Material Information (6446 PEC)					
SEQ_NO	2	Date of announcement	2025/09/18	Time of announcement	14:11:59
Subject	Announcement on Behalf of PharmaEssentia Japan KK: Filing for an Additional Indication of BESREMi (Ropeginterferon alfa-2b) for ET in Japan				
Date of events	2025/09/18	To which item it meets	paragraph 10		
Statement	1.Date of occurrence of the event:2025/09/18 2.New drug name or code:BESREMi (ropeginterferon alfa-2b, P1101) 3.Indication:Essential thrombocythemia (ET) 4.Planned development stages:Application of indication addition 5.Current development stage: (1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): PharmaEssentia Japan KK (PEJ), a Japanese subsidiary of PharmaEssentia Corporation, has submitted a Post-Approval Change Application for BESREMi (ropeginterferon alfa-2b) to add a new indication for essential thrombocythemia (ET) in Japan. (2)Risks and mitigation measures to be taken by the company upon disapproval of the competent authority: N/A (3)Strategies to be taken by the company upon approval by the competent authority: N/A (4)Accumulated investment expenditure incurred: In consideration of the future marketing strategy and to protect the rights of the company and investors, no public disclosure will be made for the time being. 6.Upcoming development plan: Review of indication addition application in Japan (1)Estimated date of completion: According to the review procedure of the Japan Pharmaceuticals and Medical Devices Agency (PMDA), the review time is about one year. The actual review time and approval shall be subject to the decision of PMDA. (2)Estimated responsibilities: N/A. 7.Market situation: Essential thrombocythemia (ET) is a myeloproliferative neoplasm (MPN) characterized by an overproduction of platelets in the blood resulting from a genetic mutation. The patient number of ET is similar to that of polycythemia vera (PV). According to the market research, there are around 30,000 patients with ET in Japan; currently, the drug for ET is hydroxyurea (HU) and anagrelide (ANA). 8.Any other matters that need to be specified(the information disclosure also meets the requirements of Article 7, subparagraph 8 of the Securities and Exchange Act Enforcement Rules, which brings forth a significant impact on shareholders rights or the price of the securities on public companies.): (1)The Japan Ministry of Health, Labour and Welfare (MHLW) approved the marketing authorization application for BESREMi (ropeginterferon alfa-2b) 500 mcg syringe and 250 mcg syringe for subcutaneous injection in adult patients with polycythemia vera (PV) who have an inadequate response or intolerance to existing treatments in March 2023. BESREMi was subsequently listed under the national health insurance coverage by MHLW in May 2023. (2)Ropeginterferon alfa-2b is an innovative monopegylated, long-acting interferon invented and manufactured by PharmaEssentia. Ropeginterferon alfa-2b is approved to treat adult patients with Polycythemia Vera (PV) in around 50 countries in the world, including major markets such as the United States, Japan, China and European Union. 9.New drug development requires long process, vast investments and with no guarantee in success which may pose investment risks.The investors are advised to exercise caution and conduct thorough evaluation.:				