



Targeted Therapies for Gastrointestinal Diseases

Corporate Overview

First Wave BioPharma 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; **capaserod**, 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, non-systemic 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



Targeted, Non-Systemic Therapies for Gastrointestinal Diseases

Therapeutic Indications

Celiac Disease

- Celiac disease (CD) 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
- CD 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 Dosing	Phase 3 Safety ★ BLA
Capeserod	Gastroparesis				Phase 2*	
Adrulipase	EPI in CF, CP			Phase 2b		

*Subject to FDA IND review

Executive Management Team

James Sapirstein	Chairman and CEO
Jack Syage, Ph.D.	President and CSO
Sarah Romano	Chief Financial Officer
Martin Krusin	SVP, Corporate Development

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