

## **Paradigm Signs Binding Veterinary Licensing and Supply Agreement for Oral PPS + COX-2 inhibitor Combination**

### **Key Highlights**

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- Paradigm and AVet Health sign binding terms to co-develop and license a PPS + COX-2 inhibitor oral therapy for veterinary osteoarthritis indications in Australia and New Zealand (ANZ).
  - Under the binding terms, AVet will hold exclusive rights in ANZ, with a first right of refusal for all other markets excluding the USA, with Paradigm eligible to receive up to A\$1 million from AVet in development milestones.
  - The definitive licensing agreement, once executed, will entitle Paradigm to tiered royalties up to 20% on net sales and run for 15 years post-registration with the Australian Pesticides and Veterinary Medicines Authority (APVMA).
  - Under the binding terms, Paradigm retains rights to the US veterinary market.
  - Partnership supports early data generation and program advancement, while Paradigm remains focused on execution of its pivotal Phase 3 iPPS clinical trial.
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**Paradigm Biopharmaceuticals Ltd. (ASX: PAR) (“Paradigm” or “the Company”)** a late-stage drug development company focused on delivering new therapies to address unmet medical needs, today announces it has entered into a binding term sheet with AVet Health Ltd (AVet) for the co-development and exclusive licensing of a novel oral combination therapy comprising pentosan polysulfate sodium (PPS) and a COX-2 inhibitor for the treatment of osteoarthritis (OA) in companion animals. The collaboration provides Paradigm a non-dilutive pathway to progress this promising asset in the animal health sector while remaining fully focused on its pivotal Phase 3 PARA\_OA\_012 clinical trial.

Paradigm acquired the intellectual property for the PPS + COX-2 inhibitor combination in 2025 as part of a strategic expansion of its osteoarthritis portfolio<sup>(1)</sup>. This acquisition laid the foundation for progressing the formulation as an oral, non-opioid therapy for the treatment of osteoarthritis in veterinary and human health, with a focus on earlier-stage disease. This oral formulation represents a first-in-class approach, combining PPS, a compound with potential disease-modifying benefits, with a COX-2 inhibitor to reduce inflammation and pain. This dual-action candidate is differentiated from injectable PPS products already marketed in the veterinary space, and may offer improved convenience, safety, and compliance for long-term OA management.

The collaboration will see the parties co-develop an oral product formulation of PPS and a COX-2 inhibitor-class anti-inflammatory drug for use in companion animals, targeting osteoarthritis and related musculoskeletal conditions. Paradigm will fund the veterinary development program through a multi-stage Development Plan, with Stage 1 activities, including formulation development and initial non-clinical work, estimated to cost approximately A\$1.0 million. AVet will contribute in-kind resources, including project management and scientific oversight, and supply and access to the Drug Master File of

commonly used COX-2 inhibitors in the veterinary space, as part of this initial development phase.

AVet is a veterinary pharmaceutical company with a strong commercial presence in ANZ and Asia. The company has registered over 95 products with APMVA including COX-2 inhibitors like meloxicam and has access to supporting Drug Master Files (DMFs), giving it the ability to streamline formulation development and regulatory filings under APVMA standards.

AVet's proven capabilities in dossier preparation, pharmacovigilance, and lifecycle product management make it an ideal partner for the veterinary development of Paradigm's oral OA candidate.

### **Binding Terms**

Under the binding term sheet, AVet receives exclusive commercialisation rights for the product in Australia and New Zealand and a first right of refusal over all other territories excluding the United States. AVet will pay Paradigm up to A\$1 million in development milestone payments, including:

- A\$200,000 upon the earlier of execution of a definitive licensing agreement or one year from the signing of the binding term sheet;
- A\$300,000 upon successful completion of formulation (Stage 1); and
- A\$500,000 upon successful product registration with the APVMA.

Under the binding terms sheet, the parties agree to use best endeavours to execute a full definitive licensing agreement within 6 months. Once executed, this definitive agreement will have a fixed term of fifteen (15) years from the date of product registration with the APVMA.

