



CARDIO3 BIOSCIENCES REPORTS 2014 HALF YEAR FINANCIAL RESULTS AND BUSINESS UPDATE

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 and its consolidated financial results for the six-month period ending 30 June 2014 prepared in accordance with IFRS as endorsed by the European Union.

Operational highlights

- Continued progress with the CHART-1 clinical trial of its lead product candidate, C-Cure®
 - To date, ten countries have granted authorization for CHART-1
 - On course for completion of enrolment towards year end 2014
 - EMA has granted Certification of Quality Data for C-Cure®
- FDA clearance to initiate CHART-2, the second phase III trial of C-Cure®
 - IND from the FDA delivered in January 2014
- Business Development Strategy confirmed at the end of 2013 strengthened by the appointment of Georges Rawadi as Vice President Business Development
- Strengthening of the operational capabilities of the Company in anticipation of commercial launch through the appointment of Hanspeter Spek, former President Global Operations at Sanofi, as independent director of the Company
- Cardio3 BioSciences' advanced technologies featured in two top tier scientific publications
- IP Portfolio strengthened with new US Patent
- First sales contract for C-Cath_{ez}®

Financial highlights

- Strong cash position with €40.1 million in cash and term deposits as of 30 June 2014, sufficient to finance the Company's existing clinical development program
- Completion of a capital increase of €25.0 million in June 2014 at €44 per share, a 14% premium to the 30 days average of the Company's shares, fully subscribed by Medisun International, and providing funding to conduct the CHART-2 clinical trial for C-Cure®
- Joint venture agreement with Medisun International to create Cardio3 BioSciences Asia Holdings Ltd, a Joint Venture aimed at conducting pivotal clinical programs in Greater China

Dr Christian Homsy, CEO of Cardio3 BioSciences, said: "Our half year financial results confirm Cardio3 BioSciences is firmly set on a good course: our finances are sound and our operations are delivering to plan. Our teams and clinical centers are, more than ever, committed to bringing innovative and ground-breaking solutions for the many patients suffering from heart failure and other cardiac diseases. With our clinical trials evolving as planned, and with our strict cash management, we can look towards more positive results and a promising future."



Operational review

CHART-1 continued progress

As of 30 June, the Company was on target for its goal to complete patient enrolment into CHART-1 by the end of 2014 and therefore confirms the planning guidance given in 2013.

At the beginning of May, the European Medicines Agency (EMA) issued a certification of quality data for C-Cure[®], the Company's lead product. The Advanced Therapy Medicinal Products (ATMP) certification recognizes the quality data generated for C-Cure[®] in its development program so far as meeting the rigorous standards imposed by the EMA. The ATMP's certification for quality data will facilitate the appraisal of the application for marketing authorization for C-Cure[®] which will be submitted once the clinical data is available from the CHART-1 Phase III clinical trial, anticipated as around the end of 2015.

Initiation of CHART-2

In January, the U.S. Food and Drug Administration (FDA) authorized the Company's Investigational New Drug (IND) application for clinical testing of the Company's proprietary regenerative medicine product C-Cure[®] as a treatment targeting heart failure. CHART-2, the Company's second Phase III clinical trial, is intended to assess, in the US, the efficacy of C-Cure[®]. The primary endpoint of the trial is the "Six Minute Walk Test" nine months post-procedure, a commonly used index of cardiovascular performance. C-Cure[®] showed a 20% improvement for treated patients versus the control group on that specific endpoint during its Phase II trial.

Senior Additions to Management Team to support new Business Development Strategy

At the end of 2013, the Company's Board of Directors defined a new Business Development Strategy where the development of strategic and industrial partnerships will create new short and mid-term value drivers through enlargement of the product pipeline. To achieve this ambition, the Company appointed two senior executives within the period.

At the end of March, the Company announced the appointment of Hanspeter Spek, a significant new addition to the Board and expected to contribute significantly to the conclusion of industrial partnerships and the preparation for the commercialization of the Company's products. Hanspeter was President Global Operations of Sanofi, prior to his retirement from the Company in mid-2013.

At the beginning of June, the Company appointed Georges Rawadi as Vice-President Business development. Leveraging more than 20 years of experience in the healthcare industry, Dr. Rawadi will be responsible for leading Cardio3BioSciences' worldwide business development efforts, by identifying avenues for growth, international expansion and managing the company's business partner relationships.



Cardio3BioSciences' advanced regenerative technology featured in top tier scientific journals

During the first quarter of 2014, Cardio3 BioSciences' lineage-specified cardiac progenitor (Cardiopoietic) technology was referenced in the journal Nature Reviews Cardiology and European Heart Journal as a next generation advancement in the science of regeneration.

