



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 - niclosamide, an oral small molecule with anti-viral and anti-inflammatory properties, and adrulipase, a recombinant lipase enzyme biologic designed to enable the digestion of fats and other nutrients.

Clinical Pipeline

	Product/Indication	Pre-IND	Phase 1	Phase 2	Phase 3
NICLOSAMIDE	FW-COV: COVID-19 GI Infection			Phase 2 RESERVOIR actively enrolling	
	FW-UP: Ulcerative Proctitis / Proctosigmoiditis			Phase 2 initiated in Q3 2021, actively enrolling	
	FW-IC-AC: Immune Checkpoint Inhibitor-Associated Colitis			Phase 2 IND clearance in Q4 2021	
	FW-UC: Ulcerative Colitis			Clinical program expected to initiate in 2022	
	FW-CD: Crohn's Disease			Clinical program expected to initiate in 2023	
ADRULIPASE	FW-EPI: Exocrine Pancreatic Insufficiency			Phase 2 expected to initiate by mid-2022	
	FW-EPI + PERT: Exocrine Pancreatic Insufficiency			Reported positive results from Phase 2 clinical trial	

Technologies

Niclosamide

Oral small molecule with anti-viral and 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 six GI-indications

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



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Therapeutic Indications

COVID-19 GI Infection

- SARS-CoV-2, the virus that causes COVID-19, has been shown to remain in the GI system following infection, leading to recurrence and fecal spread of the virus
- Data suggests that 18% of acute COVID-19 patients develop GI symptoms and almost 50% have viral RNA in their stool; ~10% of COVID patients continue to have symptoms 6+ months after infection; ~60% of these "Long COVID" patients have recurring GI infection/diarrhea



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



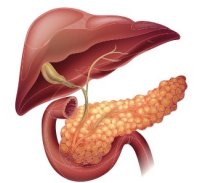
Crohn's Disease (CD)

- 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



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)



Executive Management Team

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Daniel Schneiderman	Chief Financial Officer
James Pennington	Chief Medical Officer
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