Under the definitive licensing agreement, once executed, Paradigm will retain control over manufacture and will receive royalties on net product sales in the licensed territories as follows:

- 10 percent royalty on net sales up to A\$10 million;
- 20 percent royalty on net sales exceeding A\$10 million.

**Paradigm Managing Director Paul Rennie said:** *"We are pleased to formalise our partnership with AVet to initiate development of the PPS + COX-2 inhibitor combination in the veterinary setting. This agreement enables early generation of formulation and preclinical data that could support both a faster veterinary regulatory pathway via the APVMA and also provide data for our longer-term regulatory package in humans. Importantly, this is being done in a capital-efficient manner, allowing Paradigm to remain fully focused on our pivotal Phase 3 clinical trial of Zilosul® and ongoing commercial interest as we prepare for the interim analysis."*

**AVet Health Executive Chairman Mr Sanjiv Puri added:** *"AVet is excited to be working with Paradigm on this innovative dual-action product. With 95 veterinary products already registered in our portfolio, we bring extensive regulatory, development and commercial expertise to this partnership. We see significant unmet need in the veterinary market, particularly companion animal. AVet's internal market assessment of this exciting product may generate in excess of A\$10 million per annum in ANZ alone. We look forward to working collaboratively to bring this product to market."*

## Expanding the OA Pipeline into Veterinary Markets

Osteoarthritis remains a major cause of pain and reduced mobility in companion animals. Existing treatments, particularly NSAIDs, are limited in their ability to address underlying disease processes and carry long-term safety risks.

The oral PPS + COX-2 inhibitor combination seeks to address these unmet needs by:

- Reducing required NSAID doses, thereby lowering the risk of gastrointestinal, renal, and cardiovascular complications
- Modulating NGF expression, without full blockade (as seen with monoclonal antibodies like Librela)
- Supporting cartilage structure and slowing OA progression
- Providing an oral alternative to injectable PPS with easier at-home administration
- Addressing both chronic pain and acute flare-ups

Animal data generated through this collaboration may also be incorporated into Paradigm's broader regulatory package for its human OA pipeline, particularly in indications such as mild knee OA and hand OA.

This transaction extends Paradigm's reach into the multi-billion-dollar global veterinary pain and mobility market, with companion animals, particularly dogs, representing a significant segment of unmet need in osteoarthritis care. The global veterinary analgesics and anti-inflammatory market was valued at approximately USD 2.4 billion in 2024 and is projected to grow to around USD 4.6 billion by 2034, representing an approximate 6.5 percent compound annual growth rate (CAGR) over the forecast period<sup>2</sup>.

## Strategic Significance

This agreement complements Paradigm's broader strategy of addressing the full osteoarthritis Spectrum, from early-stage intervention (mild OA) to late-stage disease management (moderate-to-severe OA) via its human pipeline, including:

- **Zilosul® (injectable PPS)**: targeting moderate-to-severe knee OA, currently in global Phase 3 trial,
- **Pentacoxib™ (oral PPS + COX-2 inhibitor)**: targeting mild OA in human trials and veterinary applications.

The veterinary agreement builds non-dilutive value for shareholders while leveraging Paradigm's proprietary PPS platform, supporting commercial optionality ahead of key human data readouts in CY2026 and CY2027. The Company will provide further updates on the veterinary development program and any additional milestones achieved under the agreement.

## About Paradigm Biopharmaceuticals

Paradigm Biopharmaceuticals Ltd. (ASX: PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies. Paradigm's current focus is developing iPPS for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of PPS, such as in osteoarthritis (phase 3).

## Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments, and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

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Authorised for release by the Paradigm Board of Directors.

### References

<sup>1</sup> ASX release titled *"Paradigm Strengthens OA Pipeline with Strategic Acquisition"*, dated 26 June 2025.

<sup>2</sup> Precedence Research, *Veterinary Analgesics & Anti-Inflammatory Market Size & Share Report* (2025 edition), available at: <https://www.precedenceresearch.com/veterinary-analgesics-anti-inflammatory-market>

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