



Global Market of Pancreatic Enzyme Replacement Therapy

(2025 – 2035)



Aging Demographics and Structural
Expansion of PERT Demand

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SUMMARY

Pancreatic Enzyme Replacement Therapy (PERT) represents an approximately \$5.26 billion global market in 2025 and is projected to reach \$11.4 billion by 2035. It serves as the clinical standard of care for Exocrine Pancreatic Insufficiency (EPI), restoring metabolic function and vital nutrient absorption through essential enzymes.

From a strategic investment perspective, PERT franchises are categorized as "Bond-Equivalent" assets, meaning they generate highly predictable, low-volatility, and recurring revenue streams. These assets are anchored by a patient base requiring lifelong daily therapy and are protected by significant biological manufacturing moats that prevent generic erosion. This combination offers the defensive stability of a fixed-income instrument with the aggressive growth upside of a specialized pharmaceutical.

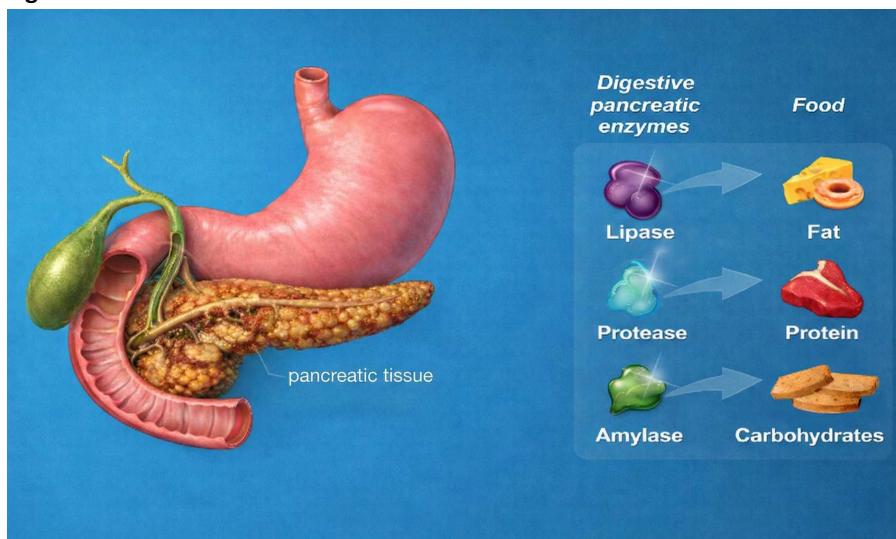
The market is entering a decisive phase of expansion, driven by the global "Silver Tsunami". As life expectancy rises, the increasing prevalence of age-related pancreatic senescence and chronic comorbidities has placed nutritional preservation at the forefront of geriatric medicine. Coupled with the widespread adoption of Fecal Elastase-1 (FE-1) testing, which is rapidly identifying the hidden population of EPI sufferers, the market is shifting from acute symptom management toward long-term wellness preservation. This structural demand ensures PERT remains a cornerstone of high-value healthcare portfolios through 2035.

Disclaimer: This report is intended for informational and strategic discussion purposes only. Market sizes and forecasts (2025-2035) are synthesized from publicly available research summaries and proprietary modeling; they are sensitive to market-definition scope (e.g., prescription pancrelipase vs. broader enzymes). Readers should perform independent due diligence and channel checks before making capital allocation decisions.

PART 1. The Biological Role of the Pancreas

The pancreas is an organ of the digestive system and the endocrine system of vertebrates. In humans, it is located in the abdomen behind the stomach and functions as a gland. The pancreas has both endocrine and exocrine functions. Approximately 99% of the pancreas is exocrine, while only about 1% serves an endocrine role. For its endocrine function, the pancreas primarily regulates blood glucose levels by secreting hormones such as insulin, glucagon, somatostatin, and pancreatic polypeptide. For its exocrine function, the pancreas releases pancreatic juice into the duodenum via the pancreatic duct. This secretion includes bicarbonate, which neutralizes gastric acid, and digestive enzymes (amylase, protease, and lipase) that facilitate the breakdown of carbohydrates, proteins, and fats, respectively (Figure 1).

