

ADMEDUS LIMITED ABN 35 088 221 078

REGISTERED OFFICE: 26 Harris Road Malaga Western Australia 6090

> Corporate Enquiries: T +61 (0)8 6240 6100 F +61 (0)8 9266 0199

E info.au@admedus.com www.admedus.com

## ANNOUNCEMENT TO THE AUSTRALIAN STOCK EXCHANGE

30th October 2015

Company Announcements Office Australian Stock Exchange Limited 10<sup>th</sup> Floor, 20 Bond Street SYDNEY NSW 2000

Dear Sir/Madam,

## Re: Appendix 4C - Quarterly Report

Please refer to the 'Appendix 4C' attached for details of financial results for the first quarter to 30 September 2015 for the Group.

## **Highlights**

- Sales for the quarter of \$3.03M, up 42.5% from the prior year period
  - o Growth reflects Cardiocel®'s increasing global availability and traction
  - o CardioCel® now in 110 centres globally
- Cash balance at 30 September 2015 of \$16.7M
- Initiated a key aortic heart valve reconstruction post-market clinical study using CardioCel® at leading global heart centres
- HSV-2 Phase II nearing completion, with interim results due at end of this calendar year
- Manufacturing of the HPV therapeutic vaccine completed in preparation for Ian Frazer's next HPV product heading into the clinic
- Admedus Vaccines rebrands as Admedus Immunotherapies

### **Post period Highlights**

• \$750K from R&D Tax Incentive received for immunotherapy programs in October 2015, with additional R&D Tax Incentives expected

### Cardiocel® grows strongly; HSV-2 Phase II trial nears completion

Admedus continued to grow successfully across its business, with sales revenue for the quarter reaching \$3.03M, up 42.5% from the previous corresponding period.

The Company finished the period with a consolidated cash balance of \$16.7M. Outside of the period, Admedus Immunotherapies received an R&D Tax Incentive in October of \$754,048 and Admedus is also anticipating a further R&D Tax Incentives this financial year.



The net cash decrease for the quarter was \$7.3M. Although up from the previous quarter, Admedus anticipates this to be reduced in the December quarter as there were two significant payments in this quarter: one for the initiation of the CardioCel® aortic heart valve reconstruction study, a study which is designed to show CardioCel®'s utility in heart valve reconstructions vs bioprosthetic replacement valves which have an estimated market valuation of \$2 billion; and another for the manufacture of the HPV therapeutic vaccine in anticipation of the Phase Ib study which is anticipated to begin in 2016 and is designed to be a treatment against HPV and cervical cancer with an estimated target market of + \$1 billion.

## Sales and marketing

During the period the number of heart centres having used CardioCel® to repair heart defects rose to 110 globally and the team achieved record sales to date in the US for the month of September. The Company continues to sell CardioCel® across Europe, North America, Hong Kong and Singapore. The team is also working on additional regulatory approvals as well as working with our partner in the MENA region for further market expansion.

The infusion portfolio continues to grow sales on a net cash flow basis. The infusion team continues to seek new tenders and the ongoing expansion of our hospital wide electronic infusion delivery systems, to complement the positioning of the entire Admedus infusion range in the Australian and New Zealand market.

## **Regenerative Tissue Portfolio**

The regenerative tissue teams remain focused on building the CardioCel® franchise and expanding the overall regenerative tissue portfolio.

Admedus initiated a post-market study in whole aortic heart valve reconstructions after a positive pre-clinical study in collaboration with the KU Leuven University. The data from this pre-clinical valve study was presented on the 5th of October by Professor Bart Meuris at the European Association for Cardiothoracic Surgery (EACTS) meeting in Amsterdam. As released on the 10th of September, this data represented a world first aortic valve repair in this model.

