



12 NOVEMBER 2013, 5:35 PM CET

CARDIO3 BIOSCIENCES ANNOUNCES Q3 2013 BUSINESS UPDATE

AND

AUTHORIZATION TO ENROLL PATIENTS IN POLAND IN ITS CHART-1 PHASE III CLINICAL TRIAL

Mont-Saint-Guibert, Belgium, – Cardio3 BioSciences SA (C3BS) (*NYSE Euronext Brussels and Paris: CARD*), a leader in the discovery and development of regenerative, protective and reconstructive therapies for the treatment of cardiac diseases, today announces:

- A business update for the nine-month period ending 30 September 2013; and
- It has received the authorization from the Polish Medicines Agency (URPL) to begin its Congestive Heart failure Cardiopoietic Regenerative Therapy (CHART-1) European Phase III trial for C-Cure® in Poland.

Highlights

- Completion of IPO on NYSE Euronext Brussels and NYSE Euronext Paris raising €26.5 million.
- Continued progress with the CHART-1 clinical trial of its lead product candidate, C-Cure®. CHART-1 is the world's first Phase III clinical trial of a regenerative medicine for the treatment of heart failure.
- To date, eight countries have granted authorization for Cardio3 BioSciences' Phase III (CHART-1).
- Strong cash position with €24.3 million in cash and short-term investments at 30 September 2013, sufficient to finance the Company's existing clinical development program.
- Executive management team strengthened with the addition of Gaetane Metz as Chief Operating Officer of the Company on 4 October 2013.

Authorization to begin CHART-1 in Poland

After the recent authorization in Italy, Spain, and earlier in United Kingdom, Belgium, Israel, Serbia and Hungary, Cardio3 BioSciences has received authorization from the Polish Medicines Agency (URPL) to begin the CHART-1 trial, the eighth country to have approved this unique study. There will be 3 leading clinical centers participating in the study in Poland.

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: "The period since the end of June 2013 has been transformational for the Company. The successful completion of our IPO and continued progress with the CHART-1 trial leave us very well placed to continue to extend our leadership in regenerative medicine for heart failure."



12 NOVEMBER 2013, 5:35 PM CET

Operational and financial review

Cardio3 BioSciences is developing its most advanced therapy, C-Cure[®], for the treatment of heart failure, one of the world's greatest unmet medical needs. During the third quarter of 2013, Cardio3 received approval from two additional European competent authorities for the initiation of the CHART-1 (Congestive Heart failure Cardiopoietic Regenerative Therapy), respectively Spain and Italy. The addition of Poland takes the total to eight countries. CHART-1 is the world's first Phase III clinical trial of a regenerative medicine for the treatment of heart failure.

As of 30 September 2013, the Company was on target for its patient enrolment with the goal to complete enrolment in CHART-1 by the end of 2014. At the time of the initial public offering in July, there were 6 centers enrolling or ready to enroll patients. At the date of this press release we have 16 centers active or ready to enroll. We are progressing towards our goal of having 25 investigational sites active or ready to enroll patients by year end 2013.

Cardio3 BioSciences completed its IPO on 5 July 2013. After the full exercise of the over-allotment option on 15 July 2013, a total of 1,588,725 new shares were on the market at the IPO price of €16.65, amounting to total gross proceeds of €26.5 million.

The Company continues to exercise tight cash management and ended the period to 30 September 2013 with €24.3 million in cash on hand. Management confirms that it anticipates the CHART-1 trial to be fully financed until the availability of the read-out of the primary endpoint which is expected at the end of 2015.

Additions to the management team

On 4 October 2013, Dr. Gaëtane Metz joined the Company as Chief Operating Officer in view of accelerating the industrialization process and preparing the commercialization of its lead product C-Cure[®].

***** END *****

For more information contact:

Cardio3 BioSciences

Dr Christian Homsy, CEO/Patrick Jeanmart CFO
Anne Portzenheim, Communication Manager

www.c3bs.com

Tel : +32 10 39 41 00

aportzenheim@c3bs.com

Citigate Dewe Rogerson

Chris Gardner/David Dible

Tel : +44 (0) 207 638 9571

chris.gardner@citigatedr.co.uk



12 NOVEMBER 2013, 5:35 PM CET

About Cardio3 BioSciences

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

The Company's lead product candidate C-Cure[®] is an innovative pharmaceutical product that is being developed for heart failure indication. C-Cure[®] consists of a patient's own cells that are harvested from the patient's bone marrow and engineered to become new cardiac progenitor cells that behave like those cells lost to heart disease. This reprogramming process is known as Cardiopoiesis.

Cardio3 BioSciences has also developed C-Cath^{®ez}, a technologically advanced injection catheter with superior efficiency of delivery of biotherapeutic agents into the myocardium.

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

C3BS-CQR-1, C-Cure[®], C-Cath, Cardio3 BioSciences and the Cardio3 BioSciences and C-Cath logos are trademarks or registered trademarks of Cardio3 BioSciences SA, in Belgium, other countries, or both. 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.
