Material Information (6446 PEC)					
SEQ_NO	2	Date of announcement	2025/09/11	Time of announcement	16:25:53
Subject	The Health Canada has Accepted the New Drug Submission of Ropeginterferon alfa-2b for PV				
Date of events	2025/09/11	To which item it meets	paragraph 10		
Statement	1.Date of occurrence of the event:2025/09/11 2.New drug name or code:BESREMi (Ropeginterferon alfa-2b, P1101) 3.Indication:Treatment of adults with Polycythemia Vera (PV) 4.Planned development stages:Review of the New Drug Submission in Canada 5.Current development stage: (1)Application submission/approval/disapproval/each of clinical trials (include interim analysis): The Health Canada has accepted the New Drug Submission of BESREMi (Ropeginterferon alfa-2b) 500 mcg/mL solution for injection in prefilled syringe for PV. (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 New Drug Submission in Canada (1)Estimated date of completion: According to Health Canada’s review procedure, the review period for a New Drug Submission is approximately 300 days from the date of acceptance. The actual review timeline and approval are subject to Health Canada’s official decision. (2)Estimated responsibilities: N/A. 7.Market situation: Polycythemia Vera (PV) is a chronic, progressive myeloproliferative neoplasm (MPN). Although the overproduction of red blood cells is most dramatic; however, in most cases, there are elevated white blood cells and platelets as well. Patients with PV are at high risk of cardiovascular complications such as thrombosis, embolism and secondary myelofibrosis or leukemic transformation. According to market research, there are around 17,000 patients living with PV in Canada, and the current treatment includes phlebotomy, hydroxyurea (HU), interferon and JAK2 inhibitors. 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)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 worldwide, including major markets such as the United States, Japan, China and European Union. (2)The Company entered into an exclusive commercial license agreement with FORUS Therapeutics Inc. for the registration and commercialization of Ropeginterferon alfa-2b in Canada. 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.:				