4 About PharmaEssentia

GRI 2-1

PharmaEssentia is based in Taiwan. With a competitive advantage in the new drug manufacturing and production, we are committed to cultivating talent in the biopharmaceutical industry and are actively expanding to global markets and developing strategic alliance partners to lead the development of Myeloproliferative Neoplasms (MPN) field.

We have developed high quality "PEGylation technology platform" and small molecule synthesis technology. We utilize the technology to develope BESREMi® for the treatment of "polycythemia vera (PV) with asymptomatic splenomegaly for adult". After obtaining marketing approvals in multiple countries in Europe, we also receive approvals in Israel, Korea, and the United States for the treatment of PV for adult. In addition, we are actively preparing for drug license applications in Japan, China, Singapore and Hong Kong. For more information, please refer to our company website.

Mission and Vision

- To become a world-class innovative Biopharmaceutical company focused on protein therapeutics
- To establish the first fully-integrated protein therapeutic company in Taiwan that combines R&D, clinical trials, manufacturing, and sales.

Operational Locations

- Headquarters of PharmaEssentia is located in Taiwan
- With global operational locations including the United States, China, Japan, Korea, Singapore, and Hong Kong.

2022 Employee and Revenue Figures

- There are 287 employees in Taiwan and a total of 470 employees worldwide.
- The net revenue is approximately NT$2.8 billion.

Overview of Ropeg's global market approval

2019	2020	2021	2022
EU	Taiwan	Israel	Macau
	Switzerland	South Korea	In the process of obtaining certification in Japan
	Liechtenstein	United States	

Overview of Ropeg's Regulatory Approvals in Global Markets Ropeg is marketed and sold under the brand name BESREMi®/Besremi®. In the EU, it is used to treat adult patients with polycythaemia vera (PV) who are resistant to or intolerant of hydroxyurea and have non-splenomegaly-related symptoms. In the US, it is used to treat adult patients with PV. PV is a type of myeloproliferative neoplasms (MPN) that can progress to acute myeloid leukemia and pose a threat to life.

Value Chain Partners GRI2-6

In order to level up Taiwan's biotechnology, we actively collaborate with partners along our value chain toward sustainability. The table below summarizes how we work with different partners along the value chain:

	New drug research and development	Clinical trials
Value chain partners	Academic research institutions (such as Academia Sinica and domestic/foreign universities), licensed domestic biotech companies, and foreign licensed partner Axis Therapeutics	Clinical trial hospitals, contract research organizations, European strategic partner AOP Orphan, licensed partner Athenex
Collaboration Models	• Collaborate with universities worldwide in industry-academia partnerships to jointly develop potential drug candidates. • Technology licensing for preclinical development with domestic biotech companies. • Technology transfer and clinical development for solid tumor (TCR-T) with foreign licensing partner Axis Therapeutics.	• Collaborate with qualified and internationally accredited outsourcing research institutions. • Actively interact with research foundations, patient advocacy groups, and hospitals in various countries to understand disease trends and needs. • License international biopharmaceutical companies for clinical trials. • Maintain unimpeded channels of communication with international drug logistics companies and to enhance their operations through methods including internal audit in order to ensure timeliness and quality of drug transportation
Management Strategy and Performance	**Early Development: Continuous Development of Innovative Drugs** • Creating value through innovation and improvement of existing drugs to reduce the risk of developing new drugs • Effectively developing diverse products using technological platforms • In 2022, the total R&D expenditure reached NT$1.43 billion, with 123 R&D personnel worldwide dedicated to addressing unmet medical needs **Intellectual Property Management: Actively Collaborating with Industry and Academia** • Cross-border industry-academia collaboration with Athenex and Axis Therapeutics • Committed to considering the access to medicine in low-income countries and least developed countries when using or applying for patents • Conducting new drug clinical trials and sales globally through licensing and external authorization • Investing in the establishment of an innovative research center in the United States	**Clinical Trials: Global Medical Clinical Trials** • Initiate multi-country and multi-center clinical trials with operational procedures following relevant regulations • Commit to assisting eligible patients to obtain legal access to appropriate treatment channels • Already promoted more than 20 clinical trial cases, and the trial data can serve as the basis for future drug approval and physician prescription applications **Compassionate Use: Supporting Critical Patients** • Provide compassionate use for patients with serious or immediately life-threatening diseases who are unable to participate in clinical trials, and initiate their urgent treatment course • In 2022, the number of patients worldwide who have cumulatively used compassionate use therapy has reached 40.

