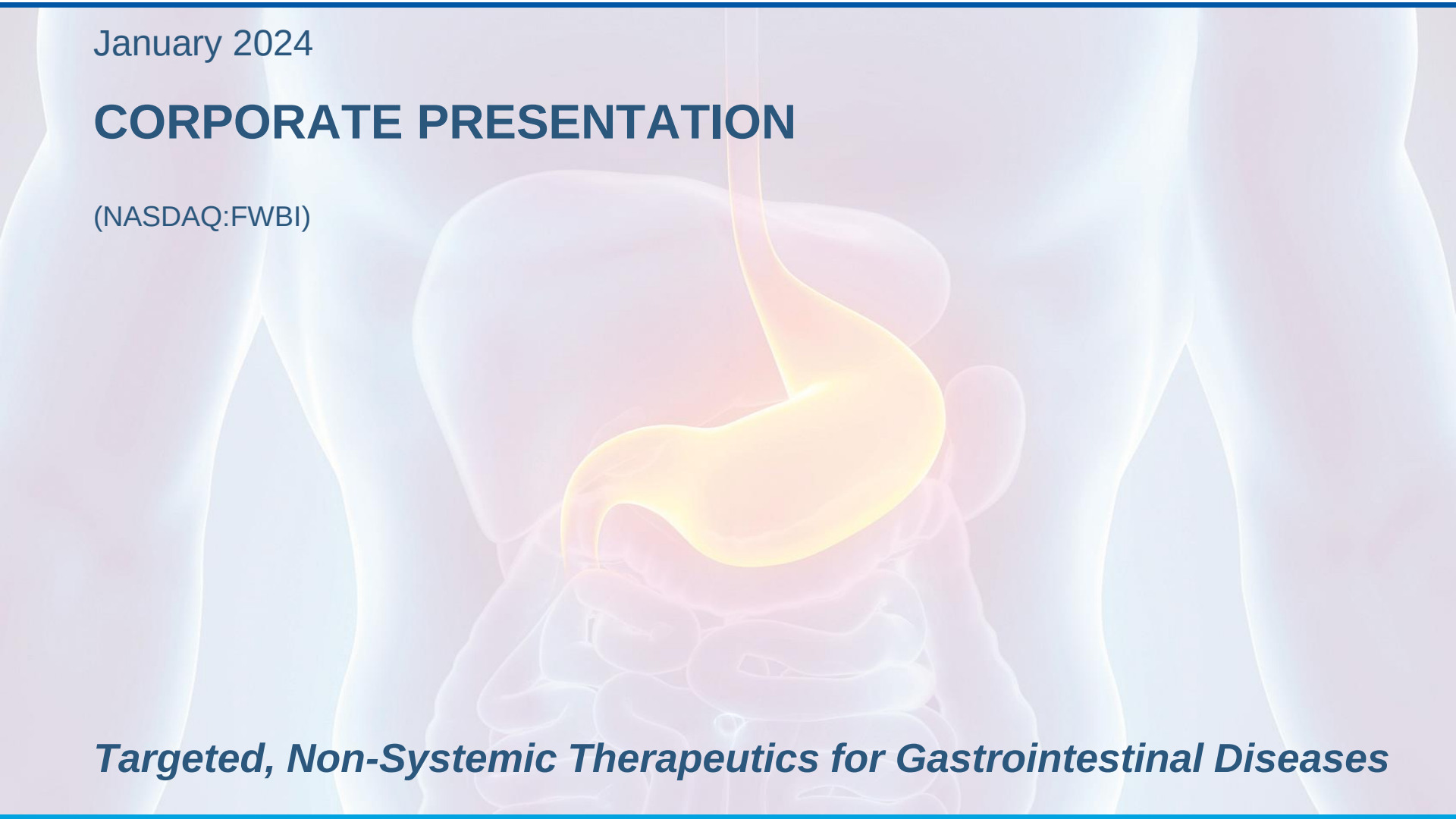
January 2024

CORPORATE PRESENTATION

(NASDAQ:FWBI)



Targeted, Non-Systemic Therapeutics for Gastrointestinal Diseases

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Overview
Three therapeutic assets and multiple Phase 2-ready clinical indications

First Wave BioPharma is a clinical stage biotechnology company currently focused on the development of targeted, non-systemic therapies for gastrointestinal diseases

ADRULIPASE

Recombinant enzyme; lipase biologic for the treatment of Exocrine Pancreatic Insufficiency (EPI)

