

# Miraculins Updates Market on Regulatory Progress in China for its Scout DS® Diabetes Screening Device

✘ May 22, 2015 (Source: Marketwired) – **Company's Preparations for CFDA Product Testing Submission Now Complete**

**Miraculins Inc. (TSX VENTURE:MOM)** (“Miraculins” or the “Company”), a medical diagnostic company focused on acquiring, developing and commercializing diagnostic tests and risk assessment technologies for unmet clinical needs, announces that it has now completed all required preparations for the submission of its Scout DS® device for product testing in compliance with Chinese Food and Drug Administration (CFDA) requirements. Product testing, which must precede clinical trials in China, relates to a series of safety and operational tests that the CFDA testing center and its engineers decide are suitable for a medical device including electrical testing, biocompatibility testing, mechanical testing, stability testing, integrity testing, and other related tests to verify the device’s specified operating parameters.

Product testing is the first major step towards securing regulatory approval for the Scout DS® in China, and the Company has been diligently working with its lead Chinese regulatory consultant, Emergo Global, towards compiling and translating all of the technical documentation required for submission to enable the product testing process to begin.

Preparation for CFDA product testing was significant and included the translation of Scout DS® device engineering drawings, circuitry diagrams, operating manuals, ISO

documentation, as well as all of the internationally-recognized electrical, safety, mechanical and related testing and performance documentation that the Company already had on file for the Scout DS<sup>®</sup> related to its prior clearances in Canada and the European Union.

Miraculins has also been working with Emergo Global to evolve a comprehensive regulatory strategy in China overall, that additionally includes the development of a study protocol for the Scout DS<sup>®</sup> clinical trials that will be conducted in China following the successful conclusion of the product testing process.

“The Company has completed a significant amount of work related to the preparation and translation of all required materials for its formal product testing submission,” said Christopher Moreau, President and CEO of Miraculins. “While the regulatory process in China is involved and time consuming, we remain focused on the end goal which is to secure CFDA regulatory clearance and commence the sale and distribution of Scout DS<sup>®</sup> diabetes screening devices into Mainland China under the terms of our previously announced agreement.”

The agreement between Miraculins and a privately-owned, Hong Kong based medical device import company named Catalyn Technologies, established the framework for the sale and distribution of up to \$90 Million USD in Scout DS<sup>®</sup> Diabetes Screening Devices in Mainland China, and also included the appointment of Cachet Pharmaceutical Co., Ltd. (“Cachet”) as the exclusive Scout DS<sup>®</sup> distributor in the territory. Cachet is a 15.8 Billion RMB market cap (or about \$2.6 Billion USD) wholesale/retail drug distribution and medical device distributor. Cachet’s largest shareholder, the China Youth Industrial Development Corporation, is owned directly by the Central Committee of the Communist Youth League of China.

Cachet is also listed on the Shenzhen Stock Exchange (stock name: Cachet; stock code: 002462).

### **About Miraculins Inc.**

Miraculins is a medical diagnostic company focused on acquiring, developing and commercializing non-invasive technologies for unmet clinical needs. A significant number of promising diagnostic opportunities remain un-commercialized because of the sizable gap between the discovery stage, when research institutions are typically involved, and the commercialization stage, when the larger commercial enterprises become interested. Miraculins has direct experience in bridging this gap. The Company's Scout DS<sup>®</sup> device has been regulatory cleared in certain markets both as a clinical tool to assist in the identification of prediabetes and type 2 diabetes, and is the first non-invasive testing system designed to provide a highly sensitive and convenient method for measuring prediabetes/type 2 diabetes related biomarkers in the skin, the accumulation of which are accelerated by abnormal blood sugar levels and oxidative stress. Unlike current testing methods, a Scout DS<sup>®</sup> test requires no blood draw, no fasting, and no waiting for a lab result. The product has been used and validated in thousands of patients around the world. For more information visit [www.miraculins.com](http://www.miraculins.com).

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### *Caution Regarding Forward-Looking Information*

*Certain statements contained in this press release constitute forward-looking information within the meaning of applicable Canadian provincial securities legislation (collectively, "forward-looking statements"). These forward-looking*

statements relate to, among other things, our objectives, goals, targets, strategies, intentions, plans, beliefs, estimates and outlook, including, without limitation, our anticipated future operating results, our regulatory, sales and distribution activities in China and can, in some cases, be identified by the use of words such as “believe,” “anticipate,” “expect,” “intend,” “plan,” “will,” “may” and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements.

These statements reflect management’s current beliefs and are based on information currently available to management. Certain material factors or assumptions are applied in making forward-looking statements, and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: Miraculins’ early stage of development, lack of product revenues and history of operating losses, uncertainties related to clinical trials and product development, rapid technological change, uncertainties related to forecasts, competition, potential product liability, additional financing requirements and access to capital, unproven markets, supply of raw materials, income tax matters, management of growth, partnerships for development and commercialization of technology, effects of insurers’ willingness to pay for products, system failures, dependence on key personnel, foreign currency risk, risks related to regulatory matters and risks related to intellectual property and other risks detailed from time to time in Miraculins’ filings with Canadian securities regulatory authorities, as well as Miraculins’ ability to anticipate and manage the risks associated with the foregoing. Additional information about these factors and about the material factors or assumptions underlying such forward-looking statements may be found in the

*body of this news release. Miraculins cautions that the foregoing list of important factors that may affect future results is not exhaustive. When relying on Miraculins' forward-looking statements to make decisions with respect to Miraculins investors and others should carefully consider the foregoing factors and other uncertainties and potential events.*

*These risks and uncertainties should be considered carefully and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in this press release are based upon what management believes to be reasonable assumptions, Miraculins cannot provide assurance that actual results will be consistent with these forward-looking statements. Miraculins undertakes no obligation to update or revise any forward-looking statements except as may be required by law.*

*Scout DS<sup>®</sup> is a registered trademark of Miraculins Inc. All Rights Reserved. 2015.*