

ASX ANNNOUNCEMENT 26 July 2021

# **CardieX June 2021 Quarter Update**

# Highlights:

- Strong sales growth in FY21 with annual sales up 32% on a constant currency basis (excluding royalties) on the comparative period in FY20;
- New patent granted for blood pressure measurement by the US Patent & Trademark Office (USPTO);
- Major corporate restructure and launch of new consumer health brand CONNEQT;
- CONNEQT product launch updates;
- Strategic collaboration signed with LifeQ for CONNEQT wearable and distribution;
- ATCOR completes world-first PPG sensor integration of its core health wearable biometrics platform;
- Mobvoi partnership launch update;
- ATCOR technology chosen for Yale University clinical trial;
- Upcoming sales and product launch conference schedule;
- Corporate update & procedure for exercise of 2021 options by shareholders;
- Total cash reserves of \$3.67 million at 30 June 2021 to be bolstered by up to \$8.16m from the November listed and unlisted option expiry (if fully exercised) – providing financial support & capability to implement identified strategic initiatives.

On behalf of CardieX Limited (CardieX, the "Company"), I'm pleased to provide the following update on our activities during the June 2021 quarter.

# Strong Sales Growth in Traditional Medical Markets

During the quarter, the Company experienced strong sales growth which has led to a total increase of 32% on a constant currency basis (excluding royalties) for the year-to-date (YTD) on the comparative period in FY20.

This is a historical 5-year high revenue growth for our ATCOR division that we expect to continue into FY22 and beyond.



Sales of the XCEL and Oscar 2 devices continue to perform very well in research, clinical trial, Pharma, and specialist clinician markets.

We now have five global trials we are supporting with the likes of AstraZeneca and Bayer, as well as being the preferred device supplier for the world's largest study on hypertension and COVID-19 - the CARTESIAN Study - which aims to explore the immediate and long-term vascular consequences of COVID-19.

Other current trials that we support target renal disease, heart failure, and diabetic retinopathy.

Based on the strong growth we are seeing in all market segments and with the addition of new devices, our internal sales target for FY22 remains for a significant increase over our results for FY21, which we anticipate will result in a return to profitability for our ATCOR division by 2022 calendar year-end.

#### **New Patent Granted for Blood Pressure Measurement**

During the quarter, CardieX subsidiary ATCOR, was granted another patent by the USPTO in relation to intellectual property (IP) surrounding the Company's patented SphygmoCor® technology.

US Patent No 11,006,842, titled "Non-Invasive Brachial Blood Pressure Measurement" was granted specifically to protect the Company's IP in relation to the measurement of central blood pressure waveforms using a brachial blood pressure cuff.

The granting of this new patent further builds on the Company's existing 13 patents surrounding the measurement of cardiovascular health parameters using both traditional brachial cuff devices as well as sensor-based wearable technologies. In May 2020, ATCOR also lodged a new patent application for what is believed to be a world-first wearable sensor technology method and system using a PPG sensor - which the Company is incorporating into upcoming product releases.

The new US Patent No 11,006,842 is in force until 2038.

# **Corporate Restructure and New Consumer Brand Launch**

In a significant move for the Company, CardieX subsidiary ATCOR Medical, Inc was separated into two distinct companies - ATCOR and CONNEQT.

ATCOR will continue to focus on vital signs monitors and SaaS solutions for hospital, research & pharma, and specialist clinician markets.

A new consumer brand, CONNEQT™ (**CONNEQT, Inc**) has been created to focus on home health, wearables, and consumer health apps.

With a number of new devices and digital products coming to market, the Company has been deeply immersed in the development of a new brand identity for their upcoming consumer products – a brand that can sit alongside and compete with the likes of Fitbit, Apple, Google Health, Peloton, and other "unicorn" private health-tech and wearable companies such as WHOOP, Oura, Garmin, and others.

We believe **CONNEQT** will be that brand.



A brand that in the years to come will be a leader in the consumer health sector – and will have the same brand recognition alongside household consumer companies – which can be extended into multiple different product sectors in health & wellness.

That is the Company's vision and mission.

Under the CONNEQT brand, CardieX is on track to launch multiple new devices and digital products to the market over the next twelve months.