Figure 1. Pancreas and its function



The pancreatic function is impaired in patients with pancreatitis, pancreatic cancer, and diabetes. Pancreatitis is the inflammation of the pancreas. It is commonly linked to recurrent gallstones or long-term alcohol consumption, but it can also result from traumatic injury, complications following ERCP (Endoscopic Retrograde Cholangiopancreatography) procedures, certain medications, infections such as mumps, and markedly elevated blood triglyceride levels. Pancreatic cancer is linked to chronic pancreatitis, older age, smoking, obesity, diabetes, and certain rare genetic conditions. When the pancreas does not produce and/or secrete enough digestive enzymes, resulting in impaired breakdown of fats, proteins, and carbohydrates and leading to poor nutrient absorption, this condition is called exocrine pancreatic insufficiency (EPI), also known as pancreatic exocrine insufficiency (PEI).

PART 2. PERT Dynamics: Market Drivers, the Big 2, and M&A Outlook

Pancreatic Enzyme Replacement Therapy (PERT) is a prescription treatment used for individuals with EPI. This treatment typically consists of porcine-derived enzyme formulations containing lipase, protease, and amylase. These enzymes support the digestion of fats, proteins, and carbohydrates, helping to prevent malnutrition and relieve symptoms such as steatorrhea, bloating, gas, and unintended weight loss. PERT is administered orally in enteric-coated capsules, which protect the enzymes from stomach acid and allow their release in the duodenum. The enzymes act locally within the intestinal lumen and are not systemically absorbed.

EPI arises from a range of underlying diseases that ultimately lead to insufficient enzymatic digestion. The condition can result from impaired production or secretion of pancreatic enzymes, reduced hormonal stimulation, obstruction of the pancreatic ducts, or diminished enzyme activity within the small intestine. EPI leads to maldigestion, steatorrhea, weight loss, fat-soluble vitamin deficiencies, and poor nutritional status. Common causes of EPI include chronic pancreatitis, pancreatic adenocarcinoma, and cystic fibrosis, among others. A more comprehensive list of etiologies is listed in Table 1.

Table 1. Causes of pancreatic exocrine insufficiency and mechanisms.

Cause	Mechanism
Chronic pancreatitis	Permanent structural damage of ducts and parenchyma
Cystic fibrosis	Dysfunctional pancreatic secretion secondary to CFTR mutations
Main pancreatic duct obstruction	Decreased secretion of pancreatic enzymes
Pancreatic resection	Decreased secretion of pancreatic enzymes
Gastric resection	Decreased hormonal stimulation, rapid transit, inadequate mixing of chyme with pancreatic enzymes
Short bowel syndrome	Decreased hormonal stimulation, rapid transit, inadequate mixing of chyme with pancreatic enzymes
Hereditary hemochromatosis	Iron deposition in the pancreas
Celiac disease	Small bowel mucosal disease leads to decreased CCK mediated pancreatic stimulation
Zollinger-Ellison syndrome	Gastrinoma causes inactivation of pancreatic enzymes via increased gastric acid

2.1 Clinical and Medical Indications: The Demand Engine

The distinction between medical pathology and clinical manifestation is a primary driver of current market acceleration. The PERT medical indications refer to the underlying diseases or pathologies that necessitate the use of PERT, and the PERT clinical indications refer to the observable signs, symptoms, and diagnostic benchmarks that trigger a physician to write a

prescription. These are the formal diagnoses that lead to EPI. While these terms are often used together, they represent different market forces that are currently accelerating PERT demand:

Medical Indications (The Underlying Diagnoses): These are the formal diseases and surgical conditions that cause EPI. Market demand is rising due to an increasing prevalence of these conditions shown in Table 2.

Clinical Indications (The Observable Need for Treatment): These are the specific symptoms and diagnostic results that prompt a physician to prescribe PERT. Demand in this area is growing because of better diagnostic screening and earlier intervention for symptoms shown in Table 2.

Table 2. Master Market Indications Matrix

Table 2. Market Indications Matrix			
Category	Indications	Definition/Symptom	Market Implication
Medical	Chronic Conditions	Chronic Pancreatitis & Cystic Fibrosis.	Provides the "Permanent" patient base; creates high lifetime value per patient.
	Surgical & Oncology	Pancreatic Cancer & Whipple Procedure (Total/Partial Pancreatectomy).	Acute onset requirement; drives high-volume, immediate hospital-based prescriptions.
Clinical	Observable Symptoms	Steatorrhea (oily, foul stools) & Post-Prandial Distress (chronic gas/bloating).	Primary driver for patient presentation and initial specialist consultation.
	Biomarkers & Diagnostics	Low Fecal Elastase-1 (FE-1) levels or a low Coefficient of Fat Absorption (CFA).	The "Objective Gatekeeper"; expanded FE-1 testing is the leading driver of new Rx growth.
	Nutritional Deficiencies	Unexplained weight loss, malnutrition, and vitamin (A, D, E, K) malabsorption.	Positions PERT as a "Longevity/Wellness" therapy in geriatric medicine.

