Q3 2024 NASDAQ: ENTO



# **Targeted Therapies for Gastrointestinal Diseases**

### **Corporate Overview**

Entero Therapeutics is a clinical-stage biopharmaceutical company specializing in the development of targeted, non-systemic therapies for gastrointestinal (GI) diseases.

The company is currently advancing a therapeutic development pipeline with multiple late-stage clinical programs built around three proprietary technologies: **latiglutenase**, a Phase 3-ready, potentially first-in-class, targeted, oral biotherapeutic for celiac disease; **capeserod**, a selective 5-HT4 receptor partial agonist being developed for gastroparesis; and **adrulipase**, a recombinant lipase enzyme designed to enable the digestion of fats and other nutrients in cystic fibrosis and chronic pancreatitis patients with exocrine pancreatic insufficiency.

# **Clinical Pipeline**

Product/Indication Pre-IND Phase 1 Phase 2 Phase 3

### **LATIGLUTENASE**

Celiac Disease	Phase 3 Ready

## **CAPESEROD**

Gastroparesis	Phase 2 Anticipated

## **ADRULIPASE**

Exocrine Pancreatic Insufficiency Monotherapy	Phase 2b Completed
Exocrine Pancreatic Insufficiency Combination w/ PERT	Phase 2a Completed

# **Technologies**

# Latiglutenase

Orally administered, Phase 3 ready, recombinant digestive enzyme therapy to treat celiac disease

- Acquired from ImmunogenX in Mar. 2024
- Demonstrated effectiveness in alleviating symptoms of celiac disease in two Phase 2 trials

# Capeserod

Re-purposed selective 5-HT4 receptor partial agonist for gastrointestinal indications

- In-licensed from Sanofi in Sept. 2023
- Unique mechanism of action applicable to several GI indications
  - Gastroparesis
  - Pediatric Ulcerative Colitis
  - Constipation

# Adrulipase

Recombinant lipase enzyme administered as an oral, nonsystemic biologic capsule for the treatment of EPI

- Non-porcine recombinant alternative
- Designed as a potential improvement over PERT
  - PERT can require upwards of 40 pills per day

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# Targeted, Non-Systemic Therapies for Gastrointestinal Diseases

# **Therapeutic Indications**

#### Celiac Disease

- Celiac disease (CeD) is an autoimmune disorder of the small intestine resulting from intolerance to gluten proteins, afflicting nearly 1% of most population (~3.3 million patients in the U.S.)
- The principal physiology is villous atrophy in the small intestinal epithelium triggered by the ingestion of cereal grains, such as wheat, rye, or barley
- CeD has no known cure and the only effective therapy is adherence to a lifelong gluten-free diet



### Gastroparesis

- Gastroparesis is the delayed movement of food from the stomach to the small intestine, not caused by blockage. Symptoms include feeling full soon after starting a meal or long after completing one, as well as nausea, and vomiting.
- Gastroparesis impacts approximately 50 in 100,000 people and is more common in women



# Exocrine Pancreatic Insufficiency (EPI) in Cystic Fibrosis

- EPI affects 40,000 cystic fibrosis patients and 95,000 chronic pancreatitis patients in the U.S.
- High daily PERT pill burden with CF patients currently taking 25 to 40 capsules daily to control symptoms; safety concerns with black box warnings for PERT therapy (risks of fibrosing colonopathy and transmission of animal pathogens)



## **Clinical Development Plans & Milestones**

Product	Indication	2023	2024	2025	2026	2027
Latiglutenase	Celiac disease			Phase 3	I)Osing	Phase 3 Safety  BLA
Capeserod	Gastroparesis			Phase	e 2*	
Adrulipase	EPI in CF, CP	Phase 2b				

<sup>\*</sup>Subject to FDA IND review

### **Executive Management Team**

James Sapirstein Chairman and CEO

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