Upcoming products include the CONNEQT "Pulse" – a dual blood pressure monitor anticipated to be the first consumer vital signs monitor to include central blood pressure and the Company's patented SphygmoCor® technology (anticipated FDA-clearance Q2FY22); and the CONNEQT Band wearable – which will include a full suite of patented health parameters as well as a comprehensive ecosystem of unique health and wellness features focused on heart health (anticipated FDA-clearance early Q4FY22).

The key differentiating feature for the CONNEQT brand and its products, will be the ability to provide medically reliable data and information in their chosen markets by obtaining 510K clearance from US FDA.

CardieX firmly believes that its focus on medically reliable parameters will differentiate it significantly from other health-tech and wearable products that are more focused on general "lifestyle" parameters.

In addition, the Company's unique focus on vascular, arterial, and heart health will position it more favorably with clinicians and medical institutions.

Partnerships in these areas are already in process.

# Strategic Collaboration with LifeQ for CONNEQT Wearable

Towards the end of the quarter, CardieX's new subsidiary, CONNEQT, announced a strategic collaboration agreement with LifeQ, a world leading provider of biometrics and health information metrics from wearable devices.

The Agreement with LifeQ provides for both companies to leverage their joint IP to be incorporated into the CONNEQT Band in order to deliver a unique combination of clinical and lifestyle related health metrics, and insights and solutions for consumer, healthcare, and enterprise customers.

Under the Agreement, CONNEQT will develop and own the CONNEQT Band (CB), which the Company anticipates being the world's first Al-powered, FDA cleared, clinical grade smart health band featuring our patent-pending dual-PPG sensing technology.

Importantly, the Agreement allows for both companies to leverage their respective expertise in PPG-based biometrics to enable the CONNEQT Band with continuous monitoring of general health parameters as well as spot checking capabilities for medical purposes and actionable health insights.

The Agreement also provides for LifeQ to promote the sales and distribution of the CB in select enterprise and business markets.



The CONNEQT Band will feature the Company's patent-pending PPG-based finger sensor technology (ASX: 24 April, 2020) as well as a second PPG sensor on the wrist for continuous monitoring of general health related biometrics.

LifeQ will be responsible for powering the delivery of biometric information obtained by way of the wrist-based PPG sensor, and integrating its on-device software for data analytics and synchronisation to CONNEQT, and LifeQ cloud-based networking infrastructure.

CONNEQT will be responsible for building the CB device, obtaining 510K clearance from US FDA and commercializing and marketing the device.

Anticipated launch with FDA clearance is early Q4FY22.

# **ATCOR World-First PPG Sensor Algorithm**

During the quarter CardieX subsidiary, ATCOR, completed a major technological innovation with a world-first algorithm for a wearable optical sensor which is able to provide a unique range of cardiovascular health parameters based around ATCOR's patented SphygmoCor® technology.

This major milestone sets the technology algorithm foundation for the CONNEQT Band and other wearables partnerships and signaled the commercial readiness of ATCOR's wearable health analytics platform, Arty™, into consumer wearable devices.

Currently, no commercially available wearable device offers the range of individualized health parameters that are proposed for incorporation into the Company's Arty™ device and digital ecosystem, which will provide unique insights into the heart and surrounding arterial systems for both consumer and medical applications.

# **Mobvoi Product Launch Update**

ATCOR and Mobvoi have an agreement for the launch of a new smartwatch incorporating a suite of ATCOR's biometric algorithms and AI powered health analytics.

This smartwatch was due for launch earlier this year and has been delayed by both parties decision to ensure that product is able to make maximum impact when released based on the unique features and health biometrics that will be available from the device.

Our Sydney based ATCOR R&D group recently delivered to Mobvoi our sensor parameters (as noted above "ATCOR World-First PPG Sensor Algorithm") – another key product development milestone.

This milestone was delivered notwithstanding the challenges faced by the Sydney team on completing our clinical studies and human trials of the device in the Australian environment of rolling lockdowns related to COVID-19 that have been imposed and experienced over the last 12-18 months.

Shareholders should gain confidence from the fact that I have been personally wearing and testing the device and I fully expect it to be a significant disruptive entrant to the landscape of current health & fitness wearables.

In addition, more confidence can be gained by the fact that I, together with my counterpart CEO at Mobvoi, last month re-affirmed in a new agreement our commercial commitment to the development and launch plan for the device.



