

ASX ANNNOUNCEMENT 29 January 2021

# **CardieX December 2020 Quarter Update**

# **Highlights**

- Unaudited sales for the 6 months YTD FY21 were up 30% over the previous comparative period (using constant currency and excluding royalties)
- Strong sales performance growth during the quarter with Q2 FY21 up 29% on a constant currency basis
- When including the impact of the strengthening AUD against the USD, sales excluding royalty for H1 were up 24% on last year
- New product launch update
- Regulatory approvals update and schedule FDA clearance, CE approval in Europe, and NMPA approval in China
- Expansion of senior executive team with two key new hires
- Launch of new "ATCOR Health" division
- Successfully completed Share Purchase Plan raising over \$3.2 million closed 31
   December 2020
- Group Cash balances of \$3.32 million at quarter end which, following the January receipt of the oversubscribed SPP of \$3.2m+, provides total adjusted cash reserves of ~\$6.55m

On behalf of CardieX Limited (CardieX, the "Company"), I'm pleased to provide the following update on our activities during the December 2020 quarter.

# **Strong Sales Growth and Report on Expenditure**

During the quarter the Company achieved strong sales growth of 29% (using constant currency and excluding royalties) against the prior comparative period.

Sales of the XCEL and Oscar 2 devices continue to perform very well despite the pandemic. Combined with the September quarter, unaudited sales for the six months ended 31 December 2020 are up 30% (using constant currency and excluding royalties) compared with the same period in FY 2020 - and after adjusting for the strengthening of the AUD against the USD were up 24%. This is the strongest 1H result for the Company over the last five years and positions the Company very well ahead of new product and market launches in CY 2021.



With respect to expenditures the Group maintained expenditures consistent with the September quarter run rate with the exception of one off items in the September quarter in the product development and corporate cost categories.

As previously announced expenditures around the new product development are milestone based and there were no payments made to the project development partner throughout the previous quarter although there have been payments made in the period subsequent to 31 December 2020 in line with the project milestones as previously announced.

Staffing costs continued to be fairly static following the consolidation of staff costs during the May to July 2020 period and represent the current run rate for staff costs across the Group.

During the December quarter the R&D Tax Incentive for the 2020 financial year was received by the Group for the amount of \$460,000. This amount was applied immediately against the loan of \$1.5m from Mitchell Asset Management ("MAM") and will see an approximate 1/3 decrease in the ongoing interest repayments to MAM in the current quarter.

For the purposes of LR 4.7.C.3 it is noted that were \$205,000 in payments to related parties in the previous quarter which represented payments to the Directors as well as executive remuneration to the CEO, Executive Chairman and CFO which are all consistent with previously disclosed executive contracts.

## **New Product Launch Update**

The Company remains on track for multiple new product launches in FY 2021 and FY 2022, including the first new smartwatch to incorporate 100% subsidiary company, ATCOR's "Arty®" heart health algorithms (a partnership with Google backed, Mobvoi), as well as the "Pulse", a new home-based heart health vital signs monitoring system based on ATCOR's FDA-cleared SphygmoCor® technology.

SphygmoCor® is the only existing FDA-cleared technology that can produce a full feature central arterial waveform in adults that identifies advanced cardiovascular diagnostics for heart and other vascular disorders.

ATCOR's new telehealth-connected "Pulse" home device, which incorporates SphygmoCor®, will be the only home-based cardiovascular device that will allow cloud-connected remote patient monitoring of a patient's cardiovascular diagnostics - which was previously only available directly through specialist clinicians.

Supporting both our wearable and other new home and clinician devices will be the corresponding launch of a new digital ecosystem for both consumers and clinicians – all based on our SphygmoCor® technology. ArtyNet® is a cloud-based infrastructure allowing clinicians to securely and remotely connect to patients in their home. ArtyGo® is our new patient/consumer app allowing consumers to access and manage a complete suite of arterial, brain, heart, renal, and other diagnostics.

Prior to launch of the Pulse, our new smartwatch, and other yet to be announced devices and solutions, the Company will continue to focus on distribution, marketing, clinical and industry partnerships, along with other initiatives as part of our go-to-market strategy. We will continue to announce any new developments as they are finalized.



Pre-orders for all new devices will commence shortly with shareholders having access to special offers and priority ordering. In the interim, shareholders are encouraged to visit cardiex.com or atcormedical.com for the chance to win one of five new smartwatches as part of a current pre-launch giveaway promotion.

#### New Product Regulatory Approval Update: FDA (USA), CE Mark (Europe), NMPA (China)

The Company anticipates FDA-clearance in the USA for its Pulse device and associated digital solutions in September 2021. The Company also anticipates both CE approval in Europe and NMPA approval in China at approximately the same time.

No FDA clearance is required for the Company's first wearable product launch in partnership with Mobvoi – which is on track for Q4 2021.

#### **Expansion of Senior Executive Team**

In December, we added two highly experienced executive team members who are positioned to make a significant impact on the Company as we move forward with our new product launches and the expansion of our traditional sales markets.

Steven Kesten M.D. joined us as our new Chief Medical Officer. Steven comes to us with a background which includes similar positions at Uptake Medical and global Pharma giant Boehringer Ingelheim. Steven will initially be focused on developing and leading our clinical advocacy programs as well as leading the efforts of the Company in developing expanded coverage for our products with insurers, Medicare and Medicaid, and the payer networks in the USA.

Mark Gorelick PhD. joined us as our new Chief Product Officer (CPO), a newly created position focused on leading our product development and delivery across the expanse of new products in development. Mark is principally charged with working closely with myself and leading the product teams in creating, developing, and delivering to market innovative and industry changing health technologies that disrupt the existing health-tech market.