- EPI in Cystic Fibrosis (CF) and Chronic Pancreatitis (CP); new enteric microgranule formulation
- Phase 2 Bridging Study initiated Jan. 2023, topline data 2H'23

CAPESEROD

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

- Asset in-licensed from Sanofi
- Phase 2 Gastroparesis trial initiation anticipated in 2025

NICLOSAMIDE

Re-purposed small molecule drug with potent anti-inflammatory properties, proprietary micronized formulation

- IBD: Ulcerative Colitis-Proctitis and Immune Checkpoint Inhibitor-Associated Colitis
- Non-Binding Term Sheet Signed for Sale of Niclosamide Asset (December 2023

Robust IP portfolio covering method, formulation and use indications; key patents secure for 15-20 years

Pipeline of gut-targeted GI therapies address significant unmet medical needs in billion-dollar markets

First Wave BioPharma Management Team

Combined Experience in Developing and Launching more than 25 Drugs

James Sapirstein

Chief Executive Officer

serono biotech & beyond

TOBIRA THERAPEUTICS

Lilly

GILEAD

Roche

Bristol-Myers Squibb

- Led Gilead's launch of Tenofovir/ Viread
- Director of BMS International Infectious Disease Group
- Founder of Tobira, sold to Allergan for $1.7B

Sarah Romano

Chief Financial Officer

Martin Krusin

SVP Corporate Development

First Wave BioPharma

First Wave BioPharma

ADRULIPASE

Exocrine Pancreatic Insufficiency in Cystic Fibrosis & Chronic Pancreatitis

CAPESEROD

New GI Orphan Disease Opportunity In-Licensed from Sanofi

NICLOSAMIDE

Non-Steroidal, Anti-Inflammatories for Mild-to-Moderate IBD

Adrulipase: Exocrine Pancreatic Insufficiency (EPI)

A chronic nutritional deficiency – the pancreas is damaged and does not produce the digestive enzymes needed to break up food in the GI tract so that nutrients can be absorbed

EPI related morbidities

- Poor fat absorption
- Unable to gain or retain weight
- Frequent bowel movements & diarrhea
- Abdominal discomfort and pain

Focus on two patient populations requiring treatment for EPI

Cystic Fibrosis

Genetic disease

- **~40,000 patients U.S., ~100K-160K* worldwide**
- Treatment begins for patients in first six months of life

Chronic Pancreatitis

Heterogeneous disease

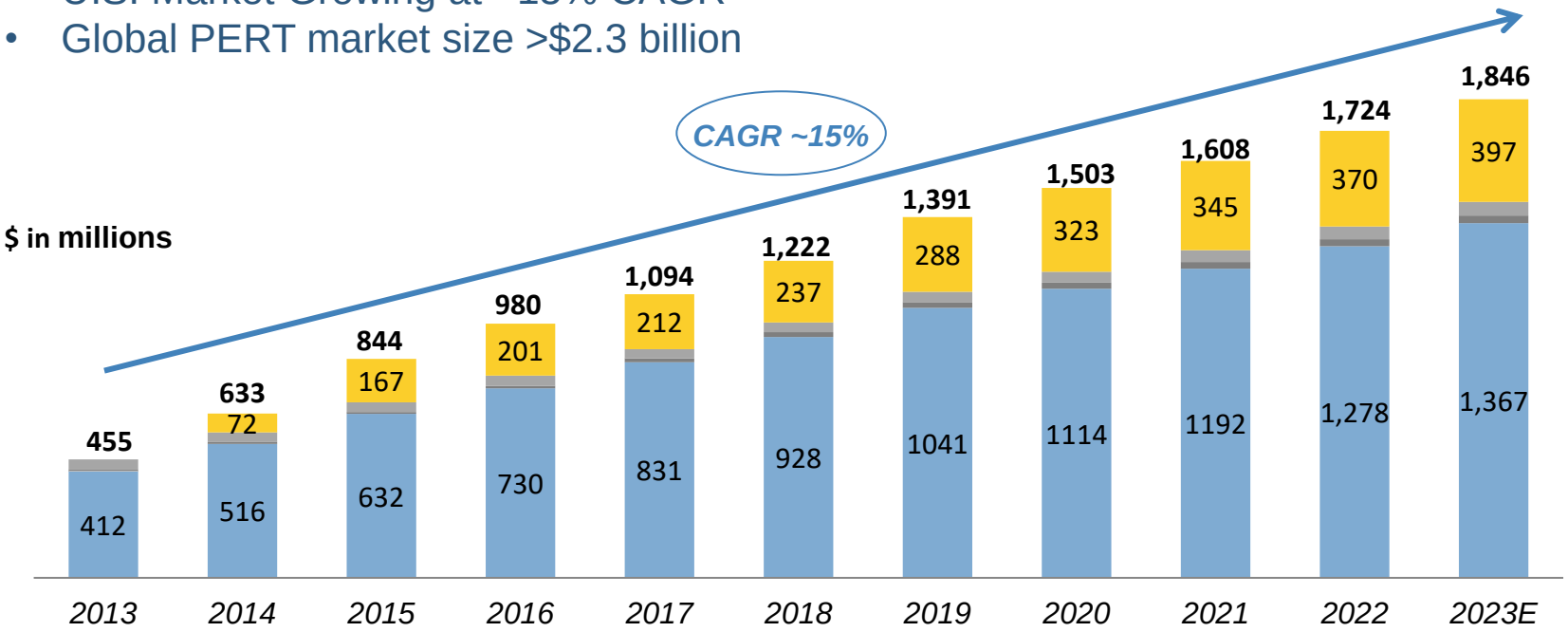
- **~95,000 patients U.S., ~450K-600K worldwide**
- Alcoholism
- Pancreatic cancer
- Pancreatic surgery

