



**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 trial initiated Q2 2021, actively enrolling			
	FW-UP: Ulcerative Proctitis / Proctosigmoiditis	Phase 2 initiated Q3 2021, actively enrolling			
	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			
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			

## 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 43% 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



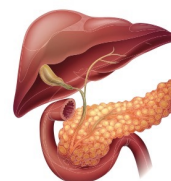
### Crohn's Disease (CD)

- 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

<b>James Sapirstein</b>	President, CEO and Chairman
<b>Daniel Schneiderman</b>	Chief Financial Officer
<b>James Pennington</b>	Chief Medical Officer
<b>Martin Krusin</b>	SVP, Corporate Development

## Investor / Media Contacts

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