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Miraculins Provides Pre-Submission De Novo Documentation to the FDA for its Scout® Diabetes Technology

Next Step Towards Securing Market Clearance in the U.S.

WINNIPEG, Manitoba – February 18, 2015 - Miraculins Inc. (TSX-V: MOM) (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 provided pre-submission documentation to the U.S. Food and Drug Administration ("FDA") regarding the *de novo* classification of its Scout® diabetes device, as a next step towards securing marketing clearance in the United States.

There is a three-tier classification system in the U.S. that the FDA has established for medical device clearance based on the risks and types of controls required to assure the public's safety:

- **Class I devices** are the lowest risk, require only general controls, and typically do not require premarket notification or approval.*
- **Class II devices** are moderate risk, require general and special controls, and typically require a 510(k) application. A 510(k) is a premarket submission that demonstrates that a device is substantially equivalent to a legally marketed device that is not subject to premarket approval (called a predicate device).*
- **Class III devices** are considered to have the highest risk and require general controls, special controls, and premarket approval. If a low to moderate risk product does not have a predicate device it receives an automatic Class III designation.*

For automatic Class III designations, the FDA amended its *de novo* classification process in 2012 to provide a pathway to Class I or Class II for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device.

Based on interactions with the FDA in 2014, including a meeting between a Miraculins delegation and FDA representatives in Washington, D.C., the Company is of the view that there is no predicate device for the Scout®, and that the *de novo* process could provide the appropriate regulatory pathway for market clearance in the U.S. The *de novo* process may be less burdensome than would be the case if the Company sought a premarket approval for the Scout® device.

**Source: Cato Research*

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® device is the first non-invasive

diabetes testing system designed to provide a highly sensitive and convenient method for measuring 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® 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. The Company's PreVu® POC Test is a revolutionary new coronary artery disease risk assessment technology that measures cholesterol levels in a patient's skin non-invasively, painlessly and without the need for fasting. For more information visit 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, the pre-submission of documentation concerning the de novo classification of our Scout® device, 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.