March 2024

- **First Wave BioPharma Merger with ImmunogenX**
- **Business Combination Creates A Best-In-Class, Late-Stage Pipeline of Targeted, Non-Systemic Therapeutics for Gastrointestinal Diseases**
- **Latiglutenase Therapeutic for Celiac Disease to be Advanced to Phase 3 Clinical Trial**

(NASDAQ:FWBI)

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Recent Developments: First Wave BioPharma Merges with ImmunogenX
March 14, 2024

- **Business Combination**: **Strong Strategic Fit**
  - First Wave (NASDAQ:FWBI) and privately-held ImmunogenX (IMGX)
  - GI pipeline expansion into Celiac Disease with a Phase 3-ready asset
  - Merged company has four gut-targeted, late-stage GI assets
  - Robust pipeline to address key unmet medical needs afflicting millions of patients in multi-billion dollar markets

- **Transaction**
  - 100% equity transaction
  - Non-binding commitment for significant financial investment from a strategic biopharmaceutical company in exchange for commercial rights to latiglutenase
  - Potential financing commitments from several institutional investors

- **Synergistic Integration of Management Teams**
  - FWBI: Operational, financial and commercial expertise
  - IMGX: Scientific, clinical and regulatory affairs expertise
  - Core competence in development of recombinant digestive enzymes

Overview: GI Company with multiple late-stage clinical assets

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

LATIGLUTENASE

Recombinant enzyme; dual-protease biologic for the treatment of Celiac Disease (CeD)

- Targeting symptom relief and quality of life (QOL) improvements
- Phase 3 clinical trial initiation anticipated in 2025

CAPESEROD

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

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

ADRULIPASE

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

- EPI in Cystic Fibrosis (CF) and Chronic Pancreatitis (CP)
- Phase 2 Bridging Study topline data 2H'23; FDA Type-C meeting to be requested 1H'24

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

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

Jack Syage, Ph.D.
Chief Operating Officer

- Serial entrepreneur, closed four acquisitions
- >30 years developing innovative technologies
- 140 publications, 80 invited talks, 30 U.S. patents, Fellow of the American Physical Society, Tibbetts Award (SBIR), OC 500

Sarah Romano
Chief Financial Officer

Martin Krusin
SVP Corporate Development

FWBI GI Clinical Pipeline (2023-2028)

	Indications	2023	2024	2025	2026	2027	2028
Latiglutenase	• Celiac Disease			Phase 3 Dosing	Phase 3 Safety	★ BLA	
Capeserod	• Gastroparesis			Phase 2*			
Adrulipase	• EPI in CF • EPI in CP	Phase 2b					
Niclosamide**	• Multiple Phase 2 Indications***		All Indications Phase 2 ready				

* Subject to FDA IND review

** A non-binding term sheet has been signed for the sale of Niclosamide

*** Ulcerative Proctitis/Proctosigmoiditis, Ulcerative Colitis, ICI-AC, Pouchitis, Crohn's Disease

First Wave BioPharma

LATIGLUTENASE

Celiac Disease

Latiglutenase: A First-to Market Opportunity in Celiac Disease

- Latiglutenase, a targeted Celiac Disease therapeutic to provide symptom relief and Quality of Life improvements, with first-to-market opportunity

- Addressing an unmet clinical need in a multi-billion dollar market, there are no commercially available therapies for Celiac Disease

- Compelling endpoint data from Phase 2 trials and solid FDA support
  - End-of-Phase 2 Meeting completed
  - Strong Peer Review Support - $7.7MM in NIH grants
  - FDA Support for Phase 3 Trial Endpoints and Fast Track Designation

