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**CARDIO3 BIOSCIENCES REPORTS 2013 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 twelve-month period ending 31 December 2013 prepared in accordance with IFRS as endorsed by the European Union.

**2013 operational highlights**

- Initiation of CHART-1, the world's first Phase III clinical trial in regenerative medicine for the treatment of heart failure
- Publication in the Journal of the American College of Cardiology (JACC) of the results of the C-Cure® Phase II study
- Publication in Circulation Cardiovascular Interventions of the C-Cath® study results
- Executive management team strengthened with the addition of Gaetane Metz as Chief Operating Officer of the Company
- Partner and exploitation manager of two FP7 research grants

**2013 financial highlights**

- Completion of a private placement of €19.0 million in May 2013
- Completion of an IPO on NYSE Euronext Brussels and NYSE Euronext Paris raising €26.5 million in July 2013
- Additional non dilutive funding of €4.0 million obtained in December from the Walloon Region resulting in a reduction of the Company's burn rate over 2014 and 2015 of a similar amount
- Strong cash position with €22.1 million in cash and term deposits as of 31 December 2013, sufficient to finance the Company's existing clinical development program

**Dr Christian Homsy, CEO of Cardio3 BioSciences, said:** "2013 was a transformational year for our Company. On the financing side, thanks to the strong support of our existing shareholders and the addition of new large international and specialized investors, we have provided the Company with the means to finance its development. This places us in a uniquely strong position in the field of regenerative therapies. On the operational side, we have initiated our CHART-1 phase III trial which we hope will confirm the promise of this breakthrough technology and give heart failure patients a new future."

**Operational 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. Over the course of 2013,



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Cardio3 BioSciences received approval from six additional competent authorities in Europe and Israel for the initiation of the CHART-1 (Congestive Heart failure Cardiopoietic Regenerative Therapy). These additions take 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 31 December 2013, the Company was on target for its patient enrolment with the goal to complete enrolment in CHART-1 by the end of 2014.

The Company continues to exercise tight cash management and ended the period to 31 December 2013 with €22.1 million in cash and term deposits. 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.

#### **Publication of C-Cure Phase II data in JACC**

In April 2013, the Phase II data of the C-Cure trial completed in January 2012 were published in the Journal of American College of Cardiology (JACC). The publication reported statistically significant improvement in cardiac function and exercise capacity of the treated patients.

#### **Publication of C-Cath<sup>®</sup> study results in CCI**

In December 2013, the study results relating to C-Cath<sup>®</sup>(C-Cath<sub>ez</sub><sup>®</sup>) our proprietary intra-myocardial percutaneous injection catheter, were published in the peer-reviewed journal Circulation Cardiovascular Interventions.

#### **Approval of CHART-2 by the FDA**

In early January 2014, the Company announced that it has received IND clearance from the FDA for its CHART-2 phase III trial with C-Cure<sup>®</sup>. This positive news came 6 months ahead of the schedule anticipated at the IPO, thereby providing ample time to negotiate the best possible options to finance CHART-2 in the best interest of the Company and its shareholders. Cardio3 BioSciences anticipates a projected start of CHART-2 in the last quarter of 2014.

#### **R&D pipeline**

Cardio3 BioSciences continued the development of its R&D pipeline beyond C-Cure<sup>®</sup>, which consists of two non-cellular therapeutic programs for the treatment of acute myocardial infarction (AMI) or "heart attack". GQR-1 is a protein-based product candidate for myocardial regeneration comprising a group of proteins. Despite encouraging preliminary preclinical studies, the complexity of the toxicology studies led us to de-prioritize this program and focus on GQR-4. GQR-4 is an early stage preclinical antibody-based product candidate for the prevention of warm reperfusion injury.



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GQR-4 will soon be tested *in-vivo* in an ischemia reperfusion injury animal model. Additional GLP preclinical studies will be initiated aiming at preparing GQR-4 for a first in man trial in 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®.

