# 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 PoNS

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 portable neurostimulation devices developed by or for the Helius Medical Technologies group ("**Helius**") (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 from A&B all assets related to the Products (the "**Assets**") in China (including Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan) (the "**Territory**") (the "**Transaction**").

The Assets were originally purchased by A&B from Helius. The Product refers to the portable neurostimulation devices (whether under the name of PoNS Devices or otherwise) developed by or for Helius, together with any subsequent improvements and replacements for such devices developed by or for Helius or subsequently acquired by Helius. The Assets include without limitation: (i) regulatory approvals for the Product in the Territory; (ii) the right to manufacture the Product for the Territory as well as the manufacturing technology of the Product exclusively related to the Territory; (iii) intellectual property rights related to the Product in the Territory; and (iv) copies of all data, books, records, commercial information,



* *For identification purpose only*

medical information and other information which are related exclusively to and necessary for the manufacture and commercialization of the Product for the Territory. In addition, pursuant to the Agreement, the Group will also acquire all the necessary licenses related to, among other things, the commercialization of the Product.

The Agreement is a framework agreement in respect of the Transaction. As 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 Product 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 any 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 Product will have broad market prospects after being commercialized in the Territory.

**About the Product**

**PoNS (registrational clinical trial has been completed; marketing clearance submission to the US Food and Drug Administration (FDA) is being planned)**

Traumatic Brain Injury (TBI), also known as brain damage or head injury, is brain tissue damage caused by trauma. Because of the high mortality and disability rate, TBI imposes a heavy burden on individuals, their families and the society. TBI is a global health problem and a study has estimated about 50 million to 60 million new TBI cases occur annually worldwide, over 90% of which are mild TBIs. In China, traffic accident is the most common cause of TBI (54%), followed by falls (32-33%) and violence (9-11%), and there are more than 1.3 million people suffering from accidental injuries each year due to traffic accidents. TBI survivors are usually accompanied by different types and degrees of dysfunction with a severe disability rate greater than 50%. Comprehensive rehabilitation training is an important method to improve the prognosis of TBI patients. TBI rehabilitation includes the recovery of consciousness, motor function and cognitive function, etc. However, TBI rehabilitation medical system in China is not yet perfect at present, and domestic scholars pay more attention to the study of cognitive function improvement rather than balance improvement, and there is no traditional rehabilitation technology to improve the walking ability of TBI patients effectively. Therefore, the improvement of balance disorders in TBI patients has been

unmet for a long time, and an effective new rehabilitation treatment is in urgent need to meet this clinical demand.

PoNS, Portable Neuromodulation Stimulator, a class II medical device, is the only tongue-delivered stimulator which stimulates the cranial nerves (trigeminal and facial nerves) by acting on the tongue. Combined with exercise training, PoNS is being developed for the adjuvant treatment of balance disorders in patients with TBI, stroke, cerebral palsy, etc.

PoNS is a non-invasive device with a compact design. It is ready-to-wear and has the characteristic of safety, easy to use and patient personalization. PoNS is comprised of two major components, an electric pulse generator and a replaceable mouthpiece. The electric pulse generator provides electrical stimulation to the mouthpiece placed in the mouth. The electrodes on mouthpiece deliver the nerve impulses to the brain through the cranial nerves on the tongue with the aim of encouraging neuroplasticity and enabling the damaged brain to compensate for lost function due to trauma or disease by recruiting existing working neurons. Compared with existing treatment methods such as transcranial stimulation, transcutaneous stimulation, etc., which take cerebral cortex, spinal cord, peripheral nerve and muscle as the main regulatory objects, PoNS can have a long-lasting effect on the dorsal pons, cerebellum and medulla. Those areas are closely related to balance, posture, gait, oculomotor function, etc. and are usually unreachable by traditional nerve stimulation methods.

PoNS is a patented product. The invention patents, protecting the product equipment, have entered into the Chinese national phase via PCT international application and entered into the stage of substantive examination, which will expire in 2035, if granted. Meanwhile, the product has design patents in China, which will expire in 2025.

In August 2017, Helius has completed the registrational clinical trial of PoNS for the marketing and is planning to submit 510(K) application to FDA in the third quarter of 2018, for the treatment of chronic balance deficit due to mild- to moderate- TBI. The marketing application is based on a randomized, double blind, multicenter clinical study designed to evaluate the safety and efficacy of PoNS in subjects with a chronic balance deficit due to mild- to moderate- TBI, and the results demonstrated significant improvement in the balance ability of subjects. The response rate analysis in this study showed that 75.4% subjects in high frequency pulse (HFP) group and 60.7% in low frequency pulse (LFP) group had at least a 15-point change in Sensory Organization Test (SOT), and both groups demonstrated statistically significant increases in composite SOT scores at 2 and 5 weeks, compared to baseline. Wherein, at 5 weeks, the mean increase in SOT score in each group, 27.6 for HFP

and 23.6 for LFP are markedly above what has been established for physical therapy alone (8 - 13 points). SOT is an objective measurement tool for patient balance assessment. SOT Composite Score is a 0 to 100-point scale where zero means the patient cannot balance unaided and 100 implies perfect balance. An average SOT score for a neurologically intact adult is 70-80 and a change in score of 8 points is clinically significant. The mean baseline score in the trials was about 40, representing a profound loss of balance. Furthermore, continuous improvement was observed after the PoNS treatment finished, and decreasing frequency in falls and headaches of subjects met the safety endpoints and no device related serious adverse events were observed.

The approval of an innovative medical device could be applied to PoNS, and exemption from clinical research in China could be applied 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, Special Examination and Approval Procedures for Innovative Medical Products (Trial) ([2014] No. 13) and Technical Guidelines for Accepting Data on Overseas Clinical Trials of Medical Devices (No. 13 of 2018) issued by the China National Drug Administration (CNDA). Classification identification application of PoNS has been submitted by the Company to Medical Device Management Center, and it is intended to be managed as Class II Device. The Company will submit clinical trial data obtained outside China to CNDA and apply for exemption from clinical trial requirements after the approval of an innovative medical device and the completion of device registration test for PoNS. If exemption from clinical research is approved, PoNS will be approved by CNDA in China as soon as possible after it is approved by FDA in America.

As mentioned above, there is a large unmet treatment need for rehabilitation of TBI prognostic balance disorders. However, no drugs or methods are approved to solve this treatment difficulty in domestic and overseas currently. PoNS has shown a good healing efficacy in the registered clinical trial. Therefore, once approved, PoNS will provide patients with a new treatment mode to improve the balance disorders, self-care ability and quality of life, and greatly reduce the financial burden for patients and their families.

Moreover, except for the treatment of TBI, further clinical researches of PoNS for sequelae of stroke and cerebral palsy are also actively progressing, based on the mechanism and approach of it. Considering the huge patient population of TBI, stroke and cerebral palsy in China, PoNS will have a fairly broad market prospect.

**Risk Warning**

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

**About Helius**

Helius Medical Technologies is a neurotech company focused on neurological wellness. Its purpose is to develop, license and acquire unique and non-invasive platform technologies that amplify the brain's ability to heal itself. Helius is a publicly traded company listed on the Toronto Stock Exchange (TSX:HSM) in Canada and the NASDAQ (OTCQB：HSDT) in the United States. For more information, please visit https://heliusmedical.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 materialise 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.*