Strengthened IP portfolio

In February, Cardio3 BioSciences strengthened its IP portfolio following the United States Patent and Trademark Office ("USPTO") issuing of a Notice of Allowance for patent application number US 12/994,626. The patent application covers compositions and methods for obtaining cells to treat heart tissue and specific parts of the Cardiopoiesis process by which Cardio3 BioSciences re-programs stem cells into cardiac progenitor cells during manufacturing.

First sales for C-Cath_{ez}[®]

In May, the Company entered into a trade agreement with ViroMed Co., LTD for the use of Cardio3 BioSciences' catheter C-Cath_{ez}[®] in the development of ViroMed's VM202-CAD product in Korea.

The Medisun deal – secures the funding of CHART-2 and opens the doors of Greater China

On 30 June, Cardio3 BioSciences announced the completion of a capital increase of €25 million, welcoming a new investor, Medisun International Limited, a Hong Kong-based investment company. This capital increase was priced at €44 per share, a 14% premium to the 30 days average price preceding the transaction. As a result of this investment, Medisun owns approximately 8% of the Company's outstanding shares. This capital increase provides the Company with the necessary funding to conduct the approved CHART-2 clinical trial for C-Cure[®] and support additional pipeline developments.

Alongside this capital increase, both parties agreed to create Cardio3 BioSciences Asia Holdings Ltd. This joint venture aims to conduct a clinical program for C-Cure[®] in Greater China, respectively the People's Republic of China, Hong Kong and Taiwan. Cardio3 BioSciences will bring to the Joint Venture the required IP rights to conduct a clinical trial in those geographies, the use of its C-Cure[®] manufacturing capabilities based in Belgium that will produce the clinical lots for the Phase III program, and its clinical and operational knowhow and expertise. Medisun will provide the funding required for the execution of the clinical program, with a minimum commitment of €20 million over a three year period, as well as local knowledge of the clinical and regulatory environment.

Cardio 3 BioSciences's ownership in the Joint Venture will initially be 40%, and will be reduced to 30% when clinical trials are running in the three geographies outlined above. A successful outcome of the Phase III clinical trials in these geographies would trigger the right for the joint venture company to commercialize C-Cure[®] in those territories with royalties to Cardio 3 BioSciences ranging between 20 and 30% of net sales depending on total revenue of the Joint Venture.



Corporate and Financial review

The Company continues to exercise tight cash management and ended the period to 30 June 2014 with €40.1 million in cash on hand and short term investment. 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 around the end of 2015.

At the end of June 2014, the Company completed a €25.0 million capital increase. The proceeds of this capital increase are aimed at providing the funding to initiate the Food and Drug Administration (FDA) approved CHART-2 clinical trial for C-Cure® in the US. In addition, the funds will support the development of the Company's product pipeline and other general corporate purposes such as strategic development opportunities.

Also in January and April 2014, 128,665 Company warrants were exercised for a total value of €0.7 million, resulting in capital increases of equivalent amounts.

As of 30 June 2014, Cardio3 BioSciences had €40.1 million in treasury compared to €22.1 million at 31 December 2013.

For the six month period ending 30 June 2014, total operating expenses of the Company amounted to €8.1 million compared to €5.2 million for the same period in 2013. The variance is mostly explained by the initiation of CHART-1 phase III trial, resulting in higher manufacturing and clinical costs.

At the end of June 2014, the loss from operations before interest and taxes was €5.9 million versus €6.0 million end of June 2013. The net loss for the six month period ending 30 June 2014 was €5.9 million versus a net loss of €6.4 million for same period in 2013.

Auditor limited review opinion

The condensed interim financial information as per 30 June 2014 has been subject to a review by external auditors which is referenced in Appendix 1.

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About Cardio3 BioSciences

Cardio3 BioSciences is a leading Belgian 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. 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.

INTERIM CONDENSED FINANCIAL STATEMENTS – FIRST HALF RESULTS 2014

Condensed statement of comprehensive income

(€'000)	For the 6 months period ended 30 June	
	2014	2013
Revenue		-
Manufacturing expenses	(2,641.45)	(992.57)
Clinical, Quality & Regulatory expenses	(2,908.22)	(2,199.11)
Research and Development expenses	(979.86)	(1,083.36)
General administrative expenses	(1,539.24)	(890.00)
Other operating income	2,135.14	167.71
Other operating expenses		(1,020.00)
Operating profit (Loss) – EBIT	(5,933.63)	(6,017.33)
Financial income	49.37	11.64
Financial expenses	(15.98)	(422.08)
Profit (Loss) before taxes	(5,900.24)	(6,427.77)
Income taxes		-
Profit (Loss) for the period ^[1]	(5,900.24)	(6,427.77)
Net result per share (in €) ^[2]	(0.92)	(3.43)

[1] As there is no other Comprehensive Income, profit/loss for the period equals total comprehensive income.