### **Corporate and Financial Review**

At the end of May 2013, Cardio3 BioSciences successfully completed a €19.0 million capital increase through a contribution in kind of shareholders debt for €12.0 million and new cash for €7.0 million.

On 5 July 2013, the Company completed an Initial Public Offering on NYSE Euronext Brussels and NYSE Euronext Paris. After the full exercise of the over-allotment option on 15 July 2013, a total of 1,588,725 new shares were issued at the IPO price of €16.65, amounting to total gross proceeds of €26.5 million. The proceeds of the IPO are intended to secure operations of the Company until the readout of the primary endpoint of the CHART-1 clinical trial.

As of 31 December 2013 Cardio3 BioSciences had €22.1 million in treasury compared to €1.6 million at 31 December 2012.

For the twelve month period ending 31 December 2013, total operating expenses of the Company amounted to €12.0 million compared to €11.1 million for the same period in 2012.

At year end 2013, the loss from operations before interest and taxes was €12.0 million versus €12.9 million in 2012. The net loss for period was €12.3 million versus a net loss of €13.5 million for same period in 2012.

The complete "2013 Annual Financial Report" will be available on the company's website at the beginning of April, together with the notice of the Annual Shareholders' meeting.

### **Auditor report**

The statutory auditor has not yet issued its audit report on the annual consolidated accounts for the year ended 31 December 2013. The statutory auditor has confirmed that his audit procedures, which have been substantially completed, have revealed no material adjustments that would have to be made to the accounting information included in this press release.



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**Conference call details**

The company will host a conference call to present its 2013 financial results on Wednesday 19 March 2014 at 2:00 pm CET – 1:00 pm UK – 8:00 am EST. The conference call will be held in English.

Dial in numbers: International +44 (0) 1452 555566 / UK 08444933800 / Belgium 081700061 / France 0176742428 / USA 16315107498.

Conference ID: 15997819

Access to the conference call 10 minutes prior to its start time.

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For more information contact:

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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<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 cardiac progenitor cells that behave like those cells lost to heart disease. This reprogramming process is known as Cardiopoiesis.



## **Regulated information**

**PRESS RELEASE**

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Cardio3 BioSciences has also developed C-Cath<sup>® eZ</sup>, 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.*

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**CONSOLIDATED FINANCIAL STATEMENTS AS OF 31 DECEMBER 2013 AND FOR THE YEAR THEN END PREPARED UNDER IFRS AS ENDORSED BY THE EUROPEAN UNION**

**Consolidated statement of comprehensive income**

(€'000)	For the 12 months period ended 31 December	
	2013	2012
<b>Revenue</b>	-	<b>54.00</b>
Manufacturing expenses	(2,415.21)	(2,185.90)
Clinical, Quality & Regulatory expenses	(4,472.70)	(3,605.14)
Research and Development expenses	(2,158.07)	(3,400.82)
General administrative expenses	(2,987.55)	(1,881.60)
Other operating income	1,084.30	2,092.28
Other operating expenses	(1,020.00)	(3,974.56)
<b>Operating profit (Loss) – EBIT</b>	<b>(11,969.23)</b>	<b>(12,901.74)</b>
Financial income	59.85	19.17
Financial expenses	(436.84)	(641.68)
<b>Profit (Loss) before taxes</b>	<b>(12,346.22)</b>	<b>(13,524.25)</b>
Income taxes	-	-
<b>Profit (Loss) for the period <sup>[1]</sup></b>	<b>(12,346.22)</b>	<b>(13,524.25)</b>
<b>Net loss attributable to Equity Holders</b>	<b>(12,346.22)</b>	<b>(13,524.25)</b>
<b>Net result per share (in €) <sup>[2]</sup></b>	<b>(3.01)</b>	<b>(11.17)</b>

[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 and the convertible loans 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.



