



**KALBE**

# Kalbe PowerPoint Slides

## Experience of Kalbe Farma in Entering Europe




# Kalbe Farma at a Glance

- The largest publicly-listed pharmaceuticals company in Southeast Asia, with market cap more than 3 billion USD
- Over 10,000 employees and a marketing and sales force of 4,000 covering 80% of the Indonesian consumer health and 100% of the Indonesian prescription pharmaceuticals market
- Kalbe markets 95% of its products in Indonesia as Indonesian pharmaceutical market still presents a very attractive market:
  - total value of 4 Billion USD and
  - annual growth of more than 10%
- Kalbe continuously expands its market. Today, it already promotes the products in 6 major markets in Southeast Asia and some countries in Africa.
- In addition, Kalbe also strives to penetrate highly regulated market such as Europe through its patented product, named Kalsolac™. But, it faced several challenges along the road...

# Kalsolac™ at a Glance

- Kalsolac is a lactate based infusion solution, invented by the late Prof. Xavier Lèverve from France
- Kalsolac composition:
  - consists of very old compounds and therefore the safety profiles of the individual compounds are highly known; mitigated a lot of risks in drug development.
- Initial pilot clinical studies showed promising results for Traumatic Brain Injury and cardiac surgery patient.
- Based on the above considerations, Kalbe decided to acquire the project in 2003.
- Through its subsidiary, Innogene Kalbiotech Pte Ltd (IGK), we filed the patent and the EU patent was granted in 2006.

# Granted EU Patent

(19)  **Europäisches Patentamt**  
**European Patent Office**  
**Office européen des brevets**



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(54) **USE OF A PHARMACEUTICAL COMPOSITION CONTAINING LACTIC ACID OR LACTATE AND POTASSIUM FOR TREATING BRAIN EDEMA OR BRAIN INJURY**

VERWENDUNG EINER PHARMAZEUTISCHEN FORMULIERUNG ENTHALTEND MILCHSÄURE ODER LAKTAT UND KALIUM ZUR BEHANDLUNG VON HIRNÖDEM UND VERLETZUNGEN DES GEHIRNS

UTILISATION D'UNE COMPOSITION PHARMACEUTIQUE COMPRENANT DE L'ACIDE LACTIQUE OU DU LACTATE DESTINEE AU TRAITEMENT DE L'OEDEME CEREBRAL OU DES LESIONS CEREBRALES

# Challenges in Penetrating EU Market

1. Availability of clinical data for the EU requirement to support the indication:
  - The clinical trial cost was very high
  - Challenges in finding suitable partners to co-develop
2. Availability of the drug supplies for both clinical study and commercialization
  - Challenges in finding manufacturer with EU GMP (Good Manuf. Practice) with reasonable investment
3. Racing with time:
  - The expiry of the patent
4. Commercialization challenge:
  - Competition in the market

***Nevertheless, we do not give up and continue our strive to overcome all the challenges to go to EU by implementing new and innovative strategies***

Thank you.