

## CARDIO3 BIOSCIENCES ANNOUNCES Q3 2014 BUSINESS UPDATE

**Mont-Saint-Guibert, Belgium** - Cardio3 BioSciences (C3BS) (*Euronext Brussels and Paris: CARD*), a leader in the discovery and development of regenerative, protective and reconstructive therapies, announces today its business update for the nine-month period ending on 30<sup>th</sup> September 2014.

### Highlights of the 3<sup>rd</sup> quarter

- The DSMB (Data Safety and Monitoring Board), a committee composed of international independent experts, unanimously recommended continuing the CHART-1 study according to the original protocol, after having analyzed safety data relating to C-Cure<sup>®</sup> and C-Cath<sub>ez</sub><sup>®</sup>.
- Strong cash position with €36.2 million in cash and short-term investments at 30 September 2014, sufficient to finance the C-Cure<sup>®</sup> clinical programs to the readout of Phase III data.

**Dr Christian Homsy, CEO of Cardio3 BioSciences, said:** *"This quarter, Cardio3 BioSciences has seen the accomplishment of a major milestone within the CHART-1 study: the approval of the safety data of the combination of C-Cure<sup>®</sup> and C-Cath<sub>ez</sub><sup>®</sup> and the unanimous conclusion of the DSMB to continue the study according to the original protocol. Further to that, we have welcomed Switzerland into our Phase III clinical study. This brings further encouragement as we continue the positive progress of our CHART-1 study. On the business side, we have announced our intention to follow a two pillar-based business development strategy, based on cellular therapies and cardiovascular diseases. With the objective of securing the access to new regenerative technologies on the long term, we have entered into an expanded relationship with the Mayo Clinic opening us the doors to new technologies in regenerative medicine. And recently, with the acquisition of CorQuest Medical Inc., we have secured several value creation milestones on the short term, with an aim to commercialize the heart access technology by 2016. Finally, our cash position remains solid which positions us well for the continuation of our C-Cure<sup>®</sup> clinical program."*

### Operational and financial review

In mid-September, Cardio3 BioSciences announced it had received the unanimous recommendation of the Data Safety and Monitoring Board (DSMB) to continue the CHART-1 clinical trial according to the original protocol. The recommendation was based on a planned analysis performed on all patient safety data available as per mid-August 2014. All the members of the DSMB approved the continuation of the trial having concluded that one month post treatment, C-Cure<sup>®</sup> and C-Cath<sub>ez</sub><sup>®</sup> showed no safety issues that compromise the continuation of the CHART-1 Phase III study.

The Company continues to exercise tight cash management and ended the period to 30 September 2014 with €36.2 million in cash. Management confirms that it anticipates the C-Cure<sup>®</sup> clinical program to be fully financed until the availability of the read-out of the primary endpoint.

**Post the period end, C3BS announced:**

- Its business development strategy, articulated around a technology pillar – cellular therapies – and a clinical application pillar – cardiovascular diseases – to further strengthen its long term growth.
- The signature of a preferred access agreement with Mayo Clinic, an extension of the long-standing relationship that linked both parties since 2007.
- The appointment of Dr. Warren Sherman, a renowned American interventional cardiologist, as Chief Medical Officer.
- The authorization to enrol patients in Switzerland in its European Phase III Clinical Trial CHART-1.
- The acquisition of CorQuest Medical Inc. and its unique heart access platform.

At the beginning of October, the Company announced that its business development strategy would be articulated around two pillars, namely a technology pillar – cellular therapies – and a clinical application pillar – cardiovascular diseases – to further strengthen its long term growth. The Company reinforced that the strategy's aim is to expand the Company's product portfolio and generate multiple short term value creation milestones.

A few days later, and as a first realization of its technology pillar expansion, Cardio3 BioSciences announced the signing of a non-exclusive preferred access agreement with the Mayo Clinic. With this agreement, Cardio3 BioSciences is granted preferred access to a broad portfolio of new cell-based technologies in multiple areas such as cardiology or oncology, developed in the Mayo Clinic Center for Regenerative Medicine. Building on its core competences and unique expertise in cellular therapies and cardiovascular diseases developed with C-Cure<sup>®</sup>, Cardio3 BioSciences' access to Mayo Clinic Center for Regenerative Medicine technologies is an extra asset to further strengthen the Company's long term plan to bring the best innovative therapeutic response to unmet medical needs.

Towards the end of October, Cardio3 BioSciences announced the appointment of Dr. Warren Sherman as Chief Medical Officer. In this new role, Dr. Sherman will leverage his deep expertise in the cardiovascular and cell therapy fields to support the continued development of Cardio3 BioSciences' product pipeline, both in cell therapies and cardiovascular diseases. Dr. Sherman is a renowned American interventional cardiologist with more than 30 years' experience in the field of cardiology, with a focus in cell-based therapies for treating patients post myocardial infarction and with heart failure.