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***Consolidated statement of financial position***

(€'000)	As of 31 December	
	2013	2012
<b>NON-CURRENT ASSETS</b>	<b>9,783.44</b>	<b>10,148.41</b>
Intangible assets	9,400.11	9,614.76
Property, Plant and Equipment	243.21	383.12
Other non-current assets	140.12	150.53
<b>CURRENT ASSETS</b>	<b>22,602.47</b>	<b>2,336.62</b>
Trade and Other Receivables	421.28	442.84
Other current assets	122.93	248.75
Short term investments	3,000.00	-
Cash and cash equivalents	19,058.26	1,645.03
<b>TOTAL ASSETS</b>	<b>32,385.91</b>	<b>12,485.03</b>
<b>EQUITY</b>	<b>16,898.01</b>	<b>(2,259.89)</b>
Share Capital	22,138.01	9,974.51
Share premium	33,326.30	-
Cost of capital	(2,853.10)	-
Convertible loans	-	11,406.35
Share-based payments	675.24	1,006.11
Retained loss	(36,388.44)	(24,646.86)
<b>NON-CURRENT LIABILITIES</b>	<b>12,099.12</b>	<b>11,265.92</b>
Finance leases	27.12	108.89
Advances repayable	12,072.00	11,157.03
Other non-current liabilities	-	-
<b>CURRENT LIABILITIES</b>	<b>3,388.78</b>	<b>3,479.00</b>
Finance leases	79.25	160.49
Advances repayable	428.45	684.66
Trade payables	2,169.36	1,770.31
Other current liabilities	608.79	807.23
Current tax liabilities	102.93	56.31
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>32,385.91</b>	<b>12,485.03</b>



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***Consolidated statement of cash flows***

(€'000)	For the 12 months period ended 31 December	
	2013	2012
Net Profit/(loss) for the period	(12,346.22)	(13,524.25)
<b>Non-cash adjustments</b>		
Depreciation of Property, Plant & Equipment	212.77	266.99
Amortisation of Intangible Assets	673.25	626.82
Interests on convertible loans	357.33	591.59
Advances received – previously derecognized	395.43	3,944.56
Share-based payments	273.77	150.78
<b>Change in working capital</b>		
Trade receivables, other receivables	(451.92)	(1,180.88)
Trade payables, other payable and accruals	247.20	787.55
<b>Net cash (used)/from in operations</b>	<b>(10,638.39)</b>	<b>(8,336.84)</b>
<b>Cash flows from investing activities</b>		
Acquisitions of Property, Plant & Equipment	(72.85)	(40.08)
Acquisitions of Intangible assets	(458.60)	(616.88)
Acquisition of short term investments	(3,000.00)	-
<b>Net cash used in investing activities</b>	<b>(3,531.45)</b>	<b>(656.96)</b>
<b>Cash flows from financing activities</b>		
Repayments of finance leases	(163.01)	(291.27)
Proceeds from issuance of shares and exercise warrants net of transactions costs	30,623.02	-
Proceeds from advances and subsidies	1,084.30	2,170.07
Proceeds from convertible loans	250.00	7,028.65
Repayment of advances	(211.24)	(20.00)
Other financing cash flows	-	-
<b>Net cash from financing activities</b>	<b>31,583.07</b>	<b>8,887.45</b>
<b>Net cash and cash equivalents at beginning of the period</b>	<b>1,645.03</b>	<b>1,751.38</b>
<b>Change in net cash and cash equivalents</b>	<b>17,413.23</b>	<b>(106.35)</b>
<b>Net cash and cash equivalents at the end of the period</b>	<b>19,058.26</b>	<b>1,645.03</b>



**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
<b>Balance as of 1 January 2013</b>	<b>9,974.51</b>	-		<b>11,406.35</b>	<b>1,006.11</b>	<b>(24,646.86)</b>	<b>(2,259.89)</b>
Capital increase in cash	7,113.27	26,338.76					33,452.03
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					(330.87)	604.64	273.77
Transaction costs associated with capital increases			(2,853.10)				(2,853.10)
Loss of the period						(12,346.22)	(12,346.22)
<b>Balance as of 31 December 2013</b>	<b>22,138.01</b>	<b>33,326.30</b>	<b>(2,853.10)</b>		<b>675.24</b>	<b>(36,388.44)</b>	<b>16,898.01</b>