[2] Basic and diluted loss per share. As the Company is suffering losses, warrants have an anti-dilutive effect. As such, there is no difference between the basic and the diluted earnings per share. In case the warrants would be included in the calculation of the loss per share, this would decrease the loss per share.



Regulated information

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22 AUGUST 2014, 5:35 PM CET

Condensed statement of financial position

(€'000)	As of 30 June 2014	As of 31 December 2013
NON-CURRENT ASSETS	9,562.99	9,783.44
Intangible assets	9,063.49	9,400.11
Property, Plant and Equipment	401.50	243.21
Other non-current assets	98.00	140.12
CURRENT ASSETS	42,241.49	22,602.47
Trade and Other Receivables	124.96	421.28
Other current assets	2,045.14	122.93
Short term investments	5,000.00	3,000.00
Cash and cash equivalents	35,071.39	19,058.26
TOTAL ASSETS	51,804.48	32,385.91
EQUITY	35,677.43	16,898.01
Share Capital	24,576.96	22,138.01
Share premium	57,011.60	33,326.30
Cost of capital	(3,970.14)	(2,853.10)
Convertible loans	-	-
Share-based payments	347.69	675.24
Retained loss	(42,288.68)	(36,388.44)
NON-CURRENT LIABILITIES	11,745.45	12,099.12
Finance leases	250.59	27.12
Advances repayable	11,494.86	12,072.00
Other non-current liabilities	-	-
CURRENT LIABILITIES	4,381.60	3,388.78
Finance leases	67.21	79.25
Advances repayable	428.45	428.45
Trade payables	3,025.78	2,169.36
Other current liabilities	846.18	608.79
Current tax liabilities	13.98	102.93
TOTAL EQUITY AND LIABILITIES	51,804.48	32,385.91

Consolidated statement of cash flows

(€'000)	For the 6 months period ended 30 June	
	2014	2013
Net Profit/(loss) for the period	(5,900.24)	(6,427.77)
Non-cash adjustments		
Depreciation of Property, Plant & Equipment	75.81	125.89
Amortisation of Intangible Assets	336.62	330.97
Interests on convertible loans	-	357.33
Advances received – previously derecognized	(577.14)	1,020.00
Share-based payments	(327.55)	27.04
Change in working capital		
Trade receivables, other receivables	(1,761.86)	(742.72)
Trade payables, other payable and accruals	1,004.88	584.78
Net cash (used)/from in operations	(7,149.48)	(4,724.48)
Cash flows from investing activities		
Acquisitions of Property, Plant & Equipment	(281.42)	(33.08)
Acquisitions of Intangible assets	-	(277.76)
Acquisition of short term investments	47.32	
Net cash used in investing activities	(234.10)	(310.84)
Cash flows from financing activities		
Proceeds from finance leases	259.77	-
Repayments of finance leases	(48.34)	(102.19)
Proceeds from issuance of shares and warrants	25,007.20	6,931.34
Proceeds from advances and subsidies	178.08	284.20
Proceeds from convertible loans	-	250.00
Repayment of advances	-	(30.00)
Net cash from financing activities	25,396.71	7,333.35
Net cash and cash equivalents at beginning of the period	22,058.26	1,645.03
Change in net cash and cash equivalents	18,013.13	2,298.03
Net cash and cash equivalents at the end of the period	40,071.39	3,943.06



Regulated information

PRESS RELEASE

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Consolidated statement of change in shareholder's equity

(€'000)	Share capital	Share premium	Cost of capital	Convertible Loans	Share-based payments	Retained loss	Total Equity
Balance as of 1 January 2013	9,974.51	-		11,406.35	1,006.11	(24,646.86)	(2,259.89)
Capital increase in cash	1,552.73	5,447.02					6,999.75
Exercise of warrants	24.09	-					24.09
Issuance of convertible loan				250.00			250.00
Interests accrued on convertible loans				357.33			357.33
Contribution in kind convertible loans	5,026.14	6,987.54		(12,013.68)			-
Shares-based payments					(577.60)	604.64	27.04
Transaction costs associated with capital increases	(92.50)						(92.50)
Loss of the period						(6,427.77)	(6,427.77)
Balance as of 30 June 2013	16,484.97	12,434.56	-	-	428.51	(30,469.99)	(1,121.95)
Balance as of 1 January 2014	22,138.01	33,326.30	(2,853.10)		675.24	(36,388.44)	16,898.01
Capital increase in cash	1,988.63	23,011.29					24,999.92
Exercise of warrants	450.32	286.52					736.84
Shares-based payments		387.49			(327.55)		59.94
Transaction costs associated with capital increases			(1,117.04)				(1,117.04)
Loss of the period						(5,900.24)	(5,900.24)
Balance at 30 June 2014	24,576.96	57,011.60	(3,970.14)	-	347.69	(42,288.68)	35,677.43