

## Partner search

**Company: Kimera Biotecnologia LTDA**

**CIF: 20.064.544/0001-24**

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### Short Company presentation

(R & D guidelines, international activities, etc.)

Founded in 2014 as a spin-off from the University of São Paulo (USP) at Ribeirão Preto, Kimera Biotecnologia is a pioneer in developing innovative biopharmaceuticals for the veterinary sector. Headquartered in the Supera Innovation and Technology Park, the company is led by Dr. Camillo Del Cistia Andrade, who has over 25 years of expertise in recombinant protein technology. Kimera's core mission is to provide the market with "Animal-Free" recombinant hormones, ensuring ethical production and superior biological safety for assisted reproduction protocols in livestock.

#### Research & Development (R&D) Guidelines

The company's R&D strategy is anchored in sustainability, efficiency, and animal welfare. Key guidelines include:

- **Technological Disruption:** Kimera replaces traditional extractive hormones often obtained through "blood farms" (serum from pregnant mares) or slaughterhouses (swine pituitaries) with recombinant DNA technology.
- **Superior Quality Standards:** The R&D process targets a purity level exceeding 95%, significantly reducing the risk of viral contaminants and endotoxins that typically cause uterine inflammation in treated animals.
- **Industrial Scalability:** Utilizing 50-liter bioreactors and CHO-K1 cell lines, Kimera's production is designed to be highly scalable, overcoming the physical limitations of animal-derived sources.
- **Regulatory Maturity:** The technology is currently transitioning from TRL 4 to TRL 8-9, with ongoing efforts to finalize registration with the Brazilian Ministry of Agriculture (MAPA) and compliance with Good Manufacturing Practices (GMP).

### Key Product Portfolio:

- r-eCG: A recombinant alternative to PMSG, used to induce and synchronize ovulation in cattle, swine, and goats.
- r-FSH: A laboratory-produced follicle-stimulating hormone intended to replace discontinued or extractive products.

### International Activities and Expansion

Kimera was established with a global vision, driven by increasing international pressure for ethical livestock practices:

- Intellectual Property: The company holds international patents (filed via PCT) in Brazil, Europe, and the USA, covering unique methods for producing and purifying recombinant glycoprotein hormones.
- Strategic Partnerships: Kimera maintains a virtual incubation at UPTEC (Porto, Portugal) and receives support from the United Kingdom Consulate to navigate European regulatory landscapes.
- The 2025 Market Opportunity: A critical driver for internationalization is the European Parliament's move to ban medications obtained through animal cruelty (effective January 2025), which will likely prohibit natural eCG and create a substantial market vacuum for Kimera's recombinant solutions.
- Target Markets: Beyond Europe, the company is targeting North America (USA and Canada) and Latin America (Argentina and Paraguay) due to their high demand for efficient reproductive technologies.

### Infrastructure and Expertise

Kimera operates a specialized biofactory certified by CTNBio, equipped with state-of-the-art laboratories for cell culture, purification, and quality control. The multidisciplinary team includes PhDs in biotechnology and specialists in regulatory affairs, ensuring that innovation translates effectively into commercial reality.

## **DESCRIPTION OF ITS TECHNOLOGY AND CAPABILITIES IN R & D**

**(Products, technologies, applications, services, etc.)**

### **1. Core Technology Platform**

Kimera's technological foundation is based on recombinant DNA technology, specifically the synthesis of glycoprotein hormones in laboratory environments.

- "Animal-Free" Production: Unlike traditional methods that rely on the extraction of hormones from the blood of pregnant mares (eCG/PMSG) or swine pituitary glands, Kimera produces these molecules using recombinant DNA technology.
- Superior Purification and Safety: This technology allows for a purity level exceeding 95%, significantly reducing the risk of viral contaminants and endotoxins that often cause uterine inflammation and infections in treated livestock.
- Proprietary IP: The company holds international patents (Brazil, USA, Europe) covering methods for producing and purifying hybrid and non-hybrid recombinant glycoprotein hormones.