In addition, in anticipation of launch, we are currently developing a PR and launch marketing plan for the device with our new brand and marketing agency for early Q2FY22 as well as being in discussions with multiple tech-exhibitions and upcoming conferences to showcase the device at launch.

We would like to provide more details of the device (proposed name, features, exact launch date etc.) but we are bound by confidentiality and especially Mobvoi's need to position the launch for maximum impact.

Taking a movie analogy, you don't release two versions of "Thor" by different studios at the same time. You take advantage of release "windows" to maximize the commercial impact of your specific product so as to gain optimal media coverage, sales, and impact.

That is what we are balancing in light of the global landscape of product releases due this year.

## **ATCOR Chosen for Yale University Clinical Trial**

The Company received another strong endorsement for its technology this quarter with ATCOR's SphygmoCor® XCEL System being selected for a clinical trial which is to be conducted by Yale University, <u>Aspirin to Prevent Preeclampsia in Women With Elevated Blood Pressure and Stage</u> 1 Hypertension (ASPPIRE).

The trial, which is currently recruiting, will test the effectiveness of aspirin for the prevention of preeclampsia in women with elevated blood pressure, using ATCOR's SphygmoCor® XCEL device to noninvasively measure central blood pressure, central arterial pressure waveform and pulse wave velocity, as well as other heart health parameters of participants.

Hypertension during pregnancy is an indicator of severe maternal morbidity and a preventable condition affecting an estimated 6.5% of women.

ATCOR's technology will provide additional data on the cardiovascular health of women enrolled in the study and support the trial's safety.

Strategic Investment Update: Blumio and inHealth

#### Blumio

Blumio continues to progress and further validate their radar-based sensor technology for blood pressure measurement. The company recently submitted its latest study to the <u>IEEE Conference on Wearable and Implantable Body Sensor Networks</u> for peer-review.

A preview of the accepted manuscript is available here.

The company will be presenting at the Body Sensor Networks conference in July, followed by <u>Cardio Wearables</u> conference in August, <u>Sensor Converge</u> conference in September, and <u>Engineering in Medicine and Biology Society</u> in October.

The goal for these conferences, particularly Cardio Wearables and Sensor Converge, is to continue building up the pipeline of potential customers who are ready to engage with the company in anticipation of commercial launch.

CardieX holds a USD\$600K convertible note in Blumio which converts into 8% of the company with a further 2% on the achievement of certain milestones.



#### inHealth

inHealth Lifestyle Therapeutics (inHealth) continued its momentum into 2021, with first half revenues exceeding the 2020 full year revenues. This has been largely driven by an expanded and exclusive relationship with a major US health insurer, growth in existing and new corporate partners, and a growing private practice customer base.

A major development has been the launch of inHealth's "Lifestyle Therapeutics Coaching Academy", which is certified by the US National Board of Health and Wellness Coaches (NBHWC), to train and develop clinical telehealth coaches. This enables inHealth to train its own coaches, develop programs for corporate and university customers, and attract individuals seeking new careers. A key differentiator is that graduates will be eligible to deliver reimbursed telehealth services in the USA.

Cardiex's CONNEQT subsidiary is also currently discussing integrating inHealth's telehealth coaching solutions into CONNEQT's companion app for its upcoming PULSE and CONNEQT Band wearable.

CardieX holds ordinary shares and a convertible note in inHealth.

#### **Conference Schedule**

With the reduced restrictions in the US we are now scheduled to be exhibiting and/or presenting live at the following sales and marketing events:

- 1. **A4M Anaheim, California -** *September, 2021* A4M is the world's largest conference for antiaging medicine. This traditionally has been the largest single sales driver event for ATCOR;
- 2. **A4M World Congress** *December, 2021* The largest of all the annual A4M events;
- 3. **Consumer Electronics Show (CES)** *January, 2022* A major launch event for our Company where we will be exhibiting the Mobvoi watch, our "Pulse" dual blood pressure monitor, and our CONNEQT Band (note that we will have the commercial CONNEQT Band for display, demonstration, and marketing while our FDA application is still in process for that device).

Please visit us if you are planning on attending any of these events.

CES is the most influential tech event of the year. We plan on making a significant impact at that show with three new products to showcase.