The use of CardioCel® in heart valve repairs and reconstructions is an important growth strategy for Admedus, as it has the potential to provide longer term improved patient outcomes and provides surgeons with a true alternative to bi-prosthetic valves. CardioCel® has already been used in a number of patient heart valve repairs and reconstructions and this post-market clinical study is aimed at positioning CardioCel® as the preferred valve tissue in the global treatment of heart valve disease.

During the quarter Admedus also progressed the commercial use of ADAPT® tissue in vascular repairs and reconstructions and these vascular products are currently in pilot studies with key US centres for applications such as Carotid Endarterectomy's (CEA's) which is a surgical procedure used to reduce the risk of strokes. Admedus expects to further rollout these vascular procedures in 2016 once these pilot studies are completed at key US centres. This is part of the ongoing strategy of the Company to develop a portfolio of bio-scaffold products across a range of surgical applications.

Additional preparation is also being undertaken for the next Dura mater study, which is designed to repair head and brain injuries and to be a study that can be used for regulatory submissions. Admedus has also recently announced a collaboration with researchers to show the utility of ADAPT® tissue as a delivery platform for stem cells, for future potential research into remodelling the heart after a heart attack (myocardial infarction).



## **Immunotherapies**

The quarter was a successful period for Admedus Immunotherapies with the preparation for the HPV therapeutic study that is designed as a treatment against HPV and cervical cancer as well as the ongoing Herpes Simplex 2 (HSV-2) Phase II clinical program as a treatment against genital herpes.

The HSV-2 clinical program continued to progress and recruit patients. Over 40 people have enrolled into the study and the study will continue to enrol until at least 40 people complete the initial 3 vaccination period to ensure that the full number of patients complete the study. Over 75% of the people in the study have already received their initial vaccine doses.

Admedus anticipates the release of initial interim results from the HSV-2 study towards the end of this year and expects additional data to be released in 2016.

The Immunotherapies team is also working on optimisation of the delivery of this technology and exploring additional applications of the technology.

During the period Admedus Vaccines was rebranded to Admedus Immunotherapies to better reflect the work it is doing in developing next generation immunotherapies (therapeutic vaccines).

Admedus is building a global healthcare company and continues to invest in the infrastructure of its sales teams and the further development of our product and R&D pipelines. We anticipate expenses will decrease in the December quarter while sales continue to grow.

Yours sincerely

Stephen Mann

**Company Secretary** 

Mann

## **Appendix 4C**

# Quarterly report for entities admitted on the basis of commitments

Introduced 31/3/2000. Amended 30/9/2001, 24/10/2005.

Name of entity			
1	Imedus Limited		

ABN Quarter ended ("current quarter")

35 088 221 078 30 September 2015

## Consolidated statement of cash flows

Cach	flows related to	operating activities	Current quarter \$A'000	Year to date (3 months)
Casii	nows related to	operating activities	ψ1 <b>1</b> 000	\$A'000
1.1	Receipts from o	eustomers	2,884	2,884
1.2	Payments for	(a) staff costs	(4,142)	(4,142)
	•	(b) advertising and marketing	(163)	(163)
		(c) research and development	(2,079)	(2,079)
		(d) leased assets	-	-
		(e) other working capital	(4,036)	(4,036)
1.3	Dividends rece	ived	-	-
1.4	Interest and other items of a similar nature received		26	26
1.5	Interest and other costs of finance paid		(21)	(21)
1.6	Income taxes refunded		163	163
1.7	Other - Commo	ercialisation Australia Grant	-	-
1.8	Other – WA In	novation Voucher Program Grant	-	-
	Net operating	cash flows	(7,368)	(7,368)

