Material Information (6446 PEC)					
SEQ_NO	2	Date of announcement	2025/07/16	Time of announcement	22:16:31
Subject	The China NMPA has Accepted the Marketing Authorization Application of Ropeginterferon alfa-2b for ET				
Date of events	2025/07/16	To which item it meets	paragraph 10		
Statement	1.Date of occurrence of the event:2025/07/16 2.New drug name or code:Ropeginterferon alfa-2b (P1101) 3.Indication:Adult patients with essential thrombocythemia (ET) who have had inadequate response to prior Hydroxyurea (HU) treatment 4.Planned development stages: Review of the Marketing Authorization Application in China 5.Current development stage: (1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): The China National Medical Products Administration (NMPA) has accepted the marketing authorization application of Ropeginterferon alfa-2b for adult patients with essential thrombocythemia (ET) who have had inadequate response to prior Hydroxyurea (HU) treatment. (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 the Marketing Authorization Application in China (1)Estimated date of completion: According to the Provisions of Drug Registration of the NMPA Center For Drug Evaluation (CDE), the standard review time of the Marketing Authorization Application is around 200 business days, and time for further documents request is not included. The actual review time and approval shall be subject to the decision of the China NMPA. (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, ET is estimated to affect 38 to 57 per 100000 people. Currently, the first-line drug for ET is Hydroxyurea (HU), which is used off-label, and the second-line drug for ET is Anagrelide, approved by the U.S. FDA in 1997. 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.): 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 40 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.:				