

Zoetis - Scaling Librela with Evidence and Discipline

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Decision scope: Hypothetical next tranche of U.S. commercial resources

Case convention: The decision and budget are classroom assumptions. Company statements and financial data are historical. This case is not veterinary advice.

The decision

On February 13, 2024, Zoetis reported full-year 2023 results and filed its annual report. The company had launched Librela in the United States in 2023 after FDA approval of bedinvetmab for control of pain associated with osteoarthritis in dogs. Librela was the first monoclonal antibody FDA approved for dogs. Its administration is prescription-only and monthly. Management described momentum in the monoclonal-antibody franchise and an ambition to build a “next billion-dollar franchise.” [S1], [S2], [S3]

For this exercise, assume you advise a hypothetical Zoetis U.S. launch committee on the next tranche of Librela commercial resources. Should Zoetis accelerate broad veterinarian-facing coverage, education and launch support, or stage the next tranche behind compliance, supply and clinic-adoption gates? A contingent plan is permitted. Recommend a policy, the evidence needed before further commitment, and the conditions that would change your view.

The company did not disclose a Librela budget, product-level sales, margin, adoption or return. Do not calculate Librela revenue, ROI or break-even from company-wide figures. Do not recommend treatment for individual animals. Use only information available through the cutoff.

A new franchise, with an attribution problem

Zoetis reported 2023 revenue of \$8.544 billion, up 6% as reported and 7% operationally. The company attributed companion-animal growth in both major geographies to Librela and Solensia alongside dermatology, parasiticides, vaccines and diagnostics. In the fourth quarter, companion-animal sales grew 10% in the U.S. and 10% operationally in International. These results make a case for investing behind a novel product and channel. They do not show Librela's contribution by itself. [S1], pp. 32, 40-42; [S2]

Exhibit 1. Selected company and companion-animal measures

Measure	FY2023	What it measures
Total revenue	\$8.544bn; +6% reported, +7% operational	All Zoetis products and geographies
Companion-animal revenue	\$5.576bn	All companion-animal products and species
Dog and cat revenue	\$5.291bn	All products sold for dogs and cats
U.S. segment gross margin	80.2%	Segment-wide gross margin
International segment gross margin	68.4%	Segment-wide gross margin
Operating cash flow	\$2.353bn	Company-wide cash generation

Sources: [S1], MD&A pp. 32, 40-42; Note 4, p. 68; segment table, p. 89; liquidity, pp. 47-48. Companion-animal and dog/cat totals include many products. Segment margins combine product and species mix. None of these measures reveals Librela sales, product margin, commercial expense or return.

The growth context is not clean. Zoetis said U.S. companion-animal growth was partly offset by distributor destocking in the first quarter and affected by purchases ahead of 2023 price increases and promotions in late 2022. International 2023 revenue grew 6% as reported and 9% operationally; foreign exchange reduced revenue by about \$116 million. Other brands and comparison-period effects may therefore explain part of the observed growth. Management guided to 7-9% operational revenue growth for 2024, using late-January exchange rates; this is a forecast, not a result. [S1], pp. 40-42; [S2]

What does the evidence support?

FDA's May 2023 approval covered the labeled indication: control of pain associated with osteoarthritis in dogs. The original approval review concluded that Librela was safe and effective when used according to labeling. In FDA's summary of the two placebo-controlled field studies, treatment success at Day 28 was 48% versus 36.1% in the U.S. study and 45.2% versus 17.0% in the EU study. Day 28 was the primary endpoint; the EU difference was statistically significant, while the U.S. difference was not. FDA based its conclusion on the weight of evidence across studies and days, including at least two doses 28 days apart. These findings do not establish commercial demand or justify claims beyond the approved indication. [S3], pp. 2, 6-11

The approval package also describes limits in the safety evidence. In a controlled EU field study (141 dogs assigned Librela and 146 control), FDA recorded two serious events in treated dogs who were euthanized: one dog with pre-existing heart failure developed worsening heart failure and renal failure; another had pancreatitis. In an open-label, uncontrolled six-month continuation of 89 dogs, two dogs presented with rear-limb paresis of unknown cause; one was euthanized. FDA reported these events but did not establish causality. [S3], pp. 12-17

Other studies were small and have defined limits. A six-month margin-of-safety study enrolled 32 Beagles; one dog in the 3X-dose group had bone and cartilage findings for which an underlying condition was possible, but a treatment relationship could not be ruled out. A two-week concurrent-NSAID study of eight Beagles did not provide sufficient data to support co-use safety. FDA also said neutralizing antibody activity was not tested and assay limits

prevented clinically relevant interpretation of immunogenicity findings. FDA nevertheless concluded the product was safe and effective for use according to the label. These study findings do not establish harm or event causality; no treatment guidance is intended. [S3], pp. 18-24

Commercial communications add a management challenge. In November 2023, FDA criticized specific professional-website graphs and p-values for secondary time points, stating the studies were not designed to support statistical conclusions at those times without adjustment for multiple testing. The letter addressed those promotional claims. It did not withdraw the approval or find that the labeled indication was ineffective. The launch team must therefore scale veterinarian education while ensuring claims remain accurate and consistent with the evidence. [S4], pp. 1-3