#### Corporate

During the quarter, the Company experienced strong sales growth which has led to a total increase of 32% on a constant currency basis (excluding royalties) for the year-to-date (YTD) on the comparative period in FY20.

This is a historical 5-year high revenue growth for our ATCOR division that we expect to continue into FY22 and beyond.

At 30 June 2021 the Company had a cash balance of AU\$3.67m.



CardieX's listed options (**ASX: CDXO** - \$0.05 exercise price, November 2021 expiry) have the potential to raise AU\$6.29m if fully exercised. Unlisted options if fully exercised would raise a further AU\$1.87m on the same terms.

Together the listed and unlisted options have the potential to raise a total of AU\$8.16m if fully exercised.

Shareholders are advised the Company has already completed a number of conversion requests from listed option holders in advance of the expiration date. Shareholders wishing to convert their options should direct their request to <a href="mailto:2021options@cardiex.com">2021options@cardiex.com</a>.

Looking ahead, the Company continues to be well funded to pursue identified growth initiatives in both the existing ATCOR business, and the new CONNEQT business.

Payments to related parties and their associates in the quarter were AU\$202k and all related to remuneration for services under existing services agreements, with no non-remuneration payments made in the quarter to those parties.

#### **Final Comments**

I thank our shareholders for their continuing support.

Reiterating my comments from the last quarterly update, launching new products is never linear, and there are always challenges along the way that face all technology growth companies.

What we are doing is not "easy".

Great companies are not born from easy challenges.

Having said that, I can assure you that we are all working hard on maintaining project schedules and launch targets for all our new products and devices.

Certain factors have impacted product launch schedules which have already been detailed above – but we now believe we have crossed the threshold of those challenges – and are moving forward rapidly to the best of our abilities in a near "normal" environment.

I know you will share my mission and vision of making sure that all our new products not only provide unique and valuable health solutions for patients and consumers alike, but also have the capacity to have a significant impact on the global healthcare market.

Finally, I want to emphasize my personal commitment and motivation to the mission we are all on.

Together with my partner and CardieX Chairman, Niall Cairns, we together own >20% of the Company stock through our C2 Ventures Pty Ltd excluding unconverted options and convertible notes.

We, along with the CardieX team, are very much committed and aligned in ensuring we continue to execute on the Company's strategic plan, which we believe will be a strong value creator for all our shareholders.



My sincere thanks for your continuing support,

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. Its ATCOR subsidiary is a world leader in medical devices and digital solutions for hypertension, cardiovascular disease, and other vascular health disorders. Its CONNEQT subsidiary develops and markets consumer home health devices and wearables. 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		30 June 2021	

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	1,272	4,475
1.2	Payments for		
	(a) research and development	(557)	(2,029)
	(b) product manufacturing and operating costs	(310)	(831)
	(c) advertising and marketing	(38)	(128)
	(d) leased assets	(37)	(241)
	(e) staff costs	(1,331)	(4,284)
	(f) administration and corporate costs	(255)	(1,893)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(29)	(175)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	523
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(1,285)	(4,583)

2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(30)	(71)
	(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 (12 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	(30)	651

3.	Cash flows from financing activities		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	81	6,385
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	_	(338)
3.5	Proceeds from borrowings	-	14
3.6	Repayment of borrowings	-	(460)
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	81	5,601

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	4,879	2,062
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,285)	(4,583)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(30)	651

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Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	81	5,601
4.5	Effect of movement in exchange rates on cash held	20	(66)
4.6	Cash and cash equivalents at end of period	3,665	3,665

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	3,665	3,665
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)	3,665	3,665

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	202
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
	f any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include ation for, such payments.	e a description of, and an

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)	-	-
7.4	Total financing facilities	1,040	1,040
7.5	Unused financing facilities available at qu	uarter 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.

On 25 March 2020, the Company entered into a \$1,500,000 term loan facility, secured against future R&D refunds to be received by the Company and its wholly owned subsidiary AtCor Medical Pty Ltd. 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 and will remit further repayment on lodgement of its 2021 R&D Incentive post 1 July 2021. 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)	(1,285)
8.2	Cash and cash equivalents at quarter end (item 4.6)	3,665
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	3,665
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	2.85
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	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: 26 July 2021

Authorised by: The Board of Directors

(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.