines, isolators, and a congressional permit for foot-and-mouth disease (FMD) work. Replacement value north of $30M, effectively secured at zero net ongoing cost.

Since our last update, we've submitted facility registration documents, begun moving equipment to Texas, and brought in the former Zoetis facility process manager. Three companies have already approached us about contracting for access to the Texas facility's capabilities. USDA has also opened discussions about transferring an internal vaccine development program into our Texas infrastructure.

3. Commercial Platform: Vaccine-Ready Because We're Already Running at Scale

We did not want our first "at scale" commercial experience to be the vaccine launch. So we used diagnostics to battle-test the system.

Metric	Achievement
Orders Processed	7,500+
Veterinary Hospitals	400+
Shipments Coordinated	15,000+ across 38 states
Monthly Volume	~600 orders, ~1,000 packages/shipments

The software update includes an internal CRM and order-tracking platform that replaced several third-party tools, real-time telemetry and monitoring, and improved data transfer performance by 70x. All of that work serves one purpose: to ensure that when vaccine orders start, the system behaves as if it's already been doing that job for years.

4. Laverdia & Dechra: Converting Software Execution into a Financing Engine

Largest nationwide canine lymphoma study, powered by software: Our pivotal canine lymphoma trial achieved 99.5% statistical confidence, far exceeding the 95% bar FDA requires. It was one of the largest nationwide lymphoma studies conducted in dogs, using our AniTrial platform to drive 40% of enrollment and increase daily applications by 460%.

Region	Milestone	Status
United States	$15.0M	FDA decision expected Q1 2026
EU	$5.0M	Year-end filing prepared
UK	$2.5M	Year-end filing prepared
Australia	$2.5M	Submission completed
Brazil	$2.5M	Submission completed
Canada	$2.0M	To follow
TOTAL	**$29.5M**	

The Dechra amendment we didn't sign: Dechra proposed converting the $15M U.S. milestone into $1M monthly payments beginning ahead of approval. With increased regulatory and revenue clarity from Laverdia's review progress and USDA confirmation, we made the deliberate decision not to execute the amendment. This shows the depth of Dechra's conviction and our discipline in preserving the full economics of the original structure.

5. Balance Sheet, Debt Strategy & Chip's Mandate

Revenue visibility without vaccine sales: Our 2026 revenue forecast, excluding vaccine sales, sits at approximately $37.5M.

Revenue Source	Amount	Timing
U.S. Laverdia Milestone	$15.0M	Q1 2026
International Laverdia Milestones	$14.5M	2026
NIH Biodefense Contracts	$6.0M	2025-2026
Cancer Diagnostic Services	$2.0M	2025-2026
TOTAL (excl. vaccine)	**$37.5M**	

Enter Chip Dorsey: We recruited Chip Dorsey as our Chief Financial Officer, with a mandate tailored to this exact moment: Build a finance organization calibrated for a commercial, multi-product business; own investor relations; lead the Leonid refinancing; and model the optimal paydown of debt from Laverdia, international milestones, and diagnostics.

6. People, Governance & the Scale of What a Small Team Is Doing

One of the things I'm most proud of is what our relatively small team has delivered in the last 12–18 months: simultaneously advanced a first-in-class vaccine to the front of USDA's queue and filed Laverdia in six countries; completed the largest nationwide canine lymphoma study with 99.5% confidence; scaled to 600+ complex diagnostic orders per month while cutting $2M in long-term costs; and secured partnerships with Kemin/HRA, Zoetis, University of Washington, and multiple NIH awards.

Board and advisor bench: Dr. Steve Fisher (Board) – Former Global Head of Purchasing at VCA/Mars; Kevin McCarthy (Board) – Former Speaker of the U.S. House; Ed Robb (Chief Strategy Officer) – Principal Investigator on NIH biodefense contract; Norm Christensen (Advisor) – Founder/CEO of Karman Space & Defense; Dr. Paul Hauer (Regulatory Advisor) – Former USDA CVB Director.

7. Human Vaccine, UW Platform & Biodefense: Multipliers on the Same Infrastructure

Everything we're building for Valley Fever in dogs is designed to be reused. On the human side, we have completed pre-IND interactions with FDA and are preparing a pre-IND package for early 2026. We submitted our application to the Commissioner's National Priority Voucher (CNPV) pilot program and secured a Boston-based manufacturing partner for Phase 1 clinical trial batches.

UW DNA/mRNA platform: We executed an exclusive license with the University of Washington for Dr. Deborah Fuller's DNA/mRNA fungal vaccine platform. That collaboration has already helped secure >$9–11M in NIH funding and extends our IP moat beyond the first generation of products.

Biodefense expansion: Beyond the $33M NIH biodefense contract already awarded, we have secured an additional NIH award for next-gen fungal vaccines, been encouraged to pursue $30M+ in further grants, and opened dialogue with USDA on FMD and other high-priority vaccines.

Closing Thoughts

If Anivive were being launched from scratch today with the assets we now have, it would be an enviable starting point: a first-in-class systemic fungal vaccine at the front of the USDA queue; primary and backup manufacturing fully de-risked, with a $30M+ biomanufacturing facility that others now want to rent from us; a commercial platform that already handles thousands of orders and shipments a quarter; a second product, Laverdia, nearing approval with nearly $30M in global milestone potential; contracted revenue visibility of roughly $37.5M through 2026 before a single dose of vaccine is sold; and a growing human, biodefense, and next-gen fungal vaccine pipeline riding on the same platform.

This is Anivive 2.0: disciplined, vaccine-first, and built to scale. Every decision we make serves one mission: Launch the world's first systemic fungal vaccine, and build a self-funding company that gives pets—and the people who love them—more time.

Thank you for your continued partnership and trust as we execute on the most important chapter in Anivive's history.

Sincerely,

Dylan Balsz
Founder & CEO
Anivive Lifesciences, Inc.
"Giving Our Best Friends More Time™"

Forward-Looking Statements: This letter contains forward-looking statements, including but not limited to expectations regarding vaccine licensure and timing, Laverdia regulatory approvals and milestone payments, potential amendments to the Dechra agreement, manufacturing scale-up and facility utilization, revenue forecasts, debt refinancing, future grant awards, biodefense and human health program development, and other strategic initiatives. These statements are based on current assumptions and information and involve risks and uncertainties that could cause actual results to differ materially, including regulatory outcomes, manufacturing and supply chain performance, clinical results, partner performance, market conditions, government funding and shutdowns, financing conditions, and other factors. Anivive undertakes no obligation to update these forward-looking statements. References to "pre-orders," "commitments," or "stockpile potential" refer to non-binding indications of interest or projected opportunities and are subject to regulatory approval, contracting, and other contingencies.