- Phase 3 Trial initiation anticipated 2025; market entry 2027

Celiac Disease (CeD)
Large Unmet Need, No Therapies Available

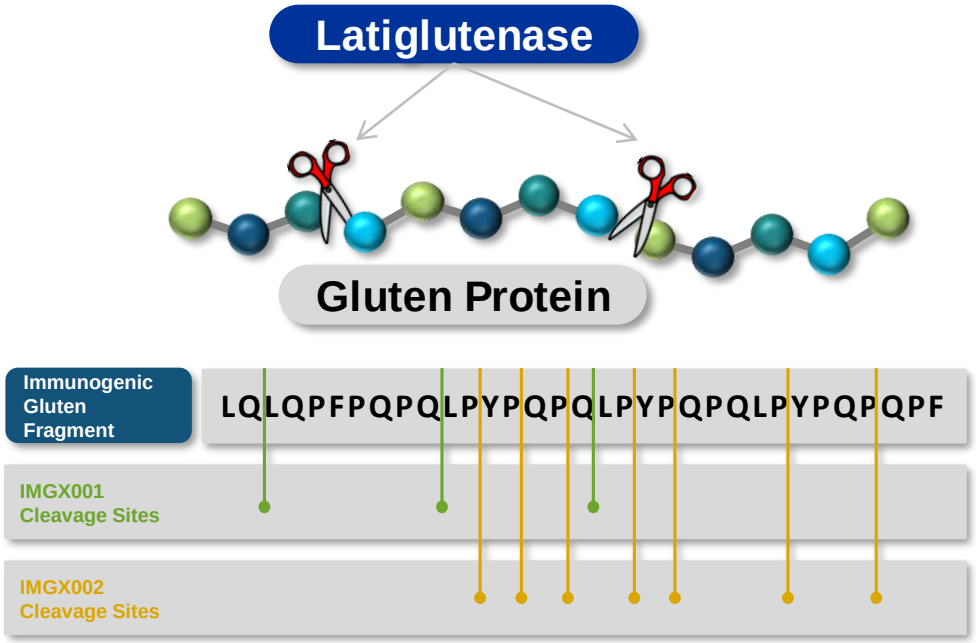
- Genetically predisposed autoimmune disease caused by eating gluten; a protein found in wheat, barley, and rye
  - ~1% of the world's population[1]
  - ~3.3 million patients in the US alone
- Chronic and debilitating gastrointestinal problems and other long-term health issues
- Only current treatment is a gluten-free diet (GFD) which is impractical and often ineffective
- CeD patients typically consume 100's of mg/day of gluten where <50 mg/day is considered safe[2]
- Patients live in fear that a trace amount of gluten can unexpectedly trigger a painful and debilitating flare-up
  - 73% of CeD patients have exposure to gluten and symptoms once a year despite being on a GFD[3]
  - Nearly 40% of CeD patients reported accidentally ingesting gluten as often as 1-5 times month with over two-thirds having severe GI symptoms[3]

[1] P Singh, A Arora, Tor Strand, et al. Global Prevalence of Celiac Disease: Systematic Review and Meta-analysis. Clinical Gastroenterology and Hepatolog. March 15, 2018 DOI: https://doi.org/10.1016/j.cgh.2017.06.03
[2] J A Syage, C.P Kelly, M A Dickason, A Cebolla-Ramirez, F Leon, R Dominguez, J A Sealey-Voyksner, Determination of Gluten Consumption in Celiac Disease Patients on a Gluten-Free Diet. Am. J. Clin. Nutr., 107, 201-207 (2018)
[3] https://www.beyondceliac.org/celiac-news/73-percent-still-exposed-gluten/

Latiglutenase is a Potential Breakthrough Treatment
Highly Differentiated Mechanism of Action

Latiglutenase is a non-systemic, orally-administered biologic enzyme treatment that degrades gluten

- Two recombinant gluten-specific enzymes (proteases) work together to break down the gluten protein in the stomach
- Gluten fragments are made too small (non-immunogenic peptides) to trigger the autoimmune response
- Safe, non-systemic drug
- It comes in a flavored powder form and is mixed together with water that CeD patients drink when eating food



$1.2 Billion Annual Market Seroactive Opportunity in Celiac Disease

- **FDA Label for Latiglutenase: Symptom Relief for Seroactive Patients**
  - Phase 2b and 3 primary endpoint: $1.2B per year
  - 2035 projection for seroactive patients only:
    - 134,000 (US – 30% penetration)
    - 180,000 (EU – 18% penetration)

- **IP through 2039, with 12 years biologics exclusivity (U.S.), 10 years Europe**