Mark is a visionary digital health innovator with a Doctorate in Biomedical Science who comes to us with` a strong history in both academia and research as well as private company expertise — having held previous CPO and Chief Science Officer positions with leading wearable and digital health companies.

#### **Launch of ATCOR Health Division**

In December, we implemented a restructuring of our corporate operations into two divisions which aligns with Mark's appointment as our CPO. Previously, all product development and operations were undertaken under one ATCOR umbrella group, however with the upcoming launch of our new product initiatives it made sense to separate the focus of our development and sales efforts under two complimentary, but distinct, operating divisions.

Going forward, our traditional sales and operations of our specialist medical, research, and clinical trial business will be undertaken by our "ATCOR Medical" division, headed by Chris Dax, the current President of ATCOR. New product development in our consumer, home, wearables, and digital health markets (including our new Pulse and Mobvoi Smartwatch initiatives) will be undertaken by our newly created "ATCOR Health" division, headed by Mark Gorelick.



Given the nature of the opportunities in both these markets it made sense to divisionalize them so as to enable focused efforts around their unique sales, marketing, and development activities.

Both Mark and Chris will report directly into myself and will both be supported by our Sydney based product engineering team headed by Lawrence Chan.

## Corporate

The Company announced a Share Purchase Plan (SPP) in early December to enable eligible shareholders to apply for new shares in the Company at an issue price of \$0.05 per share. The SPP closed on 31 December 2020 and received very strong support, raising in total \$3.207 million (before costs) representing a 220% over-subscription to the target raise of \$1 million.

At 31 December, the Company had a cash balance of \$3.32 million which following the January receipt of the oversubscribed SPP of \$3.207m provides total adjusted cash reserves of ~\$6.55m, meaning that CardieX remains well funded to achieve its current milestones related to wearable technologies and new medical device developments.

#### Outlook

The Company again delivered strong progress in sales growth from the base business during the December quarter helping to deliver the best 1H sales results for the Company in the past five years. With two key new executive hires announced this quarter along with new products set to be launched in CY 2021, the Company is very well placed to continue the growth in sales momentum. Following the SPP, the Company is in a strong financial position to capitalize on new product and market opportunities and we look forward to updating the market on our progress through calendar 2021.

Craig Cooper

**CEO & Managing Director** 

Approved by the Board of Directors and Released by Jarrod White, Director.

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## **About CardieX**

CardieX is a global health technology company that focuses on hypertension, cardiovascular disease, and other vascular health disorders. The company's <u>ATCOR</u> division is the world leader in medical devices for measuring arterial stiffness and central blood pressure waveforms based on its unique FDA-cleared and patented SphygmoCor® technology. Under the ATCOR·X brand, the company also develops and licenses its Arty™ platform consisting of physiological and health analytics for wearable devices. The company's digital platform, ArtyNet™, is a connected SaaS ecosystem providing physicians with a complete telehealth solution for remotely managing patients' health (2021 launch). CardieX is listed on the Australian Stock Exchange (ASX:CDX).

# **Appendix 4C**

# Quarterly cash flow report for entities subject to Listing Rule 4.7B

# Name of entity

CardieX Limited	
ABN	Quarter ended ("current quarter")

81 113 252 234 31 December 2020

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	1,122	2,296
1.2	Payments for		
	(a) research and development	(340)	(617)
	(b) product manufacturing and operating costs	(59)	(244)
	(c) advertising and marketing	(49)	(63)
	(d) leased assets	(41)	(135)
	(e) staff costs	(1,163)	(2,334)
	(f) administration and corporate costs	(426)	(1,042)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(49)	(106)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	460	523
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(545)	(1,722)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities		
	(b) businesses	-	-
	(c) property, plant and equipment	(6)	(9)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets		

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	722
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(6)	713

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	5	2,505
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(172)
3.5	Proceeds from borrowings	-	515
3.6	Repayment of borrowings	(475)	(475)
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	Net cash from / (used in) financing activities	(472)	2,373

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,424	2,062
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(545)	(1,722)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	713

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Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(472)	2,373
4.5	Effect of movement in exchange rates on cash held	(79)	(104)
4.6	Cash and cash equivalents at end of period	3,322	3,322

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	3,322	3,322
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	3,322	4,424

6.	Payments to related parties of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	205
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Note: i	if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must includ	de a description of, and an

explanation for, such payments.

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	1,040	1,040
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	US\$173	US\$173
7.4	Total financing facilities	AU\$1,040 + US\$173	AU\$1,040 + US\$173
7.5	Unused financing facilities available at qu	arter end	_

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

Loan facilities mentioned above include US\$173k loan under the Payroll Protection Plan (1% annual interest rate, funds would be used to cover payroll expenses and loan would be forgivable up to 60% of payroll costs for the eight week period).

On 25 March 2020, the Company entered into a \$1,500,000 term loan facility. The facility is a prepayment of forecast R&D tax incentive claim for the years ended 30 June 2020 and 2021. The Facility attracts interest at 1.25% per calendar month. The Group repaid \$460,000 in November 2020. Please refer to the ASX Announcement dated 25 March 2020 for further details.

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(545)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,322
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,322
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	6.1
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer ite figure for the estimated quarters of funding available must be included in item 8.5.	em 8.5 as "N/A". Otherwise, a

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: N/A			

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: N/A			

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer: N/A

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

# Compliance statement

- This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 29 January 2021

Authorised by: The Board

(Name of body or officer authorising release – see note 4)

#### **Notes**

- 1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
- If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, AASB 107: Statement of Cash Flows apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
- 3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
- 4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.