PharmaEssentia Corp (6446 TT)

From PV to New Indications: Unlocking Growth in Hematology and Oncology

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COMPANY OVERVIEW

PharmaEssentia is Taiwan's largest biotech company by market capitalization, pioneering treatments for rare blood disorders and tumors. It was the first company to secure US FDA approval for the only first-line treatment in a specific indication. Its flagship product, BESREMi®, a long-acting interferon therapy, was first approved in 2019 for polycythemia vera (PV). The company is expanding its indications to essential thrombocythemia (ET) (first new ET drug in 28 years) and primary myelofibrosis (PMF) while advancing a pipeline targeting various rare tumors.

KEY STATISTICS

Ticker:	6446 TT
Current Price:	NT$ 562
52-Week Range:	NT$ 285.5 - 771
Average Volume (30-Day, k shares)	3,801.2
Outstanding Shares (MN)	342
FINI Holding (%)	21.88
Market Cap (MN)	US$ 5,833

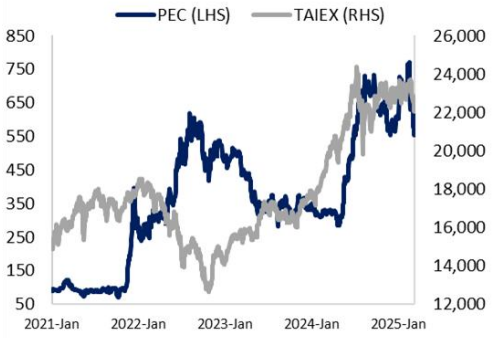
KEY POINTS

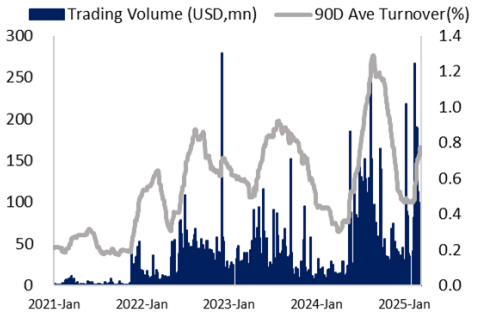
A Biotech Company with Strong Growth and FDA-Approved Product: PharmaEssentia is a biotechnology company focused on developing treatments for rare blood diseases and liquid/solid tumors. Its flagship product, Besremi (Ropeginterferon alfa-2b), is the first and only US FDA-approved all-line treatment for polycythemia vera (PV). The drug was launched in the US in December 2021 and has since been approved in the EU, Japan, China, Korea, and Taiwan. The current per-patient cost in the US is US$241,800 per year (US$9,300 per dose, 26 doses per year). Fueled by strong sales in the US and Japan, PharmaEssentia's revenue surged 15-fold, from NT$657 million in 2021 to NT$9,735 million in 2024, though it remains far from peak sales. Additionally, the company posted its first positive EPS of NT$8.96 in 2024, marking a major milestone in its growth trajectory. Patent protection extends through 2034, supported by 70 issued patents and 34 pending worldwide.

Expanding Leadership in MPN and Beyond: PharmaEssentia is expanding Ropeg's indications within myeloproliferative neoplasms (MPN) to further enhance its market potential. In January 2025, the company announced positive Phase 3 results for Ropeg in essential thrombocythemia (ET), with US FDA approval expected no later than 1Q26. The US patient population for ET (~148,000) is comparable to PV, meaning approval would double Ropeg's addressable market within MPN. Additionally, current ET treatment options are limited, with Anagrelide—the only FDA-approved drug—associated with severe side effects and low patient acceptance. Given Ropeg's established market presence and increasing physician familiarity, it is expected to hold a strong competitive advantage in ET treatment. Furthermore, PharmaEssentia has submitted a Phase 3 study protocol to the US FDA for early pre-fibrosis primary myelofibrosis (PMF), aiming for approval by 2028. To further diversify its pipeline, the company is advancing several early-stage assets, including P1801 (Ropeg + anti-PD-1 for solid tumors), P2203 (best-in-class PEG-GCSF for neutropenia), P11838 (PEG IL-2 for ulcerative colitis and atopic dermatitis), and TCR-T therapy, with an IND resubmission for solid tumors planned for 2025.

Pegasys Shortage to Accelerate Besremi's Market Penetration: Since Besremi's FDA approval, the demand for interferon therapy in PV has increased significantly, exacerbating a severe supply shortage of Pegasys—another pegylated interferon used in PV treatment. The shortage has affected major markets, including the US and Europe, and is expected to persist until at least 2Q26, according to the US FDA. In response, the latest NCCN treatment guidelines now recommend Besremi as the preferred alternative where Pegasys is unavailable. With approximately 10,000 PV patients in the US currently on Pegasys, PharmaEssentia expects a significant portion of them to switch to Besremi, reinforcing its position as the best-in-class pegylated interferon therapy. Additionally, the guideline update will expand insurance reimbursement coverage, increasing accessibility, adoption, and market penetration, further strengthening Besremi's dominance in PV treatment.

PRICE PERFORMANCE





FINANCIAL SUMMARY

mn,NTD	FY21	FY22	FY23	FY24
Revenue	657	2,882	5,106	9,735
Revenue YoY (%)	17.8	339.0	77.2	90.7
Gross Margin (%)	42.3	71.8	88.0	87.9
Op. Margin (%)	-429.9	-70.4	-37.5	17.8
Net Income	-2,811	-1,375	-624	2,966
Net Income YoY (%)	-	-	-	-
Net Margin (%)	-428.2	-47.7	-12.2	30.5
EPS (NTD)	-10.80	-4.84	-1.93	8.96
ROA (%)	-47.9	-12.8	-2.3	10.2
ROE (%)	-68.8	-16.8	-2.6	11.5
ROIC (%)	-60.1	-14.9	-3.2	11.1
P/E (x)	-	-	-	63.1
P/B (x)	18.8	11.8	4.8	6.8
P/S (x)	118.9	49.9	22.4	19.2
EV/EBITDA (x)	-	-	-	49.3

Source：TEJ

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