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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)

Voluntary and Business Update Announcement

Signing of a Framework Asset Transfer Agreement Related to NRL-1 etc.

China Medical System Holdings Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Group through its wholly-owned subsidiary (the “**CMS Subsidiary**”) entered into a framework asset transfer agreement (the “**Agreement**”) with A&B (HK) Company Limited (“**A&B**”) relating to the pharmaceutical preparation, formulation, dosage form, or delivery vehicle, containing or comprising NRL-1 etc. and/or line extensions (collectively, the “**Products**”), A&B is a company wholly-owned by Mr. Lam Kong, a controlling shareholder (as such term is defined in the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) of the Company. According to the Agreement, the Group has agreed to acquire all assets related to the products (the “**Assets**”) in China (including Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan) (the “**Territory**”) from A&B, and assumed all rights and obligations in respect of the Assets (the “**Transaction**”).

A&B obtained the Assets from an entity which in turn obtained the Assets from Neurelis, Inc. (“**Neurelis**”). The Assets include but without limitation the marketing authorization, manufacture rights, intellectual property and all commercial information, medical information, know-how and records related to the Products in and for the Territory. In addition, pursuant to the Agreement, the Group also acquired all the necessary licenses related to, among other things, the commercialization of the Products under the Agreement.

The Agreement is a framework agreement in respect of the Transaction. As and at the date of the Agreement, the parties have not agreed on the definitive terms and conditions of the Transaction, including the consideration for the transfer of the Assets under the Agreement. CMS Subsidiary and A&B will further negotiate and agree on the terms of the Transaction at a later stage prior to the launch of the Products in the Territory. The parties expect that the consideration for the Transaction will be calculated with reference to the net sales of the Product in the Territory. If and when the Company agrees the definitive terms of the Transaction with A&B, it will comply with the relevant provisions of the Listing Rules including publishing a shareholders circular and seeking independent shareholders' approval, if applicable.

This cooperation will further enrich the Group's patented innovative pipeline products and the Group believes that the Products will have broad market prospects after being commercialized in the Territory.

About the Product

NRL-1 (Registration data required for New Drug Application (NDA) submission to the US Food and Drug Administration (FDA) has been completed)

Domestic epidemiological data showed that the prevalence of epilepsy in China is 4‰ to 7‰. In recent years, domestic and foreign scholars have paid more attention to the prevalence of active epilepsy, that is, the ratio of the number of epileptic seizures occurring in a certain period of time (1 or 2 years) to the average population in the same period. The prevalence of active epilepsy in China is 4.6‰. According to this estimation, there are about 6 million active epilepsy patients in China, and about 0.4 million new cases reported each year. Due to the lack of proper understanding of epilepsy and medical resources, most patients with epilepsy did not receive reasonable and effective treatment, resulting in a treatment gap of about 63% (ie, the proportion of patients who have not received regular treatment). Based on this, it is estimated that about 4 million patients with active epilepsy in China have not received reasonable treatment. In addition, in patients with epilepsy who have received regular treatment (about 2 million), 20%-30% (about 0.4 million-0.6 million) are still out of effective control and are at risk of repetitive seizures. Data show that, patients with poorly controlled epilepsy have frequent recurrent seizures, and the mean number of seizures per year can be up to nearly 70 times. If the seizure cannot be controlled in time, it can lead to a longer duration of convulsions, and then the possibility of irreversible brain damage will be greater which even threaten the patient's life. Most of the early convulsive status epilepticus occurs outside the hospital (usually without venous access), and even if sent to the hospital in time, the patients will be usually treated in the emergency department with intravenous diazepam which will lead to the time window for reasonable treatment passing. Therefore, a

convenient, effective, safe, and timely treatment can significantly shorten the duration of epilepticus. However, unfortunately, there are currently no preparations meet the above characteristics (including but not limited to nasal sprays, rectal suppositories, etc.) at domestic currently.