		Current quarter \$A'000	Year to date (3 months) \$A'000
1.8	Net operating cash flows (carried forward)	(7,368)	(7,368)
	Cash flows related to investing activities		
1.9	Payment for acquisition of:		
	(a) businesses (item 5)	-	-
	(b) equity investments	-	=
	(c) intellectual property	(13)	(13)
	(d) physical non-current assets	(89)	(89)
	(e) other non-current assets	-	-
1.10	Proceeds from disposal of:		
	(a) businesses (item 5)	=	=
	(b) equity investments	-	-
	(c) intellectual property	-	-
	<ul><li>(d) physical non-current assets</li><li>(e) other non-current assets</li></ul>	-	-
	(e) other non-current assets	-	-
1.11	Loans to other entities	_	_
1.12	Loans repaid by other entities	-	-
1.13	Other	-	-
	Net investing cash flows	(102)	(102)
1.14	Total operating and investing cash flows	(7,470)	(7,470)
	Cash flows related to financing activities		
1.15	Proceeds from issues of shares, options, etc.	110	110
1.16	Proceeds from sale of forfeited shares	_	_
1.17	Proceeds from borrowings	_	_
1.18	Repayment of borrowings	-	_
1.19	Dividends paid	-	=
1.20	Other / Transactions with Non-controlling interests		
	Net financing cash flows	110	110
	Net increase (decrease) in cash held	(7,360)	(7,360)
1 21	Cook at harrising of anorthy/way to date	24.026	24.026
1.21 1.22	Cash at beginning of quarter/year to date Exchange rate adjustments to item 1.20	24,026	24,026
		-	<u> </u>
1.23	Cash at end of quarter	16,666	16,666

## Payments to directors of the entity and associates of the directors Payments to related entities of the entity and associates of the related entities

		Current quarter \$A'000	
1.24	Aggregate amount of payments to the parties included in item 1.2	173	
1.25	Aggregate amount of loans to the parties included in item 1.11	-	
1.26	Explanation necessary for an understanding of the transactions		
	Consultancy services \$68k Directors fees \$105k		
Non-cash financing and investing activities  2.1 Details of financing and investing transactions which have had a material effect on consolidated assets and liabilities but did not involve cash flows			
	N/A		
2.2	2.2 Details of outlays made by other entities to establish or increase their share in businesses in reporting entity has an interest		
	N/A		
Financing facilities available  Add notes as necessary for an understanding of the position. (See AASB 1026 paragraph 12.2).			

		Amount available \$A'000	Amount used \$A'000
3.1	Loan facilities	-	-
3.2	Credit standby arrangements	-	-

The Group holds an overdraft facility of \$500,000 which is completely unused at the end of the current quarter. .

## **Reconciliation of cash**

show	nciliation of cash at the end of the quarter (as in in the consolidated statement of cash flows) to lated items in the accounts is as follows.	Current quarter \$A'000	Previous quarter \$A'000
4.1	Cash on hand and at bank	16,666	24,026
4.2	Deposits at call	-	-
4.3	Bank overdraft	-	-
4.4	Other (provide details)	-	-
	Total: cash at end of quarter (item 1.23)	16,666	24,026

## Acquisitions and disposals of business entities

		Acquisitions $(Item \ 1.9(a))$	Disposals (Item $1.10(a)$ )
5.1	Name of entity		
5.2	Place of incorporation or registration		
5.3	Consideration for acquisition or disposal		
5.4	Total net assets		
5.5	Nature of business		

## **Compliance statement**

- 1 This statement has been prepared under accounting policies which comply with accounting standards as defined in the Corporations Act (except to the extent that information is not required because of note 2) or other standards acceptable to ASX.
- 2 This statement does /does not\* (delete one) give a true and fair view of the matters disclosed.

Sign here: Date: 30 October 2015 (Company Secretary)

Print name: Stephen Mann

## **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity wanting to disclose additional information is encouraged to do so, in a note or notes attached to this report.
- 2. The definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report except for any additional disclosure requirements requested by AASB 107 that are not already itemised in this report.
- 3. **Accounting Standards.** ASX will accept, for example, the use of International Financial Reporting Standards for foreign entities. If the standards used do not address a topic, the Australian standard on that topic (if any) must be complied with.