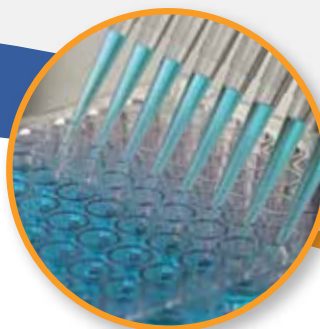




**An Innovative Oral Drug  
Technology for Peptides  
and Small Molecules**





## About Enteris

Enteris BioPharma is a privately held, New Jersey based company with an innovative formulation solution derived from our proprietary delivery technology. The acquisition of strategic and clinically proven platform technology combined with our expert staff has positioned Enteris BioPharma as an industry leader in innovative oral dosage formulation.



Our innovative formulation solutions enable the oral delivery of BCS class II, III, and IV compounds, including peptides, in an enteric coated tablet.

## Overcoming the Challenge

Advanced oral delivery of peptides and challenging small molecules has two key challenges: solubility and permeability. Enteris' formulations utilize a unique combination of functional excipients. One class of excipient solves solubility issues, while together these combined excipients successfully address permeability to increase the systemic absorption of the active pharmaceutical ingredient.

**Enteris' unique oral delivery technology enables the development of formulations that are:**

- *Clinically proven*
- *Cost effective*
- *Easily manufactured*
- *Evaluated in a rapid Proof of Concept model*
- *Released into the clinic*



## Achieving Oral Delivery

As your partner for oral formulation, our team is experienced in applying our clinically validated oral delivery technology to client's peptides and challenging small molecules. Our technology solutions to oral drug delivery are easily scalable and compatible with multiple formulation and manufacturing processes.

Within our state of the art cGMP facility, we can support your formulation and Phase 1 — 2 clinical development programs for the US, EU and the rest of the world. From process development through GMP manufacture in our dedicated manufacturing suites, Enteris offers full quality and regulatory support for your products. This includes raw material testing, final product release, optimization and validation, and stability studies.

By partnering with Enteris, you leverage robust IP protection, regulatory CMC support and finished, solid dosage formulations for preclinical and early phase clinical studies to ensure the success of your projects.

## Mechanism of Delivery

Enteris BioPharma has proven ability to effectively deliver a variety of molecules across multiple therapeutic indications. Our clinically proven, cutting edge formulation technology enables the oral delivery of BCS class II, III and IV compounds, including peptides, in an enteric-coated tablet formulation. Enteris' formulation technology is made up of two key components, the first being a permeation enhancer which loosens tight junctions in the intestinal enterocytes and allows paracellular transport. The permeation enhancer, being a surfactant, acts as an excellent solubilizing agent. The second main excipient acts as an enzyme inhibitor and also plays an active, multifunctional role in transport by acting as a calcium chelator and membrane permeation enhancer, a pH lowering agent that increases absorptive flux, and a membrane wetting/charge dispersal agent.

**Enteris' Mechanism of Delivery is summarized in four key steps:**

- 1** Enteric Coating provides protection from the tablet opening in the low pH of the stomach
- 2** The Enteric Coat dissolves at a neutral pH targeting the small intestine
- 3** Protease inhibitors, Permeability Enhancers and API are released
- 4** API is absorbed across the intestinal wall via paracellular transport

## Peptelligence™ Internal and External Pipeline

Candidate	Preclinical	Phase 1	Phase 2	Phase 3	Sponsor
Ovarest™ (oral leuprolide tablet)	Endometriosis				enteris BIOPHARMA
Tobrate™ (oral tobramycin tablet)	uUTI				enteris BIOPHARMA
TBR1A™	Osteoporosis				TARSA Therapeutics
CR845	Chronic Pain; Osteoarthritis & Pruritus				CARA Therapeutics
GLP-1 analogs	Type 2 Diabetes				External Programs (undisclosed)
Peptides & Small Molecules	Urology, Gynecology, Other				External Programs (undisclosed)

## Clinically Validated

Enteris has demonstrated a simple proof of concept model with a track record of clinical success across a range of compounds and therapeutic indications. Multiple clinical studies have been carried out with peptides utilizing our proprietary technology including:

- Positive Phase 3 oral Calcitonin: Osteoporosis
- Positive Phase 2 oral PTH: Osteoporosis
- Positive Phase 2 oral Calcitonin: Osteopenia
- Positive Phase 2a oral CR845: Osteoarthritis

**Make Enteris BioPharma your partner of choice for oral delivery**



**For more information about working with Enteris, please contact:**

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