### **2. Main Products**

The company's portfolio addresses critical gaps in the animal reproduction market caused by ethical concerns and product discontinuations:

- r-eCG (Recombinant Equine Chorionic Gonadotropin): An ethical alternative to PMSG, used to induce and synchronize ovulation in cattle, swine, and goats.
- r-FSH (Recombinant Follicle-Stimulating Hormone): A laboratory-synthesized hormone designed to replace swine-extractive FSH, critical for superovulation protocols in embryo transfer (TE) and In Vitro Fertilization (IVF).
- Additional Molecules: The technology platform can produce other glycoproteins like r-LH (Luteinizing Hormone) and r-TSH (Thyroid-Stimulating Hormone).

### **3. Applications in Animal Production**

Kimera's products are applied across various assisted reproduction protocols to increase fertility and productivity:

- Cattle (Beef and Dairy): Optimization of IATF (Fixed-time Artificial Insemination), TETF (Fixed-time Embryo Transfer), and IVF, improving pregnancy rates and genetic gain.

- Swine and Goats: Enhancing litter size and reducing the weaning-to-estrus interval (WEI).
- Genetic Improvement: Providing high-performance hormones for superovulation and embryo production programs.

#### **4. R&D Capabilities and Infrastructure**

Kimera operates a specialized infrastructure designed for high-standard biotechnological development:

- Biofactory and Labs: Located at the Supera Innovation Park, the facility includes a P&D and Quality Control (CQ) lab and an ISO 7 (Class 10,000) cleanroom biofactory.
- Advanced Equipment: The company utilizes 50-liter bioreactor, tangential filtration systems, automated cell counters, and chromatography systems (HPLC) for large-scale production and purification.
- Validation Expertise: Capabilities include performing in vitro bioactivity assays and in vivo field tests (in cattle and swine) to evaluate hormonal dynamics and safety.
- Certifications: The infrastructure is certified by CTNBio (Biosafety) and is in the final stages of approval by the Ministry of Agriculture (MAPA) to produce injectable hormones.

#### **5. Services Offered**

Beyond its own product line, Kimera leverages its expertise to provide high-tech services:

- P&D Services: Contract research for the development of new recombinant molecules for animal health and nutrition.
- Bio-manufacturing: Providing manufacturing and bottling services for recombinant proteins in its certified plant.

## PROPOSED COLLABORATIVE PROJECT IN R & D

(As much detail as possible, both in what it offers and what you want in a potential partner)

**Proposed Project Title:** *Animal-Free Recombinant eCG for Sustainable Bovine and Swine Reproduction.*

### 1. Technology Offered to International Partners

Kimera Biotecnologia offers a patented technology platform to produce recombinant hormones, specifically **r-eCG (recombinant Equine Chorionic Gonadotropin)**, providing a superior alternative to traditional extractive methods.

- **"Animal-Free" Ethics:** Production is 100% laboratory-based, eliminating the need for "blood farms" (bleeding pregnant mares) and induced abortions.
- **Superior Purity & Safety:** The technology ensures a **purity level >95%**, removing serum proteins, viral contaminants, and endotoxins that typically cause uterine inflammation and infections in treated sows and cows.
- **Industrial Scalability:** One liter of lab production replaces the hormone yield of 10 pregnant mares.
- **Physicochemical Stability:** Unlike competitors requiring lyophilization, Kimera's hormone is presented in a **stable, liquid, "ready-to-use"**, reducing production costs and field handling complexity.
- **Proven Field Performance:**
  - **Bovine:** Extensive field tests (~2,000 animals) demonstrating equivalent or superior efficiency to natural eCG in IATF and superovulation protocols.
  - **Swine:** Documented increments of **1.5 live piglets per litter** in young sows, generating a financial return of **US\$ 4.00 for every dollar invested**.

### 2. International Partnership

Kimera seeks a Spanish partner (Veterinary Pharmaceutical Industry or Research Center) to facilitate the leap into the European market, focusing on:

- **Regulatory Navigation (EMA/Spanish Authorities):** Expertise in navigating the European Medicines Agency (EMA) and local Spanish regulatory dossiers for the registration of recombinant biological products.
- **Localized Clinical Validation:** Conducting localized field trials in Spain to validate the performance of r-eCG across specific European breeds and environmental conditions for both beef/dairy cattle and swine.

