



Targeted, Non-Systemic Therapies for Gastrointestinal Diseases

Corporate Overview

First Wave BioPharma, Inc. is a clinical stage biopharmaceutical company specializing in the development of targeted, non-systemic therapies for gastrointestinal (GI) diseases. The Company's pipeline is highlighted by two gut-restricted GI clinical programs.

The company is currently advancing a therapeutic development pipeline populated with multiple clinical stage programs built around its two proprietary technologies - adrulipase, a recombinant lipase enzyme biologic designed to enable the digestion of fats and other nutrients, and niclosamide, an oral small molecule with anti-inflammatory properties.

Clinical Pipeline

	Product/Indication	Pre-IND	Phase 1	Phase 2	Phase 3
ADRULIPASE	FW-EPI: Exocrine Pancreatic Insufficiency	Phase 2 with enteric granule formulation expected to initiate 2H 2022			
	FW-EPI + PERT: Exocrine Pancreatic Insufficiency	Reported positive results from Phase 2 clinical trial in Q2 2021			
NICLOSAMIDE	FW-UP: Ulcerative Proctitis / Proctosigmoiditis	Phase 2 initiated Q3 2021			
	FW-IC-AC: Immune Checkpoint Inhibitor-Associated Colitis	Phase 2 IND clearance in Q4 2021			
	FW-UC: Ulcerative Colitis	File IND			
	FW-CD: Crohn's Disease	File IND			

Technologies

Adrulipase

Recombinant lipase enzyme administered as an oral, non-systemic biologic capsule for the treatment of EPI

- Designed as a potential improvement over porcine-derived PERT (pancreas enzyme replacement therapy)
- Development strategy: provide CF and CP patients with a safe and effective therapy to control EPI that offers the potential to dramatically reduce their daily pill burden
 - PERT can require upwards of 40 pills per day
- EPI is a condition characterized by deficiency of the exocrine pancreatic enzymes, resulting in a patient's inability to digest food properly, or maldigestion

Niclosamide

Oral small molecule with anti-inflammatory properties

- FDA-approved drug (1982) that has been safely used on millions of patients worldwide
 - Listed as an essential medicine by the World Health Organization (WHO)
- Patented micronized formulation improves beneficial properties while maintaining safety profile
- First Wave BioPharma is currently advancing programs in four GI-indications



Therapeutic Indications

Exocrine Pancreatic Insufficiency (EPI) in Cystic Fibrosis

- EPI affects 30,000 cystic fibrosis patients and 90,000 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)



Ulcerative Proctitis / Proctosigmoiditis (UP/UPS)

- UP and UPS are two types of ulcerative colitis. UPS causes inflammation in the colon and rectum, while UP is confined only to the rectum
- UP and UPS can occur at any point throughout life, with a high occurrence in young children and then again around 40-50 years of age



Immune Checkpoint Inhibitor-Associated Colitis (ICI-AC)

- Use of immune checkpoint inhibitors (ICIs), particularly higher dose and combinations of ICIs, can cause potentially life-threatening side-effects, including ICI-AC
- Patients who exhibit these issues can become severely debilitated and risk interrupting or stopping their cancer therapy



Ulcerative Colitis (UC)

- UC is an inflammatory bowel disease (IBD) that causes irritation, inflammation, and ulcers in the lining of the colon
- In 2020, it was estimated that there were more than 825,000 UC diagnoses in the U.S. That figure is expected to increase to more than 850,000 by 2026



Crohn's Disease (CD)

- CD is an IBD that causes chronic inflammation of the gastrointestinal tract. Inflammation caused by Crohn's disease can involve different areas of the digestive tract in different people
- In 2020, it was estimated that there were more than 625,000 Crohn's disease diagnoses in the U.S. That figure is expected to increase to more than 810,000 by 2026



Executive Management Team

James Sapirstein	President, CEO and Chairman
Sarah Romano	Chief Financial Officer
James Pennington	Chief Medical Officer
Martin Krusin	SVP, Corporate Development

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