Sources: Guo, J. Worldwide rates of diagnosis and effective treatment for cystic fibrosis, Journal of Cystic Fibrosis 21(2022) 456-462 – estimate of ~ 60K undiagnosed individuals with CF. Cystic Fibrosis Foundation 2023. The CorStar Group 2019.

Adrulipase: Large Established U.S. Market Of ~$1.8 Billion(1)

All lipase products are pig derived and are less active at the pH in humans resulting in a large pill burden

- U.S. Market Growing at ~15% CAGR
- Global PERT market size >$2.3 billion

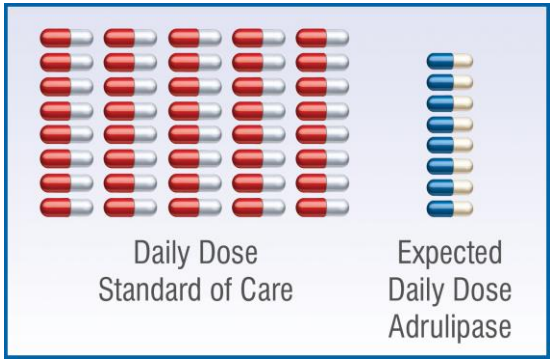


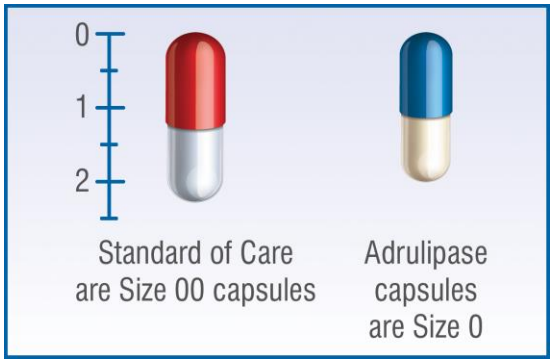
Top 4 PERT Players U.S.)
Creon (AbbVie)
Zenpep (Nestle)
Pancreaze (Vivus)
Pertzye (Chiesi)

Sources: Global Market Size: Symphony Health 2019. The CorStar Group (2019). U.S. Market Size: Creon 2013-2023 AbbVie 10-K's, 2021 Mgmt. Estimate; Zenpep, Allergan 2014-2020 10-Ks, 2021 Mgmt. Estimate; Vivus and Pertzye.

Adrulipase: Fulfilling an Unmet Medical Need

	PERT	ADRULIPASE
Drug Substance	▪ **Porcine-derived** pancreatic enzyme replacement therapy (PERT)	▪ **Recombinant yeast** (*Yarrowia lipolytica*) lipase-derived replacement therapy
Safety	▪ **Adverse event: fibrosing colonopathy at high doses** ▪ FDA black box warning ▪ ~30% of CF patients are not well controlled on PERT	▪ **Safe and well tolerated to date** ▪ No fibrosing colonopathy ▪ No porcine allergies
Pill Burden	▪ **25-40 pills per day (CF)**	▪ **5-8 pills per day (CF)**
Sourcing & Supply	▪ Subject to pig herd management ▪ ***Risk of transmission of animal pathogens*** ▪ Manufacturing + supply chain inconsistency	▪ GRAS (Generally Regarded as Safe) ▪ ***No risk of animal pathogens*** ▪ Manufacturing + supply chain consistency