- **Industrial Co-Development:** Scaling production or bottling processes within the EU to meet local Good Manufacturing Practices (GMP) and logistics standards.
- **Market Penetration & Distribution:** Access to established distribution networks in Spain and the broader EU to capitalize on the upcoming regulatory shift.

### 3. Specifications, Requirements, or Comments

- **The 2025 Regulatory Deadline:** The European Parliament has approved a ban on the sale of medications derived from animal cruelty (extractive PMSG) effective **January 2025**. This creates an immediate market vacuum that this project is designed to fill.
- **Intellectual Property:** Kimera holds international patent protection (PCT/BR-10-2016006222-5) covering the production and purification of hybrid and non-hybrid recombinant hormones in Brazil, Europe, and the USA.
- **Academic Synergy:** Kimera is a spin-off of the **University of São Paulo (USP)**, ensuring continuous R&D support and scientific rigor.
- **Existing Network:** Kimera is already involved with the **SPIN network** (cooperation between Universities of Spain, Portugal, and Latin America) and maintains a virtual incubation at **UPTEC** (Portugal).

### 4. Proposed Collaborative Project

The overarching objective of this collaboration is the co-development and European regulatory alignment of Kimera's recombinant eCG (r-eCG), enabling its registration and commercialization in the European Union, with Spain as the initial reference market.

The project is structured to leverage Brazilian biotechnological production of the active pharmaceutical ingredient (API) while finalizing product formulation, regulatory positioning, and clinical validation in Europe, in full compliance with EU veterinary medicinal product regulations and EMA/CVMP expectations.

The desired partner may contribute to one or more of the following work packages.

#### I. Regulatory Alignment & Technical Dossier (Co-Development Phase)

- Joint assessment of EU and Spanish regulatory requirements applicable to recombinant veterinary hormones, including centralised procedure eligibility and MRL considerations.
- Co-development and finalization of the finished product formulation in Europe, using the Brazilian-produced API, to ensure full alignment with EU CMC, stability, and quality expectations.
- Generation of EU-compliant stability data for the final "ready-to-use" liquid formulation under relevant ICH/VICH climatic zones.

- Evaluation of intellectual property opportunities arising from process, formulation, or regulatory adaptations developed during the European phase (e.g., Certificates of Addition or equivalent filings).

## **II. Local Clinical and Field Validation in Spain**

- Swine Segment: Field trials in intensive Spanish swine production systems to confirm reduction of the weaning-to-estrus interval and increase in litter size (target: +1.0 to +1.5 piglets).
- Bovine Segment: Validation of r-eCG in Spanish dairy and beef cattle within IATF protocols, benchmarking pregnancy rates against current market standards (target: >50%).
- Safety Monitoring: Confirmation of the absence of adverse effects typically associated with extractive PMSG, including uterine inflammation and allergic reactions.

## **III. European Manufacturing Integration & GMP Readiness**

- Evaluation of European manufacturing pathways, including technology transfer of the recombinant API process and/or contract manufacturing models suitable for EU regulatory expectations.
- Adaptation and final validation of the purification and formulation steps to ensure batch-to-batch consistency, traceability, and GMP compliance for the European market.
- Definition of the long-term manufacturing and quality strategy supporting EMA submission and post-authorisation supply.

## **IV. Commercial Strategy & ESG-Driven Market Entry**

- Development of a joint go-to-market strategy positioning r-eCG as a non-extractive, animal-free, and cruelty-free alternative to traditional PMSG, aligned with European ESG and animal welfare standards.
- Integration into distribution channels serving Spanish cooperatives, integrators, and large-scale livestock producers, with scalability to other EU member states following authorization.

### **General comments:**

- By sending this information, I authorize its dissemination.
- A company profile must be attached or a link to the company's website must be provided: <https://www.kimerabiotech.com/en>