Production and manufacturing

Drug application services

Marketing and sales

	Production and manufacturing	Drug application services	Marketing and sales
Value chain partners	Suppliers/contractors, outsourcing organizations, external consultants	International biopharmaceutical companies/contract research organizations with licensing cooperation, foreign pharmaceutical companies	Licensing strategy cooperation sales partners/ outsourced marketing channels, international pharmaceutical logistics providers
Collaboration Models	• Maintain good communication channels with international pharmaceutical transportation companies and improve their operations through internal audits to ensure the quality and timeliness of drug transportation. • Require manufacturers to sign a "Quality Agreement" to ensure mutual product and quality requirements are consistent. • Establish supplier management procedures that specify re-evaluation frequency and shorten the re-evaluation interval for high-risk suppliers to ensure product quality. • Collaborate with qualified and internationally accredited outsourced manufacturing/inspection institutions.	• License international biopharmaceutical companies or outsourcing research institutions for clinical trials and drug application.	• Strategically ally with foreign partners familiar with the local market or appoint commissioned sales channels to expand sales in local markets. • Maintain good communication channels with international pharmaceutical transportation companies and improve their operations through internal audits to ensure the quality and timeliness of drug transportation.
Management Strategy and Performance	**Product Quality: Rigorous and Legal Production of Products** • The production process has been approved and inspected, and complies with GMP certifications from the US FDA, EU EMA, Japan PMDA, Taiwan TFDA, and other agencies. **Transportation and Supply: Timely and Stable Supply of Medications** • Establishing a global safe and stable drug supply chain. • Stable and timely supply of raw materials from suppliers and production scheduling control through production management mechanisms to meet the needs of patients.	**Plan short and medium-term drug registration applications around the world.** • BESREMi® has currently obtained regulatory approval in 38 countries and is continuously increasing, expanding global patient access to equal medical rights. • Tirbanibulin (KX01) has recently passed the new drug verification and registration review of Taiwan's Ministry of Health and Welfare and is indicated for actinic keratosis (AK).	**Academic Exchange: Demonstrating the Value of Medical Products** • Sponsorship of the Annual Meeting of the Taiwan Society of Hematology • Collaborating with value chain partners to enhance the social impact of the local biopharmaceutical industry • Promoting advocacy on issues related to access to medicine and sponsoring related organizational activities **Medical Contribution: Enhancing awareness and sharing of experience in the effectiveness of new therapies** • Obtaining health insurance price listing benefits for more patients in 2022 • Organizing over 12 regional and healthcare professional medical lectures in 2022 • Holding 11 in-hospital seminars in 2022 • The board of directors has approved the terms for the distribution and authorization of Ropeginterferon alfa-2b products in Latin America.

Global Strategy

PharmaEssentia Corporation adopts two major strategies, namely "establishing multinational subsidiaries" and "licensing and cooperation alliances," as our global market deployment strategy. We also develop three major strategic directions and gather about 470 outstanding talents worldwide to dedicate ourselves to the field of rare blood diseases, particularly Myeloproliferative Neoplasms (MPN), which currently have no adequate treatment. We strive to continually improve drug development and market efficiency. Our independently developed Ropeg, used to treat polycythemia vera (PV) and marketed under the brand names BESREMi®, has obtained drug marketing approvals in over 30 countries worldwide, benefiting PV patients. We have also initiated phase III clinical trials of Ropeg for the treatment of essential thrombocythemia (ET) in many parts of the world, with the hope of offering treatment options for other patients as well. These achievements have proven that our core base of research and development and manufacturing in Taiwan can successfully expand to international markets.