NRL-1 (intranasal diazepam) is a proprietary formulation of diazepam, delivered via a nasal formulation in a spray, being developed for the management of pediatric and adult patients who require intermittent use of diazepam to control bouts of increased seizure activity, also known as acute repetitive or cluster seizures. Compared with intravenous diazepam, the product is administered intranasally and shows 96% absolute bioavailability with low variability. In addition, the plasma profile of diazepam with NRL-1 is consistent with the rectal gel formulation of diazepam, associated with a rapid onset and low plasma peak to eliminate concerns of respiratory depression. When patients are uncontrolled with seizure, they can use nasal diazepam to receive timely treatment by themselves or with the help of caregivers. Simple and rapid administration can shorten the duration of epileptic seizures and lead to better treatment outcomes for patients. Therefore, it is intended to satisfy the treatment needs of special preparations which are effective, convenient and can be applied anytime and anywhere in patients with cluster seizures in China.

NRL-1's formulation incorporates the unique combination of a Vitamin E-based solvent and Intravail® absorption enhancement with the goal of obtaining unparalleled absorption, tolerability, and reliability in a nasal formulation. NRL-1 allows delivery of a therapeutic dose of diazepam via a well-tolerated nasal spray in order to provide rapid, reliable treatment of these seizures where they occur - at home, work, school or elsewhere. Moreover, NRL-1 has been granted Orphan Drug and Fast Track Designations by FDA. The formulation patents for this product have entered into Chinese national phase via PCT international application, and entered into the substantive examination.

Neurelis is planning to submit a 505(b) (2) marketing authorization application of NRL-1 to FDA. The marketing authorization application is based on multiple clinical trials. PK studies in NRL-1 in healthy subjects demonstrated 96% absolute bioavailability and comparable bioavailability to Diastat (rectal diazepam gel, not launched in China) with significantly less variability. Preliminary results of PK study in seizing patients showed similar exposure of NRL-1 in seizing or non-seizing state/strong correlation to PK in healthy subjects. The 12-month open-label, long-term safety phase III clinical trial evaluating repeated use in patients with epilepsy showed exceptional tolerability and safety of NRL-1 in repeated at-home use during seizure conditions.

In China, NRL-1 is classified as a modified new drug for class 2 according to Chemical Drug Registration Classification. NRL-1 is identified as orphan drug, pediatric drug and emergency drug in America, furthermore its API (raw material) has been used globally for decades, no ethnic difference has been found, and on the basis of that, the Company will apply for marketing authorization with submitting overseas clinical research data (including PK comparison reports in Asian and other ethnic population) to the China National Drug Administration (CNDA) for exemption from clinical trial according to Opinions on Deepening the Reform of Review and Approval System and Encouraging Innovation of Pharmaceutical Medical Devices issued by General Office of State Council of China, Decision of the China Food and Drug Administration on Adjusting the Registration and Administration Matters of Imported Drugs (Order No.35 of CNDA) and Technical Guidelines for Accepting Data on Overseas Clinical Trials of Drugs (No. 52 of 2018) issued by CNDA, etc. If exemption from clinical research is approved, NRL-1 will be approved by CNDA in China as soon as possible after it is approved by FDA in America.

In summary, NRL-1 will not only provide convenient, effective and safe first-aid treatment to rescue cluster seizures, but also greatly improve the quality of life of patients and their caregivers and reduce their huge economic burden. It could be foreseen that once this product is approved in China, it will certainly become a long-term prepared and essential medicine for patients with acute repetitive seizures, and the market prospects are promising.

Risk Warning

There are risks that the Products in the pipeline could not be launched in the market due to the failure of the clinical trials.

About Neurelis

Neurelis is a privately-held San Diego-based specialty pharmaceutical company organized to license, develop, and commercialize product candidates for epilepsy and the broader central nervous system (CNS) market. It leverages its expertise in the development and commercialization of CNS compounds and strong relationships with leading researchers and clinicians in these markets to advance unique product candidates, such as NRL-1 for the treatment of acute repetitive or cluster seizures, to address significant unmet medical needs. For more information, please visit <https://www.neurelis.com/>.

The parties to the Agreement will further negotiate the terms and conditions of the Transaction, and there is no assurance that the Transaction will as contemplated by the

Agreement or at all. Therefore, shareholders and investors are advised to exercise caution in dealing in the shares and other securities of the Company.

By order of the Board
China Medical System Holdings Limited
Lam Kong
Chairman

Hong Kong, 20 August 2018

As at the date of the announcement, the directors of the Company comprise (i) Mr. Lam Kong, Mr. Chen Hongbing and Ms. Chen Yanling as executive directors; and (ii) Mr. Cheung Kam Shing, Terry, Mr. Wu Chi Keung and Mr. Leung Chong Shun as independent non-executive directors.