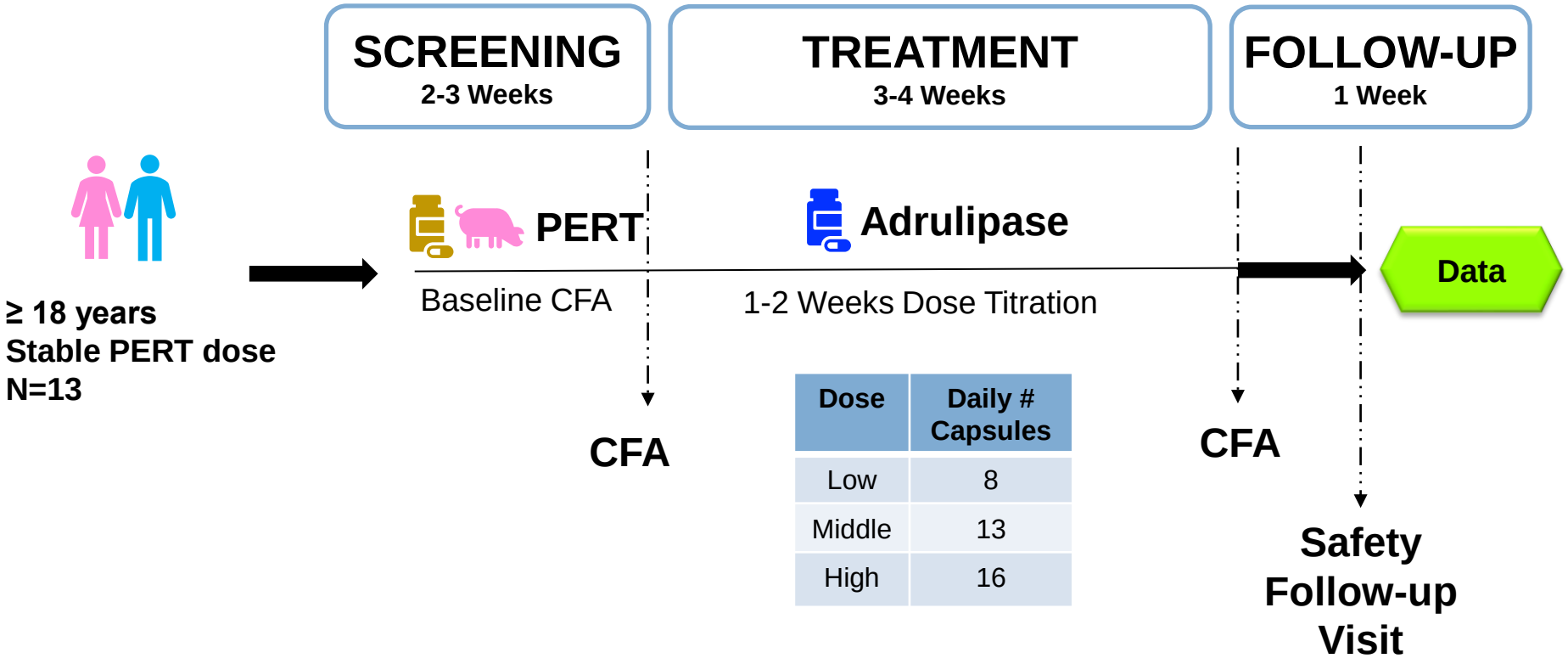


Differentiated mechanism of action | **No dose-limiting safety issues to date on ~100 patients**

Sources: Results from the Company's clinical trials, internal studies and management estimates.

Adrulipase: Phase 2 SPAN Bridging Study
Trial Initiated Jan. 2023, Completed July 2023

A Phase 2, Open Label, Multicenter, Pilot Study to Assess Safety and Efficacy of an Enteric Microgranule Formulation of Adrulipase in Patients with Exocrine Pancreatic Insufficiency (EPI) due to Cystic Fibrosis (CF)



Dose	Daily # Capsules
Low	8
Middle	13
High	16

Adrulipase: Summary

- Targeting patients with **Cystic Fibrosis (CF)** and **Chronic Pancreatitis (CP)**
- Addressing an established PERT global market (>$2 billion)

- **Recombinant alternative to porcine pancreatic enzyme replacement therapy (PERT)**

- **A safer and more convenient therapy with a reduced daily pill burden**

- **Pursuing parallel monotherapy and combination therapy clinical pathways**

- **New enteric microgranule formulation developed**
- **Phase 2 bridging study completed, topline data July 2023**
- **FDA Type-C Meeting request to be scheduled in Q1’24**