- **Payor support for higher price points, CeD severity viewed as being comparable to Ulcerative Colitis and Crohn's Disease**

Latiglutenase Phase 3 Plan – Alignment with FDA Established

- **Label: FDA recommends symptom reduction and histologic non-worsening in active symptomatic Celiac Disease**
- Dual (two replicate) 26-week Phase 3 efficacy trials with an additional 26-week safety run-out in symptom responders
- Efficacy endpoints (change from baseline to week 24)
  - **Primary: Non-stool GI (abdominal pain, bloating, nausea) composite score reduction**
  - **Secondary: Histologic non-worsening as measured by VCIEL (Vh:Cd + IEL)**
- Three cohorts (placebo, 600 mg, 1200 mg)
- Stratify to:
  - **Seroactive, Vh:Cd < 1.8**
  - **Seroactive, 1.8 ≤ Vh:Cd ≤ 2.8**
  - Non-seroactive, Vh:Cd < 1.8
- Total anticipated completed patients N = 900-1152 (total for both Phase 3 studies)

All components of the Phase 3 Plan are agreed to by the FDA

- **Type C Meeting (Aug 31, 2022) Minutes**
- **EOP2 Meeting (Apr 12, 2023) Minutes**

Vh:Cd *Villous Height/Crypt Depth*
IEL *Intraepithelial Lymphocytes*

First Wave BioPharma

CAPESEROD

New GI Opportunity In-Licensed from Sanofi

ADRULIPASE

Exocrine Pancreatic Insufficiency in Cystic Fibrosis & Chronic Pancreatitis

Capeserod: Proprietary 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 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

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

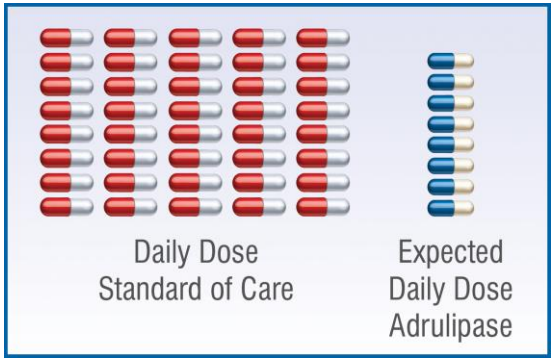
Heterogeneous disease

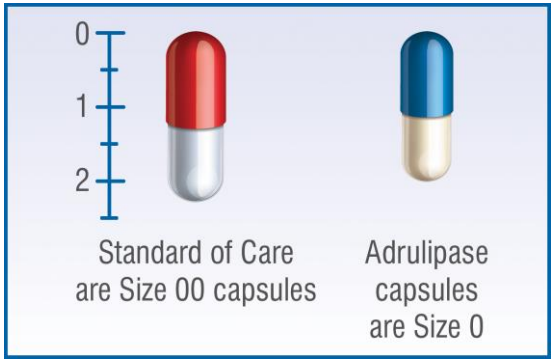
- **~95,000 patients U.S., ~450K-600K worldwide**
- Alcoholism
- Pancreatic cancer
- Pancreatic surgery

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: Fulfilling an Unmet Medical Need
Large Established U.S. Market Of ~$1.8 Billion ($2.3B Global)

	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.

Four Therapeutic Assets and Multiple Phase 2 and 3 Clinical Indications

Program	Preclinical	Phase 1	Phase 2	Phase 3	Next milestone
Latiglutenase					
	Celiac Disease Phase 2b Topline data: 2022				**Phase 3 Initiation: 2025***
Capeserod					
	Gastroparesis				**Phase 2a Initiation: 2025***
Adrulipase					
Monotherapy (FW-EPI)	**Exocrine pancreatic insufficiency in cystic fibrosis – enteric microgranule formulation** Phase 2b Bridging Study Topline data: Q3'23				**FDA Type-C Meeting Request 1H'24***
Combination (FW-EPI+ PERT)	**Severe exocrine pancreatic insufficiency in cystic fibrosis** Phase 2 Topline data: Q3'21				
Niclosamide					
FW-UP	**IBD: Ulcerative colitis-proctitis** Phase 2a 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