

## Miraculins Updates Market on its U.S. FDA Strategy for the Scout DS<sup>®</sup> Device

**WINNIPEG, Manitoba – August 28, 2014 - Miraculins Inc. (TSX-V: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, has announced its plans to file pre-submission documentation with the United States Food and Drug Administration (USFDA) regarding the *de novo* classification of its Scout DS<sup>®</sup> device, as a next step in securing marketing clearance in the United States.

The *de novo* classification process provides a potential pathway to Class I or Class II classification 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.

The Scout DS<sup>®</sup> device is the world’s first non-invasive and highly-sensitive test designed to measure diabetes related biomarkers in the skin. It does not require a blood draw or fasting and generates a result in as little as 80 seconds. The Scout DS<sup>®</sup> device uses visible light to measure the optical signature of fluorescent biomarkers in the skin, the accumulation of which are accelerated by abnormal blood sugar levels and oxidative stress.

The Company had previously filed documentation with the USFDA for the Scout DS<sup>®</sup> device in December 2013. The purpose of that documentation was to solicit general feedback from regulatory officials for assistance in establishing a specific clinical and regulatory plan for the marketing clearance of the Scout DS<sup>®</sup> device in the United States. The process highlighted the need for the Company to compile a more detailed information package including a study protocol intended to support regulatory clearance.

The pre-submission for a *de novo* process is intended to allow the USFDA to review and provide feedback on the suitability of the *de novo* classification process for the Scout DS<sup>®</sup> device, as well as for the planned data to be gathered and submitted by the Company to obtain marketing clearance. The *de novo* process is generally considered to be appropriate for “novel” medical devices whose risk profiles do not warrant Class III designation which is a more expensive and time consuming approval process.

Almost 26 million people in the U.S. are presently estimated to have diabetes, with 7 million of these being undiagnosed. A further estimated 80 million people in the U.S. are pre-diabetic, with approximately 90% of these being completely unaware of their condition. It is expected that more than 500 million people globally could be affected by diabetes by the year 2030.

### **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 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 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. The Company's PreVu<sup>®</sup> 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](http://www.miraculins.com)

**For more information, please contact:**

Christopher J. Moreau  
President & CEO  
Miraculins Inc.  
Ph: 204-477-7599  
Fax: 204-453-1546

info@miraculins.com  
www.miraculins.com

*Neither the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.*

**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, 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.*

*Scout DS<sup>®</sup> and PreVu<sup>®</sup> are registered trademarks of Miraculins Inc. All Rights Reserved. 2014.*