Although medical indications define the total potential patient population, clinical indications are the source of market growth. This is because clinicians are now more likely to treat mild clinical symptoms earlier, even before a severe medical diagnosis is fully realized.

2.2 The Big 2 Duopoly: Market Hegemony and Competition

In contrast to the precipitous revenue erosion typical of traditional therapeutic classes post-patent, the global PERT market operates as a consolidated oligopoly. Its structural resilience is less a function of intellectual property and more a result of significant barriers to entry. This "Big 2" dominance creates a level of defensive durability rarely seen in mature pharmaceutical markets (Figure 2). The market architecture is defined by a dichotomy:

Creon (AbbVie) holds a large portion of the global prescription market, generating approximately \$2.4 billion in revenue in 2025. It is the standard of care (SoC) for adult patient populations. Zenpep (Nestlé Health Science) has an estimated \$350M - \$450M in revenue in 2025. It focuses on a nutrition-integrated fortress strategy, cornering the pediatric and Cystic Fibrosis (CF) patient populations.

From an investment perspective, PERT franchises are viewed as "Bond-Equivalents" within a pharma portfolio. They offer predictable, recurring revenue from chronic daily use with exceptionally low volatility compared to biotech or commoditized generics.

In a volatile macroeconomic environment, PERT assets continue to command premium valuations, with EBITDA multiples reaching 12x-14x, reflecting their exceptional cash-flow stability. This resilience is illustrated by Nestlé Health Science's (NHSc) "String of Pearls" strategy, a platform-based consolidation model aimed at bridging medical nutrition and therapeutics. A

pivotal element of this approach was the 2020 acquisition of Zenpep from Allergan, which established a prescription anchor for Nestlé's digestive health portfolio. The 2024-2025 \$175 million+ Vowst acquisition reinforced this strategy, signaling a deliberate push to lead the "Microbiome & Enzyme" vertical by leveraging scale and existing gastrointestinal sales infrastructure.

Figure 2. Key Rx pancrelipase products



2.3 Structural Moats: Why PERT Assets Command Premium Valuations

The high-valuation M&A activity and Bond-Equivalent status of PERT franchises are underpinned by significant entry barriers that protect incumbents from generic competition. Unlike standard small-molecule pills, PERT is a complex biological product supported by logistical advantages that are difficult for new competitors to replicate. These entry barriers fall into four reinforcing categories:

The Porcine Supply Chain Barrier: Manufacturing requires massive quantities of pharmaceutical-grade porcine (pig) pancreas glands. Sourcing is restricted to highly regulated, disease-free supply chains. The dependence on a consistent, high-volume biological source creates a massive barrier to entry for any new manufacturer.

The Galenic Complexity (pH-Sensitivity): The therapy relies on sophisticated enteric-coated microspheres. To be effective, the enzymes must remain intact in the highly acidic stomach ($\text{pH} < 4$) but dissolve instantly upon reaching the duodenum ($\text{pH} > 5.5$). Engineering a coating that is this precise and ensuring it performs consistently across every batch is a significant R&D hurdle that prevents simple generics.

Bioequivalence and Regulatory Hurdles: Because these enzymes work locally in the gut and are not absorbed into the bloodstream, proving if a new version is identical to a market leader like Creon is difficult.

Supply Vulnerabilities as a Market Signal: The PERT market is frequently capacity constrained. Recurring supply disruptions in the UK and parts of Europe often linked to raw ingredient shortages underscore the fragility and value of the existing infrastructure.

These constraints act as a natural barrier to competition. For an acquirer, owning a PERT franchise means owning a rare, high-demand manufacturing slot in a market where supply not demand is the primary bottleneck. This scarcity and durability are what drive the 12x-14x EBITDA multiples seen in recent transactions.

PART 3. Global Market Sizing, Forecasts, and Regional Outlook (2025–2035)

The global PERT market is transitioning from a stable specialty sector into a high-growth therapeutic category. Currently valued at approximately \$5.26 billion in 2025, the market is projected to reach \$11.4 billion by 2035. This robust growth is supported by the compounding effect of chronic therapy: once a patient starts PERT, they typically remain on it for life.

3.1 Global Revenue Forecasts and Growth Drivers

The market's expansion is driven by a shift from treating only severe cases to a broader wellness and maintenance model in chronic disease management. A primary driver of this expansion is the improved diagnostic adoption of Fecal Elastase-1 (FE-1) testing, which allows clinicians to identify patients much earlier in the disease progression.