SPAN
ADRULIPASE BRIDGING STUDY

First Wave BioPharma

Capeserod: Unique Mechanism of Action Applicable to New GI Indications

- Capeserod, a selective 5-HT4 receptor partial agonist small molecule, was in-licensed from Sanofi in September 2023
- In previous Sanofi Phase 1 and Phase 2 CNS trials, involving over 600 patients, Capeserod appeared safe and well-tolerated
- Research on Capeserod and subsequent artificial intelligence (AI)-empowered analyses suggest that the drug possesses a unique prokinetic mechanism of action that increases gastric motility that is applicable to several GI indications underserved by currently available therapeutics in multi-billion dollar markets.
- First Wave will repurpose Capeserod for gastrointestinal (GI) indications, and plans to initiate a Phase 2 gastroparesis clinical development program
- Sanofi retains the right of first refusal (ROFR) to develop and commercialize Capeserod

Niclosamide: Significant Unmet Need in IBD

Large Multi-Billion Dollar Mild-to-Moderate IBD Market Opportunity

- Large Mild-to-Moderate market size (U.S.)[2]

Mild-to-Moderate	Prevalence	Market Size
Ulcerative Colitis	~700K	$4.6B
Crohn's Disease	~500K	$4.3B

- Current mild-to-moderate treatments are ineffective: 5-ASA (oral, rectal, or both together) in the hope of inducing and maintaining remission

- Remission fails to occur in patients all too often
  - *~54% fail remission with oral 5-ASA[3]*
  - *~59% fail remission with rectal 5-ASA[4]*

[1] Crohns and Colitis Foundation 2022
[2] GlobalData Ulcerative Colitis Global Drug Forecast and Market Analysis to 2026: US Adults. 2018; GlobalData Crohn's Disease Global Drug Forecast and Market Analysis to 2029: US. 2020
[3] Wang, Y. et al. Oral 5-aminosalicylic acid for induction of remission in ulcerative colitis. *Cochrane Database of Systematic Reviews*. August 2020.; Feagan, B. and Macdonald, J. Oral 5-aminosalicylic acid for induction of remission in ulcerative colitis. *Cochrane Database Syst Rev.* 2012 Oct 17;10:CD000543.
[4] Ham, M. and Moss, C. Mesalamine in the treatment and maintenance of remission of ulcerative colitis. Expert Rev Clin Pharmacol. 2012 Mar; 5(2): 113–123.

Niclosamide: Ideal profile for a GI-targeted agent
Multiple Phase 2 ready IBD indications

- **FDA approved (1982) small molecule anthelmintic drug used for intestinal tapeworm infections; clean safety history**
- **Low oral bio-availability with minimal systemic exposure**
  - Pharmacology ideal for local bowel disease; not absorbed from GI tract
- **Niclosamide inhibits pro-inflammatory pathways**
  - Mechanism of action is to impair oxidative phosphorylation
  - Non-steroidal anti-inflammatory option
  - Opportunities for combinations with standard of care for multiple indications without systemic immunosuppression
- **Data from Phase 1b study of niclosamide in ulcerative proctitis/proctosigmoiditis (UP/UPS) shows promising results**
  - Clinical remission efficacy of 59% compares favorably to steroids (38-44% remission rate for budesonide)
- **Niclosamide IP portfolio purchased in 2021**
  - Multiple Phase 2 ready IBD indications (UP/UPS, Ulcerative Colitis, Immune-Checkpoint Inhibitor-Associated Colitis)

Three therapeutic assets and multiple Phase 2-ready clinical indications

Program	Preclinical	Phase 1	Phase 2	Phase 3	Next milestone
Adrulipase					
Monotherapy (FW-EPI)	**Exocrine pancreatic insufficiency in cystic fibrosis – enteric microgranule formulation** Phase 2 Bridging Study				**FDA Type-C Meeting Request 1H'24***
Combination (FW-EPI+ PERT)	**Severe exocrine pancreatic insufficiency in cystic fibrosis** Phase 2 Topline data: Q3'21				
Capeserod					
	Gastroparesis				Phase 2a Initiation*
Niclosamide					
FW-UP	**IBD: Ulcerative colitis-proctitis** Phase 2 Initiation: Q3'21				Phase 2 Topline data: 2H'22
FW-ICI-AC	**Immune checkpoint inhibitor colitis** Phase 2 IND clearance: Q4'21				Phase 2a Initiation*

* Anticipated