Launch execution and the value of learning

Librela is a prescription product administered by veterinary professionals. Zoetis identifies service, quality, price and promotion to veterinary professionals as competitive factors, and notes veterinary-workforce availability and customer cost sensitivity as demand risks. Its filings also describe complex manufacturing, capacity risks and past pandemic-era component constraints affecting Librela and Solensia. The public record does not say whether a current product-specific supply constraint or clinic bottleneck exists. [S1], pp. 8, 16-22, 32-35

That leaves two kinds of uncertainty. Broad launch investment might help clinics learn about a new product category, establish routines and meet demand while momentum is high. But it could also commit commercial resources before the company can observe product-specific uptake, repeat ordering, fill rates or margin. A narrow rollout could generate useful learning only if the measures arrive in time and Zoetis can redirect resources based on them. If a staged plan waits without decision-relevant indicators, it may lose the launch window without reducing uncertainty.

Research on real-options reasoning offers a process lens. McGrath and Nerkar's study of follow-on patenting by large pharmaceutical firms suggests that firms can make incremental commitments as opportunity and competitor signals evolve; its historical human-pharma patent data do not estimate commercial returns for an animal-health launch. Huchzermeier and Loch's model distinguishes actions to continue, improve or abandon a project and shows why flexibility is useful only when information arrives while decisions remain changeable. Neither paper tells Zoetis which option to choose. [S5], pp. 6-16; [S6], pp. 85-101

Exhibit 2. What the public evidence does and does not show

Decision issue	Evidence available by cutoff	Evidence not publicly disclosed
Franchise opportunity	Management attributed companion-animal growth to Librela and Solensia among other brands; described Librela momentum.	Librela revenue, units, market share, gross-to-net price, margin or launch return.
Professional channel	Prescription and veterinary administration; company identifies service, promotion and workforce availability as relevant.	Clinic coverage, onboarding, staff capacity, adoption, reorder behavior, persistence or customer-level outcomes.
Supply	Company discloses manufacturing complexity and past component constraints.	Current Librela capacity, fill rates, inventory, lead times or product-specific shortage status.
Claims and evidence	FDA approval package and November 2023 promotional letter define evidence boundaries.	Internal promotional-review costs, corrective actions or compliance metrics.
Ability to invest	Company-wide cash, revenue, and segment financial data.	Incremental commercial spending, product cost, hurdle rate or competing-project returns.

Source: [S1]-[S6]. Missing data are part of the decision. Do not replace them with invented product economics.

The alternatives

Accelerate broad U.S. rollout. Add veterinarian education, field coverage and launch support across a wider clinic base. This may build category awareness and establish professional-channel routines while management reports momentum. It also risks committing cost before product economics and supply are visible, and increases the need for strong claims controls after FDA's letter.

Stage the next tranche. Continue baseline launch support, then release expansion funds in short tranches when compliant materials, supply readiness and observable clinic onboarding or demand indicators meet pre-set conditions. Staging may contain sunk cost and locate bottlenecks. It could miss demand if gates are too slow, too narrow or based on measures that do not change decisions.

Use a contingent combination. Maintain core launch capacity and accelerate only in geographies or clinic cohorts that satisfy the selected gates. State what remains funded during the learning period, what evidence is reviewed, how often the committee revisits the decision, and what would trigger a faster or slower deployment.

The gates and review period are assumptions for the exercise, not Zoetis policy. Measures should describe commercial readiness and channel execution, not invite students to infer individual veterinary care. Product-specific sales, margin and ROI remain unknown regardless of the choice.

Assignment

Prepare a two-page recommendation to the hypothetical launch committee. Choose an approach and explain:

1. how much of the next commercial tranche to commit now versus reserve, using explicit classroom assumptions;
2. what supply, claims-compliance and clinic-adoption indicators should govern further spending;
3. how quickly those indicators can inform a change in deployment;
4. the strongest argument against your recommendation; and
5. what evidence would cause the committee to change course.

Use information available through February 13, 2024. Distinguish company-level 2023 category/segment economics from Librela-specific results. Treat serious events with their study context and do not claim causality. The case provides no veterinary advice and no later safety or commercial outcomes.

Sources

S1. Zoetis Inc., [2023 Form 10-K](#), filed February 13, 2024. Locators are printed page numbers in the case text.

S2. Zoetis, [“Zoetis Reports Fourth Quarter and Full Year 2023 Results”](#), February 13, 2024.

S3. FDA Center for Veterinary Medicine, [Freedom of Information Summary, NADA 141-562, Librela \(bedinvetmab injection\)](#), approved May 5, 2023. See cited page numbers.

S4. FDA Center for Veterinary Medicine, [Untitled Letter, NADA 141-562](#), November 20, 2023.

S5. McGrath, R. G., & Nerkar, A. (2004). “Real Options Reasoning and a New Look at the R&D Investment Strategies of Pharmaceutical Firms.” *Strategic Management Journal*, 25(1), 1-21. [Full text](#).

S6. Huchzermeier, A., & Loch, C. H. (2001). “Project Management Under Risk: Using the Real Options Approach to Evaluate Flexibility in R&D.” *Management Science*, 47(1), 85-101. [Publisher record](#).

This teaching case uses public information and classroom assumptions. It is not an investment recommendation, and it does not provide veterinary advice.