Total global employees: **470**

Total global R&D clinical staff: **123**

Strategy 1

Maximizing the value of our technology platform and products to increase profitability

- Promoting Ropeg as the leading brand for the treatment of myeloproliferative neoplasms (MPNs) to increase patient loyalty
- Utilizing PEGylation as our technology platform, we will leverage the research and development expertise gained from the development of Ropeg to continuously develop new products for the treatment of other indications, shortening development timelines, reducing research risks, and costs.

Strategy 2

Recruiting exceptional talent and establishing sound operational management

- Combining our global strategy with the recruitment of local high-level talent in our subsidiaries, we aim to minimize differences between countries and accelerate market entry
- Establishing operational service centers for local patients in each subsidiary and implementing efficient operational management to reduce overall costs and benefit patients.

Strategy 3

Continuously innovating and developing to create long-term value for the company

- Expanding our product line through licensing, cooperation, or permission agreements with strategic alliance partners to jointly develop or introduce new drug candidates
- Establishing sustainable development, risk management, or other functional teams to plan, promote, execute, track, respond to, and optimize sustainability management issues, as well as enhance corporate governance and meet stakeholder expectations.

Establishment of cross-border subsidiary operation strategies

- Establishment of operational bases in the United States, China, Japan, South Korea, Singapore, and Hong Kong
- Hiring local scientists and senior management personnel to communicate with local regulatory agencies regarding clinical drug certification applications and marketing layouts

Global expansion of PharmaEssentia

Licensing cooperation alliance model

- License Ropeg to Austrian AOP Orphan to develop and market drugs in Europe, the Middle East, and the CIS region
- License the introduction of Tirbanibulin ointment (KX 01) from US-based Athenex and collaborate to develop oral paclitaxel for cancer treatment, Oraxol®
- Conduct technology transfer and clinical development of solid tumor (TCR-T) with licensed partner Axis Therapeutics
- License cooperation partners in Hong Kong, Macau, and other regions to assist in submitting Ropeg drug certification applications in 2023
- Continuously enhance the visibility of PharmaEssentia internationally through strategic alliances
- For more information on licensing cooperation, see Chapter 6, Section 4.1.

Massachusetts, USA

PharmaEssentia USA Corporation

The US subsidiary / 110 employees, 100% ownership, total investment of 2,975,791

PharmaEssentia Innovation Research Center, Inc.

USA innovation research center / 3 employees, 100% ownership, total investment of 45,938

Tokyo, Japan

PharmaEssentia Japan KK

Japan subsidiary / 26 employees, 100% ownership, total investment of 735,595

Seoul, South Korea

PharmaEssentia Korea Corporation

Korea subsidiary / 8 employees, 100% ownership, total investment of 147,970

Beijing, China

PharmaEssentia Biotech (Beijing) Co., Ltd.

Beijing subsidiary / 12 employees, 100% ownership, total investment of 122,500

Taiwan

PharmaEssentia Corporation

Global headquarters / 287 employees

Panco Healthcare Taiwan Medical (PTM) Corporation

Taiwan subsidiary / 18 employees, 100% ownership, total investment of 102,500

Austria

AOP Orphan Pharmaceuticals

AG European licensing partner

Hong Kong

PharmaEssentia Asia(Hong Kong) Limited

Hong Kong subsidiary/2 employees, 100% ownership, total investment of 196,292

PharmaEssentia Pharmaceuticals (Hong Kong) Limited

Only completed registration process, no capital has been transferred out yet

Singapore

PharmaEssentia Singapore Pte. Ltd.

Singapore subsidiary / 1 employee, 100% ownership, total investment of 1,394

Note: Investment amounts are in thousands of New Taiwan Dollars.