3.2 The Silver Tsunami: Demographic Tailwinds

The most critical driver of the PERT market forecast is the Silver Tsunami, the unprecedented global growth of the geriatric population. Aging is the primary risk factor for pancreatic senescence, the natural decline in digestive enzyme production. As life expectancy rises, this gradual loss of pancreatic function is expected to drive a significant increase in sub-clinical and undiagnosed EPI among older adults.

At the same time, the clinical role of PERT is expanding within geriatric care. There is growing consensus that maintaining adequate digestion and nutrition is essential to healthy aging. PERT supports nutrient absorption, helping preserve muscle mass and bone density and reducing the risks and costs associated with sarcopenia, frailty, falls, and fractures. This demand is further reinforced by the increasing prevalence of chronic age-related conditions such as Type 2 diabetes and chronic pancreatitis, which create a durable, long-term patient population requiring ongoing enzyme supplementation.

3.3 Market Dynamics and Outlook

The global PERT market is shaped by regional differences in maturity, pricing power, and patient volume. North America, the value anchor, accounts for roughly 45–55% of global revenue, with growth driven by premium pricing and strong awareness of EPI in secondary indications such as Type 2 diabetes and post-oncology care. Europe, the quality and volume hub, features high diagnostic standards and strict regulatory oversight; although pricing is moderated by national health systems, the region leads in early-intervention clinical protocols. Meanwhile, Asia-Pacific represents the growth frontier, projected to achieve the highest CAGR through 2035, fueled by rapid healthcare infrastructure development in China and India and an aging population increasingly accessing Western diagnostic standards.

For the investor, the regional and demographic data suggests a locked-in growth curve. The combination of a mathematically certain aging population (the Silver Tsunami) and the high barriers to entry for new competitors ensures that the current market leaders are positioned to capture the majority of this \$11B+ opportunity (Table 3).

Table 3. Illustrative regional share assumptions (2025 vs. 2035)

Illustrative regional share assumptions (2025 vs. 2035)			
Region	2025 Share	2035 Share	Why (Summary)
North America	56%	50%	Highest diagnosis/treatment rates; strong reimbursement; mature CF/EPI pathways ⁷
Europe	22%	21%	Large treated base; guideline-driven care; periodic supply/reimbursement variability
Asia-Pacific	17%	22%	Fastest growth from improving diagnosis/access and rising pancreatitis/cancer burden
Latin America	4%	4%	Access expansion over time
Middle East & Africa	2%	3%	Gradual access expansion

⁷ Cystic Fibrosis (CF); Exocrine Pancreatic Insufficiency (EPI)

PART 4. Strategic Outlook for 2035

As we look toward 2035, the Pancreatic Enzyme Replacement Therapy (PERT) market is positioned as one of the most resilient and predictable verticals in the specialized pharmaceutical landscape. The transition from a \$5.26 billion market in 2025 to an \$11.4 billion market by 2035 is not merely a projection of volume, but a reflection of a fundamental shift in how global healthcare systems prioritize nutritional preservation.

4.1 The Convergence of Stability and Growth

The PERT investment thesis is defined by a rare Dual-Moat architecture:

The Clinical Engine: The Silver Tsunami ensures a mathematically certain expansion of the patient base. As the global population ages, PERT is moving from a niche orphan-adjacent therapy to a foundational component of geriatric wellness and chronic disease management.

The Structural Shield: The biological and logistical complexities of porcine-derived manufacturing protect the "Big 2" (AbbVie and Nestlé) from the steep revenue loss seen in traditional drugs. This helps keep the market concentrated and difficult to enter for the foreseeable future.

4.2 Final Investment Verdict

By 2035, the successful stakeholders will be those who have secured their positions within the limited manufacturing slots of this supply-constrained market. With diagnostic standards like Fecal Elastase-1 testing becoming ubiquitous, the hidden population of EPI patients will become a visible, long-term revenue stream.

For the strategic investor, PERT represents a defensive growth play: it offers the safety of a chronic-use legacy medication with the upside of a demographic-driven expansion, making it a cornerstone asset for any diversified healthcare portfolio in the coming decade.

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Core Research and Authorship

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- Hesen Huang: As the research analyst who received M.S. in Applied Mathematics from Northeastern University, Hesen is responsible for the following tasks: Report Embellishment; Data Analysis and Visualization; AI-assisted Research & Review.
- Mengdie Zhao: A contributor, with a Master's degree from Georgetown University, supported market research and conducted competitive landscape analysis.
- Alyssa Li: A financial analyst with a Master's degree in Economics from Northeastern University, specializing in financial modeling and investor relations. Alyssa served as a content advisor for this analysis, overseeing the selection of market-critical data.