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# CHINA MEDICAL SYSTEM HOLDINGS LIMITED

康哲藥業控股有限公司\*

## (Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 867)

# Announcement Related to the Asset Purchase of the Product Traumakine® of Faron

The board of directors (the "Board") of China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") announces that, it was informed that on 8 May2015, A&B (HK) Company Limited("A&B"), a company 100% owned by Dr.Lam Kong (a controlling shareholder (as defined in the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules")) of the Company) entered into agreements (the "Faron Agreements") with Faron Pharmaceuticals, Ltd ("Faron"), pursuant to which, among other things, A&B (i) acquired15.72% of the shareholding of Faron; (ii) acquired the assets (the "Product Assets")related to the product Traumakine® (the "Product") in China, Hong Kong, Macau and Taiwan(the "Territory"); (iii)was licensed to use certain intellectual properties related to the Product from the Territory; and (iv) was granted the right to exchange Product information with Faron. The Product Assets include marketing authorization in Switzerland and the Territory and certain intellectual properties related to the Product. The Board was further informed that A&B will continue to invest in the development of the Product in the Territory.

On 19 May 2015, a wholly-owned subsidiary of the Company (the "**CMS Subsidiary**"), entered into agreements with A&B and/or Faron respectively ("**Transfer Agreements**"). Pursuant to the Transfer Agreements, A&B shall transfer and CMS Subsidiary shall acquire the Product Assets in the Territory. Whilst terms and conditions of such transfer, including the consideration for the transfer of the Product Assets, will be further negotiated and agreed between A&B and CMS Subsidiary at a later stage prior to the launch of the Product in the Territory, the parties intend that the consideration for such transfer will be

calculated with reference to the net sales of the Product in the Territory. The Company will comply with the relevant provisions of the Listing Rules from time to time in relation to the transfer as and when appropriate.

Entering into these agreements initiated a new mode for the Group to bring and develop new products. This transaction shows that the Group has extended the bring-in products assets from marketed types to the overseas products which in the late research and development stage. The Directors consider that the products which can be acquired through this mode generally are products that (i) target at major diseases of human kind and have been proven to be good treatment in the early trials; and (ii) have registered and valid patents. The Board believes that the Group will benefit from this mode of cooperation given that the Group will not undertake the research risks in connection with the pre-launched products. The Boardbelieves that this cooperation mode will become one of the main modes of introduction of future products of this type.

#### About Traumakine®

Traumakine® is a Recombinant Human Interferon beta-1a intravenous lyophilized preparation for the treatment of acute respiratory distress syndrome (ARDS). ARDS is an acute respiratory failure caused by many reasons, with progressive respiratory distress, refractory hypoxemia and non-cardiogenic pulmonary edema as clinical symptoms, it is one of the common clinical acute and critical diseases. ARDS involves several clinical sections, and the common causes including systemic infection, trauma, shock, burns, acute severe pancreatitis and so on. For this disease, there are no targeted drug treatments currently, primary diseases treatment and respiratory supportive treatment are the main treatment strategies for ARDS at present, but they didn't get an ideal efficacy with high mortality (China 50%, Europe and America 35-45%). Therefore, once the Product is approved by EMA, it will become the first life-saving drug approved for the treatment of ARDS in the world.

Traumakine® has applied 4 use patents in the world, in which 3 have been authorized in America, EU and China, and the remaining one is a PCT application.

The product was designated as an orphan drug for acute lung injury by EU on November 29, 2007.

Traumakine® has finished phase I/II clinical study in UK with28-day mortality as the primary effectiveness endpoint. The result showed that the Product improved the mortality significantly (the mortality in treatment group is 8% vs the control group 32%, with an 81% reduction in odds of 28-day mortality, p=0.01). Related research result has been published on the famous Lancet Respir Med journal (Lancet RespirMed.2014Feb;2(2):98-107).

Based on the positive result of the phase I/II clinical trial, EMA CHMP held a SAWP meeting for the project in November 2013, the SAWP agreed on the advice to be given to the applicant, and CHMP adopted the advice to be given to the applicant. Based on the advice, the phase III clinical trial protocols have been finalized. The phase III clinical trial is divided into two separate phase III studies conducted sequentially in time, the first phase III study, carried out in seven European countries initiates recruitment in Q3 of 2015, and is planned to complete the recruitment in 12 months.

## **Risk Warning**

While the result of phase I/II clinical trials of Traumakine® is positive, there is still a risk that Traumakine® could not be launched in the market due to the failure of the phase III clinical trial, or a risk that Traumakine® could not be sold on the market because its market application is not approved by EMA, as well as a risk that could not be sold on the market because of not acquiring the approval of CFDA though acquired the approval of EMA.

## About Faron Pharmaceuticals, Ltd.

Faron Pharmaceutical, Ltd. is a privately owned late clinical stage drug discovery and development company in Turku, Finland, focusing on acute lung injury, cancer growth and spread, and vascular inflammatory diseases. For more information of the company, please visit <u>www.faronphamaceuticals.com</u>(the contents of which do not form part of this announcement).

The parties to the Transfer Agreements will further negotiate terms and conditions for the transfer of the Product Assets to CMS Subsidiary as and when appropriate, and there is no assurance that the transfer of Product Assets will materialise in accordance as contemplated or at all. Shareholders and potential investors are therefore advised to exercise caution when dealing in the securities of the Company.

By Order of the Board

China Medical System Holdings Limited

Lam Kong

Chairman

19 May 2015, Hong Kong

As at the date of the announcement, the directors of the Company include (i) executive directors: Mr. Lam Kong, Mr. Chen Hongbing, Ms. Chen Yanling and Ms. Sa Manlin; (ii) independent non-executive directors: Mr. Cheung Kam Shing, Terry, Mr. Wu Chi Keung and Mr. Huang Ming.