At the same time in October, Cardio3 BioSciences received authorization to enrol patients in Switzerland in its Phase III Clinical Trial CHART-1. After the recent authorization in Bulgaria, and earlier in Sweden, Ireland, the United Kingdom, Belgium, Israel, Serbia, Hungary, Spain, Italy, and Poland, Switzerland is the 12<sup>th</sup> country to have authorized this unique study, which aims to treat ischemic congestive heart failure.

18 NOVEMBER 2014 – 5:45 PM CET

Beginning of November, the Company announced a further achievement within the clinical application pillar of its business development strategy: the acquisition of CorQuest Medical Inc. and its unique heart access platform. CorQuest's revolutionary technology is designed to enable cardiologists to take a unique access route directly to the patient's left atrium and therefore has the potential to become a major breakthrough innovation for therapeutic indications such as mitral valve disorders and structural heart disease, conditions often linked to heart failure. Specifically, CorQuest's novel heart access technology comprises a number of instruments which allows for quick, user friendly and easy trans-thoracic access to the heart, directly into the left atrium, ensuring a minimally invasive approach to deliver numerous existing therapeutic devices. Currently in the advanced pre-clinical development phase, Cardio3 BioSciences intends to progress the device through the appropriate clinical and regulatory approval processes, with the aim of obtaining CE mark approval by the end of 2016, which would allow commercialisation in Europe. With the development of this new technology, Cardio3 BioSciences aims to build on its leadership position in innovative therapies and devices for cardiovascular diseases.

\*\*\* END \*\*\*

For more information, please contact:

**Cardio3 BioSciences**

Christian Homsy, CEO

Julie Grade, Corporate Communications Manager

[www.c3bs.com](http://www.c3bs.com)

Tel. : +32 10 39 41 00

[jgrade@c3bs.com](mailto:jgrade@c3bs.com)**For Europe: Citigate Dewe Rogerson**

Chris Gardner

Tel : +44 (0) 207 638 9571

[Chris.Gardner@citigatedr.co.uk](mailto:Chris.Gardner@citigatedr.co.uk)**For the U.S: Rx Communications Group**

Eric Goldman

Tel: +1 917 322 2563

[egoldman@RxIR.com](mailto:egoldman@RxIR.com)

To subscribe to Cardio3 BioSciences' newsletter, visit [www.c3bs.com](http://www.c3bs.com).

 Follow us on Twitter [@Cardio3Bio](https://twitter.com/Cardio3Bio).

**About Cardio3 BioSciences**

Cardio3 BioSciences is a Belgian leading biotechnology company focused on the discovery and development of regenerative and protective therapies for the treatment of cardiac diseases. The company was founded in 2007 and is based in the Walloon region of Belgium. Cardio3 BioSciences leverages research collaborations in the US and in Europe with Mayo Clinic and the Cardiovascular Centre Aalst, Belgium.

The Company's lead product candidate C-Cure<sup>®</sup> is an innovative pharmaceutical product that is being developed for heart failure indication. C-Cure<sup>®</sup> consists of a patient's own cells that are harvested from the patient's bone marrow and engineered to become new heart muscle. This process is known as Cardiopoiesis.



PRESS RELEASE

REGULATED INFORMATION

18 NOVEMBER 2014 – 5:45 PM CET

Cardio3 BioSciences has also developed C-Cath<sub>ez</sub><sup>®</sup>, the most technologically advanced injection catheter with superior efficiency of delivery of bio therapeutic agents into the myocardium.

Cardio3 BioSciences' shares are listed on Euronext Brussels and Euronext Paris under the ticker symbol CARD.

*C3BS-CQR-1, C-Cure, C-Cath<sub>ez</sub>, Cardio3 BioSciences and the Cardio3 BioSciences and C-Cath<sub>ez</sub> logos are trademarks or registered trademarks of Cardio3 BioSciences SA, in Belgium, other countries, or both. Mayo Clinic holds equity in Cardio3 BioSciences as a result of intellectual property licensed to the company. In addition to historical facts or statements of current condition, this press release contains forward-looking statements, which reflect our current expectations and projections about future events, and involve certain known and unknown risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. These forward-looking statements are further qualified by important factors, which could cause actual results to differ materially from those in the forward-looking statements, including timely submission and approval of anticipated regulatory filings; the successful initiation and completion of required Phase III studies; additional clinical results validating the use of adult autologous stem cells to treat heart failure; satisfaction of regulatory and other requirements; and actions of regulatory bodies and other governmental authorities.*